FOI RELEASABLE OUTPUT

User Name: 136576
Report Date: 11/02/2010
Notes: 2009-9701
Application: MAUDE QUERY (GUI)
Report Name: EVENT REPORT DETAIL LISTING
Report Description: DETAIL SUMMARY REPORT, BOTH IN-HOUSE & FOI FORMAT, WILL BE GENERATED FROM THE INFORMATION OBTAINED ON THE MEDWATCH FORMS.

Search Criteria: Date of The Event
BETWEEN 01-JAN-1990 AND 03-DEC-2009

Generic Name (D2 Device Type)
- LASER VISION CORRECTION SURGERY MACHINE
- LASER VISION CORRECTION
- LASER VEIN TREATMENT
- LASER VARICOSITY REMOVAL SYSTEM
- LASER USED FOR PERMANENT HAIR REMOVAL
- LASER USED FOR LASIK
- LASER UNIT
- LASER TUBE
- LASER TREATMENT, SURGICAL, POWERED
- LASER RESISTANT ENDOTRACHEAL TUBE, CUFFED, 5.5MM
- LASER REFRACTIVE EYE SURGERY SYSTEM
- LASER PRODUCT
- LASER PROBE, OPHTHALMIC
- LASER PROBE, OPHTHALMIC
- LASER PROBE SMTR 1.5
Generic Name (D2 Device Type)

LASER PROBE
LASER POWERED SURGICAL INSTRUMENT (GEX)
LASER POWERED SURGICAL INSTRUMENT
LASER PHOTODISRUPTOR
LASER PHOTODISRUPTER
LASER PHOTOCOAGULATOR
LASER PHOTOCOAGULTOR
LASER PHOTOCOAGULATOR
LASER PERFORATOR
LASER MACHINE
LASER LITHOTRIPSER
LASER LIGHTGUIDE
LASER LASIK
LASER KEROTOME
LASER KERATOME
LASER-FLEX TRACHEAL TUBE 6.0MM
LASER-FLEX TRACHEAL TUBE 5.0MM
LASER KARATOME
LASER INSTRUMENT, SURGICAL, POWERED
LASER INSTRUMENT, SURGICAL, POWERED.
LASER INSTRUMENT, SURGICAL, POWERED
LASER INSTRUMENT SURGICAL, POWERED
LASER INSTRUMENT SURGICAL, POWERED
LASER INSTRUMENT FIBER AND PROCEDURE KIT
LASER INSTRUMENT FIBER AND KIT
LASER INSTRUMENT FIBER & PROCEDURE KIT
LASER INSTRUMENT FIBER
LASER INSTRUMENT
LASER INDIRECT OPHTHALMOSCOPE
LASER HOLMIUM FIBER
LASER HEADPIECE USED IN RETINAL SURGERY
LASER HANDPIECE
LASER HAIR THERAPY
LASER HAIR REMOVAL SYSTEM
LASER HAIR REMOVAL DEVICE
LASER HAIR REMOVAL
LASER GENERATOR
LASER FOR TREATMENT OF SECONDARY MEMBRANE FOLLOWING CATARACT
Generic Name (D2 Device Type)
LASER FOR SKIN RESURFACING
LASER FOR PROSTATE ABLATION
LASER FOR LASIK EYE SURGERY
LASER FOR HAIR REMOVAL
LASER FOR EYE SURGERY FOR VISION CORRECTION
LASER FOR EYE CORRECTION
LASER FOR CORRECTIVE EYE SURGERY
LASER FLEX
LASER FIBOR WITH RIGID HANDPIECE
LASERTUBUS 6MM
LASERTUBUS 4MM
LASERTUBUS
LASERTRIPITER
LASERTRACHEAL TUBE
LASERSCOPE GREEN LIGHT PV-ADDSTAT FIBERS
LASERSCOPE FIBER
LASERSCOPE 20 DEGREE TIP
LASERSCOPE
LASERS FOR HAIR REMOVAL
LASERS
LASERBLADE FIBER
LASERBALDE FIBER
LASER/LIGHT DEVICE
LASER-SURGERY DEVICES-REUSABLE
LASER-SURGERY DEVICES - REUSABLE
LASER-SURGERY DEVICES
LASER-SURGERY DEVICE
LASER-SHIELD 11 TUBE
LASER-POWERED SURGICAL INSTRUMENT
LASER-GENTLELASE/COOLGLIDE/GENTLE YAG
LASER-FLEX TRACHEAL TUBE WITH CUFF 6.0MM
LASER-FLEX TRACHEAL TUBE CUFFED 5.5MM
LASER-FLEX TRACHEAL TUBE CUFFED 5.0
LASER-FLEX TRACHEAL TUBE 6.0MM.
LASER DELIVERY AND ELECTROCAUTERY HANDPIECE
LASER SLIT LAMP USED IN OPHTHALMOLOGY
LASER SLIT LAMP PROTECTION DEVICE (ARGON)
LASER SLIT LAMP ATTACHMENT
Generic Name (D2 Device Type)
LASER SKIN RESURFACER
LASER SHIELD ENDOTRACHEAL TUBE
LASER SHEATH FOR CHRONIC LEAD REMOVAL
LASER SHEATH
LASER SCALPEL
LASER RESISTANT ENDOTRACHEAL TUBE, CUFFED, 6.0
LASER FIBER FOR LASERSCOPE KTP/YAG LASER
LASER FIBER DELIVERY DEVICE
LASER FIBER DEFLECTOR
LASER FIBER AND PROCEDURE KITS
LASER FIBER AND PROCEDURE KIT
LASER FIBER AND KIT
LASER FIBER 7FR FLEX WRERTOSCOPE
LASER FIBER - LIGHTGUIDE
LASER FIBER - FIBER OPTIC LASER DELIVERY SYSTEM
LASER FIBER (REUSABLE)
LASER FIBER (LIGHT GUARD)
LASER FIBER (200)
LASER FIBER
LASER EYE SURGERY
LASER EXCIM
LASER ET TUBE
LASER ENERY DELIVERY PROBE
LASER ENPROBE
LASER DOPPLER BLOOD FLOW MONITOR
LASER DISCECTOMY ENDSCOPE KIT
LASER DISCECTOMY DEVICE
LASER DISC DECOMPRESSION PROBE
LASER DIODE HAIR REMOVER SYSTEM
LASER DELIVERY SYSTEM
LASER DELIVERY FIBER, FIBER OPTIC
LASER DELIVERY DEVICE
LASER CORD
LASER CONSOLE
LASER CATHETER
LASER CARDIAC LEAD REMOVAL DEVICE
LASER BEAM MACHINE
LASER BASKET, 4 WIRE
Generic Name (D2 Device Type)

LASER-FLEX ENDOTRACHEAL TUBE
LASER, FIBER
LASER, ENDOVENOUS DEVICE
LASER, DERMATOLOGIC
LASER, CUTERA INC
LASER, COSMETIC
LASER, CO2
LASER, CARDIAC LEAD REMOVAL SYSTEM
LASER YAG ADD
LASER YAG
LASER WAVEGUIDE FIBER
LASER, SURGICAL, FOR USE IN DERMATOLOGY
LASER, SURGICAL, CO2
LASER, SURGICAL, CARBON-DIOXIDE
LASER, SURGICAL
LASER, Q-SWITCHED ND: YAG
LASER, PVP
LASER, PROSTATE
LASER, OPHTHALMOLOGY
LASER, OPHTHALMIC
LASER, OPHTHALMIC, DIODE
LASER, OPHTHALMIC
LASER, ND:YAG (KTP)
LASER, ND: YAG
LASER, KTP, UROLOGIC
LASER, KTP
LASER, INSTRUMENT, SURGICAL, POWERED
LASER, INSTRUMENT, SURGICAL POWERED
LASER - GEN 4.0R
LASER - FLEX TRACHEAL TUBE 6.0MM
LASER
LASER (LASER TRIPTER)
LASER & FIBER
LASER TREATMENT CARD
LASER TIP (CONE)
LASER TIP
LASER TATTOO REMOVAL
LASER TATTOO REMOVAL SYSTEM
<table>
<thead>
<tr>
<th>Generic Name (D2 Device Type)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LASER SYSTEM, EYE TRACKING DEVICE</td>
</tr>
<tr>
<td>LASER SYSTEM, ENDOVENOUS, PROCEDURE KIT</td>
</tr>
<tr>
<td>LASER SYSTEM</td>
</tr>
<tr>
<td>LASER SWITCHABLE TIP 90 DEGREE</td>
</tr>
<tr>
<td>LASER SURGICAL INSTRUMENT</td>
</tr>
<tr>
<td>LASER SURGICAL EXCIMER</td>
</tr>
<tr>
<td>LASER, INSTRUMENT SURGICAL, POWERED</td>
</tr>
<tr>
<td>LASER, HOLMIUM, UROLOGICAL</td>
</tr>
<tr>
<td>LASER, HOLMIUM</td>
</tr>
<tr>
<td>LASER, HO:YAG, GENERAL PURPOSE</td>
</tr>
<tr>
<td>LASER, HANDPIECE</td>
</tr>
<tr>
<td>LASER, GREENLIGHT PVP</td>
</tr>
<tr>
<td>LASER, GREENLIGHT</td>
</tr>
<tr>
<td>LASER FIBERTONE</td>
</tr>
<tr>
<td>LASER FIBERT</td>
</tr>
<tr>
<td>LASER FIBER; IMPLANT WIRE</td>
</tr>
<tr>
<td>LASER FIBER.</td>
</tr>
<tr>
<td>LASER FIBER-600 MICRON-CONTACT SCAPEL</td>
</tr>
<tr>
<td>LASER FIBER, SURGICAL, REUSEABLE</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.

Event Date (B3): 01-Apr-1992
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 08-Apr-1992
Event Outcome (B2):

Report Date (F8): 08-Apr-1992
Event Location (F12): HOSPITAL

Date Mfr Rec'd (G4):
Reporter Occupation (E3): 999 - UNKNOWN
Device Operator: OTHER HEALTH CARE PROFE

Product Code: (GU)-ENDOSCOPE, FIBER OPTIC (GDB)
Device Age (F9): 0 YR 91 DAYS (01-JAN-92)
Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):

DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: SATISFACTORY CONDITION. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: ACTUAL DEVICE INVOLVED IN INCIDENT WAS EVALUATED, MECHANICAL TESTS PERFORMED, VISUAL EXAMINATION, OTHER. RESULTS OF EVALUATION: COMPONENT FAILURE, TELEMERTY FAILURE, NONE OR UNKNOWN, NONE OR UNKNOWN. CONCLUSION: DEVICE FAILURE DIRECTLY CONTRIBUTED TO EVENT. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: YES. CORRECTIVE ACTIONS: DEVICE RETURNED TO MANUFACTURER/DEALER/DISTRIBUTOR, USER EDUCATION PROVIDED, INSERVICED BY BIOMEDICAL ENGINEERING DEPT. STAFF. THE DEVICE WAS NOT DESTROYED/DISPOSED OF.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Concomitant Medical Products:

Mfr Name: SURGICAL LASER TECHNOLOGIES-SLT
Address: ,

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

07-MAY-1992:

DEVICE INFORMATION:

Brand: SLT LARGE DIAMETER FLEXIBLE ENDOSCOPIC FIBER
Device Type: LASER FIBER-600 MICRON-CONTACT SCapel
Device Type: FEF-LARGE
Catalog: GRP8
Serial: (*confidential*)
Lot: 1103010
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: 
Address: 

EMAIL: 
Phone: 
International: 
Fax:

Health Professional: Unknown

Occupation: 999 - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### User Facility Report No:

#### Event Date (B3):
- 26-Mar-1992

#### Mfr Name:
- SHARPLAN LASERS, INC.

#### Adverse Event (B1): Y

#### Problem (B1): N

#### Date Mfr Rec'd (G4):
- 29-Apr-1992

#### Event Report Type:
- INJURY

#### Event Outcome (B2):
- 999 - UNKNOWN

#### Event Location (F12):
- HOSPITAL

#### Reporter Occupation (E3):
- OTHER HEALTH CARE PROFESSIONAL

#### Device Operator:
- OTHER HEALTH CARE PROFESSIONAL

#### Reporter Occupation (E3):
- 999 - UNKNOWN

#### Product Code:
- (SU)-LASER FOR WOUND HEALING (LXU)

#### Device Age (F9):
- 3 YR - 35 DAYS (01-MAY-89)

#### Report Date (B4):
- 29-Apr-1992

#### Report Date (F8):
- 999 - UNKNOWN

#### Device Usage (H8):

#### Event Description (B5):

Unk 19-MAY-1992: WHEN WET TOWELS WERE REMOVED FROM A PATIENT'S L. INNER THIGH AFTER A SURGICAL PROCEDURE, THERE WERE 3 SMALL WELT LIKE AREAS WHICH APPEARED TO BE AREAS THAT HAD BURNED THROUGH THE WET TONGUE BLADE DURING TESTING PROCEDURES PRIOR TO THE STARTING OF THE SURGICAL CASE. THERE WERE NO LARGE BURNED AREAS AND THESE WERE SIMPLY VERY SMALL WELT-LIKE AREAS. THE AREAS WERE COVERED WITH BETADINE OINTMENT AT THAT TIME AND WILL BE FOLLOWED POST OPERATIVELY

DEVICE NOT LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: SATISFACTORY CONDITION. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

DEVICE SERVICED IN ACCORDANCE WITH SERVICE SCHEDULE. DATE LAST SERVICED: 01-MAR-92. SERVICE PROVIDED BY: USER FACILITY BIOMEDICAL/BIOENGINEERING DEPARTMENT. SERVICE RECORDS AVAILABLE.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: ACTUAL DEVICE INVOLVED IN INCIDENT WAS EVALUATED, PERFORMANCE TESTS PERFORMED. RESULTS OF EVALUATION: INCORRECT TECHNIQUE/PROCEDURE. CONCLUSION: NO FAILURE DETECTED AND PRODUCT WITHIN SPECIFICATION. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: YES. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

### Concomitant Medical Products:

#### Mfr Name:
- SHARPLAN 1060 C02 LASER

#### Address:
- ,

Recd: 2  Page: 3  Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-MAY-1992:

DEVICE INFORMATION:

Brand: CO2 LASER
Device Type: LASER
Device Type: 1060
Catalog: UNKNOWN
Serial: (*confidential*)
Lot: N/A
Other ID: CE 1790

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:

EMAIL:
Phone:
International:
Fax:

Health Professional: Unknown

Occupation: 999 - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>29-Jan-1992</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4)</td>
<td>13-Feb-1992</td>
</tr>
<tr>
<td>Report Date (F8)</td>
<td>13-Feb-1992</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Sep-1992</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 05-APR-1993: DEVICES - YAG LASER, LASER FIBER

DURING AN ARTHROSCOPIC PROCEDURE, THE TIP OF A LASER FIBER BROKE OFF IN THE PATIENT'S KNEE. SEVERAL ATTEMPTS WERE MADE TO RETRIEVE THE TIP, BUT EFFORTS WERE UNSUCCESSFUL. X-RAYS WERE TAKEN WITH NEGATIVE RESULTS. IT WAS DETERMINED THAT THE TIP IS POSSIBLY IN THE SOFT TISSUE

DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: FAIR CONDITION. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: ACTUAL DEVICE INVOLVED IN INCIDENT WAS EVALUATED, VISUAL EXAMINATION. RESULTS OF EVALUATION: OTHER. CONCLUSION: NONE OR UNKNOWN. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: DEVICE PERMANENTLY REMOVED FROM SERVICE, OTHER. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

**Concomitant Medical Products:**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Mfr Name: SURGIMEDICS
Address: ,

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
05-APR-1993:

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand:</th>
<th>Device Type: LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type: N/A</td>
<td></td>
</tr>
<tr>
<td>Catalog: 9S-5602</td>
<td></td>
</tr>
<tr>
<td>Serial: (<em>confidential</em>)</td>
<td></td>
</tr>
<tr>
<td>Lot: 080000</td>
<td></td>
</tr>
<tr>
<td>Other ID: N/A</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Phone:</td>
</tr>
<tr>
<td>Health Professional: Unknown</td>
<td>International:</td>
</tr>
<tr>
<td></td>
<td>Fax:</td>
</tr>
</tbody>
</table>

| Occupation: 999 - UNKNOWN |

Recd: 3 Page: 6 Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Date Mfr Rec’d (G4):</th>
<th>Mfr Name:</th>
<th>Device Operator:</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Event Outcome (B2):</th>
<th>Event Location (F12):</th>
<th>Report Source (G3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>02-Nov-2010</td>
<td>28-Dec-1992</td>
<td>LUMENIS, INC.</td>
<td>OTHER HEALTH CARE PROFE</td>
<td>MALFUNCTION</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>HOSPITAL</td>
<td>OTHER HEALTH CARE PROFE</td>
</tr>
<tr>
<td></td>
<td>23-Dec-1992</td>
<td>Device Age (F9):</td>
<td>0 YR 77 DAYS (01-OCT-92)</td>
<td>Manufacturing Date (H4):</td>
<td>01-Feb-1993</td>
<td>Single Use (H5):</td>
<td>SINGLE USE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>23-Dec-1992</td>
<td>Expiration Date:</td>
<td>01-Feb-1993</td>
<td>Service Provided By:</td>
<td>INVALID DATA</td>
<td>Service Provided By:</td>
<td>INVALID DATA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>23-Dec-1992</td>
<td>Device Usage (H8):</td>
<td>SINGLE USE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Mfr Name: COHERENT
Address: ,
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
23-APR-1993:

DEVICE INFORMATION:
Brand: COHERENT 30 DEGREE FIBER HANDPIECE
Device Type: LASER HANDPIECE
Device Type: 30 DEGREE PROBE 0614-459-03
Catalog: Serial: (*confidential*)
Lot: 021991-01
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:
Name: EMAIL: Phone:
Address: International:
Fax:

Health Professional: Unknown Occupation: 999 - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 30-Jun-1992

User Facility Report No: 

Mfr Name: LASERSCOPE

Event Date (B3): 18-Mar-1992
Report Date (B4): 27-Mar-1992
Report Date (F8): 27-Mar-1992
Date Mfr Rec'd (G4): 

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Operator: OTHER HEALTH CARE PROFE

Adverse Event (B1): Problem (B1): Y

Event Report Type: MALFUNCTION

Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Reporter Occupation (E3): OTHER HEALTH CARE PROFE

Event Location (F12): HOSPITAL

Report Source (G3): OTHER HEALTH CARE PROFE

Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):

User 28-MAY-1993: OTHER DEVICES USED: LASERSCOPE LASER

DURING LASER DISC DECOMPRESSION PROCEDURE THE LDD PROBE TIP BROKE OFF AND APPROXIMATELY 1/4/ INCH REMAINS IN PATIENT'S BACK. PHYSICIAN DOES NOT EXPECT FUTURE COMPLICATIONS. AT TIME OF DISCHARGE FROM THE HOSPITAL FACILITY, THE PATIENT'S BACK DISCOMFORT WAS LESS THAN UPON ARRIVAL TO THE FACILITY

DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: SATISFACTORY CONDITION. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:

Mfr Name: LASERSCOPE
Address:

Recd: 5
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
28-MAY-1993:

DEVICE INFORMATION:

- **Brand:** LDD PROBE FOR USE WITH KTP/532 LASER
- **Device Type:** LASER DISC DECOMPRESSION PROBE
- **Device Type:** 10-2030
- **Catalog:** 10-2030
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:** N/A

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** Unknown
- **Occupation:** 999 - UNKNOWN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SHARPLAN LASERS, INC.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 31-Jan-1994</th>
<th>Event Report Type: DEATH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 08-Feb-1994</td>
<td>Event Outcome (B2): DEATH</td>
</tr>
<tr>
<td>Report Date (F8): 08-Feb-1994</td>
<td>Reporter Occupation (E3): 999 - UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 08-Feb-1994</td>
<td>Device Operator: INVALID DATA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9): 1 YR -121 DAYS (01-JUN-93)</td>
</tr>
<tr>
<td>Expiration Date:</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
</tr>
</tbody>
</table>

| Event Description (B5): |

INVALID DATA - REGARDING SINGLE USE LABELING OF DEVICE. PATIENT MEDICAL STATUS PRIOR TO EVENT: INVALID DATA. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

DEVICE SERVICED IN ACCORDANCE WITH SERVICE SCHEDULE. DATE LAST SERVICED: 01-NOV-93. SERVICE PROVIDED BY: FACTORY TRAINED/AUTHORIZED/OWNED SERVICE ORGANIZATION. SERVICE RECORDS AVAILABLE.

NO IMMINENT HAZARD TO PUBLIC HEALTHclaimed. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: NO FAILURE DETECTED AND PRODUCT WITHIN SPECIFICATION. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: UNKNOWN (CANNOT DETERMINE). CORRECTIVE ACTIONS: INVALID DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:

Mfr Name: SHARPLAN LASERS, INC.
Address: ,

Recd: 6 Page: 11 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
08-APR-1994:

DEVICE INFORMATION:

Brand: SHARPLAN
Device Type: LASER, SURGICAL, CARBON-DIOXIDE
Device Type: 1055
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: 0SMC12388

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: 
Address: 

EMAIL: 
Phone: 
International: 
Fax: 

Health Professional: Unknown

Occupation: 999 - UNKNOWN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 13-Jul-1994</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3): OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator: OTHER HEALTH CARE PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3): 999 - UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>DEVICE NOT LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: SATISFACTORY CONDITION. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.</td>
<td></td>
</tr>
<tr>
<td>DEVICE SERVICED IN ACCORDANCE WITH SERVICE SCHEDULE. DATE LAST SERVICED: 01-AUG-94. SERVICE PROVIDED BY: MANUFACTURER. SERVICE RECORDS AVAILABLE.</td>
<td></td>
</tr>
<tr>
<td>NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.</td>
<td></td>
</tr>
<tr>
<td>DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: ACTUAL DEVICE INVOLVED IN INCIDENT WAS EVALUATED, NONE OR UNKNOWN. RESULTS OF EVALUATION: NONE OR UNKNOWN. CONCLUSION: NONE OR UNKNOWN. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: DEVICE RETURNED TO MANUFACTURER/DEALER/DISTRIBUTOR. THE DEVICE WAS NOT DESTROYED/DISPOSED OF.</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

| Mfr Name: SURGICAL LASER TECHNOLOGIES |
| Address: |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-JAN-1995:

DEVICE INFORMATION:

Brand: LASER FIBOR WITH RIGID HANDPIECE
Device Type: LASER FIBOR WITH RIGID HANDPIECE
Device Type: TCRH7
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: 
Address: 

EMAIL: 
Phone: 
International: 
Fax: 

Health Professional: Unknown

Occupation: 999 - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 30-Nov-1993

User Facility Report No: 1
Mfr Name: MYRIAD LASE, INC.

Event Date (B3): 18-Nov-1993
Report Date (B4): 28-Nov-1993
Report Date (F8): 28-Nov-1993
Date Mfr Rec'd (G4): 30-Nov-1993

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8): 

Event Description (B5):
User 05-JAN-1994: DURING A VISUAL LASER ABLATION OF PROSTATE, THE LASER FIBER TIP CAME OFF INSIDE PT. IT WAS RETRIEVED WITH A BIOPSY FORCEP WITH NO INJURY TO THE PT.

Concomitant Medical Products:

Mfr Name: MYRIAD LASE, INC.
Address: FOREST HILL, TX 76140 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
05-JAN-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SIDEFIRE DISPOSABLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DLF-1000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** 308121
- **Other ID:**
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Dec-1993</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>30-Dec-1993</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>30-Dec-1993</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
</tbody>
</table>

Mfr Name: SURGICAL LASER TECHNOLOGIES
Address: OAKS, PA 19456
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
11-MAR-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SSRH II LASER HANDPIECE
- **Device Type:** LASER HANDPIECE
- **Device Type:** SSRH11
- **Catalog:** SSRH11
- **Serial:** (*confidential*)
- **Lot:** 3137-05
- **Other ID:**

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 16-Feb-1994

User Facility Report No:

Mfr Name: MYRIADLASE, INC.

Event Date (B3): 02-Feb-1994
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Event Outcome (B2):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL
Event Location (F12): HOSPITAL
Report Source (G3):

Date Mfr Rec'd (G4):

Product Code: ()-()
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 24-MAR-1994: LASER FIBER CRACKED DURING A VISUAL LASER ABLATION OF PROSTATE. FIBER DISENTEGRATED. LASER SHUT DOWN WHEN EVENT OCCURRED. POWER CHECK SHOWED NO VARIANCE. RECALIBRATION DONE WITH IDENTICAL RESULTS. NO ADVERSE EFFECT TO PT.

Concomitant Medical Products:

Mfr Name: MYRIADLASE, INC.
Address: FOREST HILL, TX 76140 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
24-MAR-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SIDEFIRE DISPOSABLE LASER FIBER
Device Type: LASER FIBER
Device Type: DLF-1000
Catalog: 
Serial: (*confidential*)
Lot: 308121
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b]
Address: [b] [b]
EMAIL: 
Phone: 
International: 
Fax: 
Health Professional: Yes

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**User Facility Report No:**

**Mfr Name:** HGM, INC.

| Event Date (B3): | 09-Jun-1994 |
| Report Date (B4): | 13-Jun-1994 |
| Report Date (F8): | 13-Jun-1994 |
| Date Mfr Rec'd (G4): | |

**Event Report Type:** INJURY

**Event Outcome (B2):** REQUIRED INTERVENTION

**Adverse Event (B1):** Problem (B1): N

**Reporter Occupation (E3):** 002 - NURSE

**Device Operator:** HEALTH PROFESSIONAL

**Report Date (F8):** 002 - NURSE

**Event Location (F12):** HOSPITAL

**Report Source (G3):** HEALTH PROFESSIONAL

**Product Code:** (OP)-PHOTOCOAGULATOR AND ACCESSORIES (HQB)

**Device Age (F9):** 8 YR 2 DAYS (8 YR)

**Expiration Date:**

**Manufacture Date (H4):**

**Device Usage (H8):**

**Event Description (B5):**

User 08-JUL-1994: THE LASER WAS THEN USED TO APPLY PHOTOCOAGULATION TO THE PERIPHERY AS WELL AS TO BLEEDERS. AT THE START OF THE LASER THERE WAS A FIRST SHOT WITH SETTING ON 0.2 WATTS. THERE WAS AN INTENSE RETINAL BREAK WITH A RESULTANT RETINAL HOLE CREATED. THERE WERE TWO OTHER TIMES WHEN THE LASER APPEARED TO HAVE SURGES WHERE TWO OTHER SMALL RETINAL BREAKS WERE CREATED. LASER HAD MALFUNCTIONED CAUSING MULTIPLE RETINAL HOLES. THE EVENING PRIOR TO THE SURGERY, THE SVC REP DID PREVENTIVE MAINTENANCE ON THE MACHINE. THE MACHINE WAS NOT USED AFTER THIS SERVICING UNTIL THIS SURGERY WAS DONE.

**Concomitant Medical Products:**

**Mfr Name:** HGM, INC.
**Address:** SALT LAKE CITY, UT 84104 UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
08-JUL-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASER
- **Device Type:** LASER
- **Device Type:** 8
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**
User 28-JUL-1994: PT UNDERGOING VISUAL LASER ABLATION OF PROSTATE. UNIT MALFUNCTIONED APPROX 1 HR INTO SURGERY. CASE HAD TO BE ABORTED, THE PT RECOVERED AND RESCHEDULED FOR 2/15/94 TO COMPLETE THE PROCEDURE. THIS REQUIRED 2ND ANESTHETIC, RECOVERY, ETC. THE MFR CONTACT PERSON REPAIRING THE UNIT HAS INDICATED THEY ARE STILL UNSURE WHAT WENT WRONG BUT IT WAS NOT RELATED TO USER ERROR. THIS INFO ABOUT THE PRODUCT OR USER ORIGIN OF MALFUNCTION WAS UNAVAILABLE TO THIS WRITER UNTIL 3/2/94. CONSEQUENTLY THE REPORT COULD NOT BE FILED WITHIN THE 10 DAY REQUIREMENT.

**Concomitant Medical Products:**

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
28-JUL-1994:

---

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

User Facility Report No: 
Mfr Name: DORNIER MEDTECH AMERICA, INC.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-Feb-1994</td>
<td>INJURY</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (B4):</th>
<th>Event Outcome (B2):</th>
</tr>
</thead>
<tbody>
<tr>
<td>03-Mar-1994</td>
<td>HOSPITALIZATION</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (F8):</th>
<th>Reporter Occupation (E3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>03-Mar-1994</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Mfr Rec’d (G4):</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-Mar-1994</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Device Age (F9):</th>
<th>Manufacture Date (H4):</th>
</tr>
</thead>
<tbody>
<tr>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Expiration Date:</th>
<th>Device Usage (H8):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Adverse Event (B1):** Y
**Problem (B1):** Y

**Event Location (F12):** HOSPITAL

**Report Source (G3):** HEALTH PROFESSIONAL

**Report Date (F8):** OTHER

**Other Mfr Narrative (H10 & H11):**
28-JUL-1994:

---

**Mfr Name:** DORNIER MEDICAL SYSTEMS
**Address:** KENNESAW, GA 30144
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>LAG LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBERTONE</td>
</tr>
<tr>
<td>Device Type</td>
<td>460597</td>
</tr>
<tr>
<td>Catalog</td>
<td></td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td></td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

| Name:          | (b) (6)                     |
| Address:       | (b) (6)                     |
| Health Professional: | Yes                     |

 Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 18-Jul-1994

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: CARDIOGENES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 17-May-1994</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (F8): 07-Jun-1994</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 07-Jun-1994</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: ()-()</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 09-SEP-1994: DURING AN ARTHROSCOPIC PROCEDURE, THE DOCUTOR WHILE USING THE ECLIPSE LASER SUSTAINED A BURN TO HIS (L) MIDDLE FINGER. FIBER BROKE WITHIN RUBBER SLEEVE.

Concomitant Medical Products:
HOLMIUM LASER

Mfr Name: ECLIPSE SURGICAL TECHNOLOGY
Address: P.O. BOX 50875
PALO ALTO, CA 94303
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
09-SEP-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>ECLIPSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER TIP</td>
</tr>
<tr>
<td>Catalog</td>
<td></td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>TA 00366</td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

| Name:          | (b) (6)        |
| Address:       | (b) (6)        |
| Health Professional: | Yes |
| EMAIL:         |                |
| Phone:         |                |
| International: |                |
| Fax:           |                |

Occupation: 002 - NURSE
Event Date (B3): 10-May-1994
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): * - INVALID DATA
Device Operator: HEALTH PROFESSIONAL
Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Event Description (B5):
User 16-SEP-1994: AT THE BEGINNING OF LASER PTCA PROCEDURE, COOLANT FLUID WAS NOTED TO BE LEAKING FROM UNDERSIDE OF LASER.

THE MANUFACTURER WAS NOTIFIED AND ADVISED STAFF NO TO USE TH ELASER. PROCEDURE WAS CANCELLED.

Concomitant Medical Products:
N/A

Mfr Name: SPECTRANETICS, INCORPORATED
Address: 96 TALAMINE COURT
COLORADO SPRINGS, CO 80907
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-SEP-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVELOPMENT INFORMATION:

   Brand: SPECTRANETICS
   Device Type: LASER GENERATOR
   Device Type: CVV-300
   Catalog: UNKNOWN
   Serial: (*confidential*)
   Lot: UNKNOWN
   Other ID: UNKNOWN

   Reprocessed & Reused: N/A

REPORTER INFORMATION:

   Name: [redacted]
   Address: [redacted]
   Phone: [redacted]
   International: [redacted]
   Fax: [redacted]
   EMAIL: [redacted]
   Occupation: * - INVALID DATA

   Health Professional: No Information
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
Mfr Name: COHERENT MEDICAL DIVISION
02-Sep-1994

Event Date (B3): 23-Aug-1994
Report Date (B4): 23-Aug-1994
Report Date (F8): 23-Aug-1994
Date Mfr Rec'd (G4): 02-Sep-1994

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (B4): 23-Aug-1994
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 03-Jun-1996
Single Use (H5): Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:

Mfr Name: COHERENT MEDICAL GROUP
Address: PALO ALTO, CA 94303 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
22-NOV-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: COHERENT  
Device Type: LASER HANDPIECE  
Device Type: 0614-459-03  
Catalog: 0614-459-03  
Serial: (*confidential*)  
Lot: 060394  
Other ID:  

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)  
Address: (b) (6)  
Health Professional: Yes  

EMAIL:  
Phone: (b) (6)  
International:  
Fax:  

Occupation: 002 - NURSE
User Facility Report No: 

Mfr Name: XOMED-TREACE, INC.

Event Date (B3): 19-Jan-1994
Report Date (B4): 26-Jan-1994
Report Date (F8): 26-Jan-1994

Date Mfr Rec'd (G4): 

Event Report Type: MALFUNCTION
Event Outcome (B2):

Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Date Received: 21-Sep-1994

Product Code: (AN)-CHANGER, TUBE, ENDOTRACHEAL (LNZ)

Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
SUCINYLCHOLINE PRIOR TO INTUBATION.

Mfr Name: XOMED-TREACE
Address: 6743 SOUTHPOINT DRIVE N
JACKSONVILLE, FL 32216
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11): 10-JAN-1995:
DEVICE INFORMATION:

- **Brand:** XOMED-TREACE
- **Device Type:** LASER SHIELD ENDOTRACHEAL TUBE
- **Catalog:** 70-60100
- **Serial:** (*confidential*)
- **Lot:** N/A
- **Other ID:**
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: HERAEUS LASERSONICS, INC.</th>
<th>Date Received: 22-Feb-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 17-Feb-1995</td>
<td>Event Report Type: OTHER</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8): 22-Feb-1995</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 1 YR -95 DAYS (9 MO)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: HERAEUS LASERSONICS, INC.

Address: MILIPITAS, CA 95035

UNITED STATES

Device Available for Evaluation: R

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):

Correction/Removal No (H9): 

Additional Mfr Narrative (H10 & H11):

23-MAR-1995:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASERBLADE FIBER
- **Device Type:** LASERBALDE FIBER
- **Catalog:** 0016-5601-91
- **Serial:** (*confidential*)
- **Lot:** 302140

Other ID:

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: HARAEUS LASERSONICS, INC.</th>
<th>Date Received</th>
<th>29-Jun-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Feb-1995</td>
<td>Event Report Type: *</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Event Date (F8):</td>
<td>22-Feb-1995</td>
<td>Reporter Occupation (E3): OTHER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR -95 DAYS (9 MO)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: HARAEUS LASERSONICS, INC.
Address: MILIPITAS, CA 95035
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASERBLADE FIBER
- **Device Type:** LASERBLADE FIBER
- **Catalog:** 0016-5601-91
- **Serial:** (*confidential*)
- **Lot:** 302140
- **Other ID:**

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** *(censored)*
- **Address:** *(censored)*
- **EMAIL:** *(censored)*
- **Phone:** *(censored)*
- **International:** *(censored)*
- **Fax:** *(censored)*
- **Health Professional:** No
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: COHERENT MEDICAL DIVISION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 08-Feb-1995</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (F8): 20-Feb-1995</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (EN)-LASER, ENT MICRO SURGICAL CARBON-DIOXIDE (EWG)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 1 YR 0 DAYS (12 MO)</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 09-AUG-1995: PT SUSTAINED FIRST DEGREE BURNS, WITH A SMALL AREA OF SECOND DEGREE BURN, WHICH REQUIRED MEDICAL INTERVENTION, AS A RESULT OF A FIRE STARTED BY A LASER. SURGEON WAS PERFORMING A BEAM ALIGNMENT BEFORE SURGICAL PROCEDURE, IN ACCORDANCE WITH THE RECOMMENDATIONS SET FORTH IN THE OPERATING MANUAL. LASER WAS SET AT 10 MJ - 6W IN CW MODE. A 0.2 MM HANDPIECE WAS USED. WHEN SURGEON ACTIVATED FOOT PEDAL, THE LASER BEAM IMMEDIATELY PASSED THROUGH THE TONGUE DEPRESSOR USED FOR ALIGNMENT AND IGNITED A SMALL FIRE ON SURGICAL DRAPES. SURGEON DESCRIBED THE ENERGY OUTPUT FROM THE LASER AS UNUSUAL. FIRE WAS QUICKLY EXTINGUISHED BY OR PERSONNEL.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name: COHERENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: PALO ALTO, CA 94303 UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
09-AUG-1995:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** CO2 LASER
- **Device Type:** LASER
- **Device Type:** UP 5000C
- **Catalog:** NI
- **Serial:** (*confidential*)
- **Lot:** NI
- **Other ID:** UNIT 51318

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER

**EMAIL:** [redacted]
**Phone:** [redacted]
**International:** [redacted]
**Fax:** [redacted]
User Facility Report No:  
Mfr Name: LASERSCOPE  

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Report Date (B4):</th>
<th>Event Report Type:</th>
<th>Event Date (B3):</th>
<th>Event Outcome (B2):</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Location (F12):</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITAL</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

| Mfr Name: LASERSCOPE SURGICAL SYSTEMS  
Address: SAN JOSE, CA 95134  
UNITED STATES  
| Device Available for Evaluation: Y  
| Device Evaluated by Manufacturer (H3): No Answer  

Remedial Action (H7):  
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11):  
23-AUG-1995:


Concomitant Medical Products:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: KTP LASER
Device Type: LASER
Device Type: 801
Catalog: NA
Serial: (*confidential*)
Lot: 10-0622-433
Other ID: REORDER #10-0622

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b]
Address: [b] [b]

Health Professional: No

EMAIL: [b] [b]
Phone: [b] [b]
International: 
Fax: 

Occupation: 401 - BIOMEDICAL ENGINEER
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: COHERENT MEDICAL DIVISION</th>
<th>Date Received: 02-Oct-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 20-Sep-1995</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 20-Sep-1995</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 22-Mar-2000</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

User 15-NOV-1995: PT UNDERGOING ARTHROSCOPIC SURGERY TO RIGHT KNEE. DISPOSABLE HANDPIECE TO THE LASER HAS A PIECE OF FIBER EXPOSED IN THE TIP AND THIS PIECE OF FIBER CAME OFF AND WENT INTO PT'S KNEE; UNABLE TO FIND.

Concomitant Medical Products:

Mfr Name: COHERENT MEDICAL
Address: 3270 W BAYSHORE RD
PALO ALTO, CA 94303
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
15-NOV-1995:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INFRATOME HANDPIECE TIP
- **Device Type**: LASER HANDPIECE
- **Catalog**: (*confidential*)
- **Serial**: 032295
- **Lot**: 032295
- **Other ID**: N/A

**Reprocessed & Reused**: N/A
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
<th>Date Received</th>
<th>31-Jan-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 19-Jan-1996</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (B4): 24-Jan-1996</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Event Location (F12): INVALID DATA</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 24-Jan-1996</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (AN)-YAG (LLO)</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 12-FEB-1996: DURING BRONCHOSCOPY, LASER TREATMENT OF TUMOR ATTEMPTED. FIRE ERUPTED IN AIRWAY AFTER INITIAL FIRING OF LASERSCOPE.

Concomitant Medical Products:

Mfr Name: LASERSCOPE
Address: 3052 ORCHARD
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
DeviceEvaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-FEB-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASERSCOPE LASER
- **Device Type:** LASER
- **Device Type:** KTP-532
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: 16-Jan-1996
Mfr Name: CANDELA LASER CORP.

Date Received: 28-Jan-1996
Mfr Name: CANDELA LASER CORP.
Address: 530 BOSTON POST ROAD
WAYLAND, MA 01778
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-FEB-1996:

Event Date (B3): 18-Jan-1995
Report Date (B4): 10-Aug-1995
Report Date (F8): 10-Aug-1995
Date Mfr Rec’d (G4):
Event Description (B5):

Concomitant Medical Products:

Mfr Name: CANDELA LASER CORP
Address: 530 BOSTON POST ROAD
WAYLAND, MA 01778
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-FEB-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** CANDELA LASER
- **Device Type:** LASER & FIBER
- **Device Type:** MDL 2000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

- **Reprocessed & Reused:** N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>31-Oct-1995</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 27-FEB-1996: LASER OVERHEATED SURROUNDING INSTRUMENT, CAUSING LIP BURN. ON FOLLOW UP EXAM OF LASER FIBER HANDPIECE, FIBER WAS NOTED TO BE PROTRUDING FROM HANDPIECE TIP, CAUSING UNEVEN HEAT TRANSFER.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>0 YR 30 DAYS (1 MO)</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>SURGICAL LASER TECHNOLOGIES, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>200 CRESSON BLVD., PO 880</td>
</tr>
<tr>
<td></td>
<td>OAKS, PA 19456</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>27-FEB-1996:</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand:  ND: YAG LASER FIBER
Device Type:  LASER FIBER
Device Type:  
Catalog:

  Serial:  (*confidential*)
  Lot:  
Other ID:  STYLE SSRH5

Reprocessed & Reused:  N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

User Facility Report No: | Mfr Name: SURGICAL LASER TECHNOLOGIES, INC. | 29-Dec-1995
---|---|---
**Event Date (B3):** 18-May-1995 | **Event Report Type:** MALFUNCTION | **Adverse Event (B1):** Problem (B1): Y
**Report Date (B4):** 29-Dec-1995 | **Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) | **Event Location (F12):** HOSPITAL
**Report Date (F8):** 29-Dec-1995 | **Reporter Occupation (E3):** 600 - ATTORNEY | **Report Source (G3):** HEALTH PROFESSIONAL
**Date Mfr Rec'd (G4):** | **Device Operator:** HEALTH PROFESSIONAL | 
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) | **Device Evaluated by Manufacturer (H3):** No Answer |  
**Device Age (F9):** Manufacture Date (H4): | **Expiry Date:** | **Device Usage (H8):** 
**Event Description (B5):**

User 19-MAR-1996: DEVICE BEING USED TO EXCISE UTERINE TISSUE. WHEN LASER FIBER WITHDRAWN FROM ABDOMEN VIA SUCTION PORT WITH SCALPEL ATTACHED, IT WAS PLACED ON THE ABDOMEN. ON REPLACING THE FIBER DOWN THE SUCTION PORT THE SCALPEL WAS NOT VISIBLE. THE SURGEON USED THE LAPAROSCOPY CAMERA TO SEARCH THE ABDOMINAL AREA BUT THE PROBE WAS NOT FOUND. IT IS BELIEVED THAT THE SCALPEL MAY HAVE BECOME LOOSE AND FALLEN OFF THE LASER FIBER POSSIBLY BECAUSE IT HAD NOT BEEN TIGHTENED SUFFICIENTLY.

**Concomitant Medical Products:**

Mfr Name: SURGICAL LASER TECHNOLOGIES, INC. 
Address: PO BOX 880
200 CRESSON BLVD
OAKS, PA 19456
UNITED STATES

Device Available for Evaluation: N

Remedial Action (H7):

Correction/Removal No (H9): No Answer

Additional Mfr Narrative (H10 & H11):

19-MAR-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER SCALPEL
- **Device Type:** LASER SCALPEL
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: DIOMEDICS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Date (B3):** 15-Feb-1996  
**Report Date (B4):** 19-Feb-1996  
**Report Date (F8):** 19-Feb-1996  
**Date Mfr Rec'd (G4):** 20-Feb-1996  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):** HOSPITAL  
**Event Description (B5):**  
User 28-MAR-1996: LASER TIP DISLODGED FROM LASER PROBE DURING PROCEDURE.  
**Concomitant Medical Products:**  
**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
28-MAR-1996:

Mfr Name: DIOMEDICS, INC.  
Address: 2828 N CRESCENT RIDGE DR  
THE WOODLANDS, TX 77381  
UNITED STATES

Report Source (G3): HEALTH PROFESSIONAL  
Device Evaluated by Manufacturer (H3): No Answer  
Remedial Action (H7):  
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11):  
28-MAR-1996:

Recd: 26  
Page: 51  
Date Last Updated: 11/2/2010 9:17 AM
Device Information:

Brand: DIODE LASER PROBE
Device Type: LASER PROBE
Catalog: MS-9201
Serial: (*confidential*)
Lot: 302469
Other ID:

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitutean admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: 

Mfr Name: DIOMEDICS, INC.

Event Date (B3): 01-Feb-1996
Report Date (B4): 12-Feb-1996
Report Date (F8): 
Date Mfr Rec'd (G4): 

Event Report Type: MALFUNCTION
Event Outcome (B2): 
Report Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3): 

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): 

Event Description (B5):
User 10-APR-1996: TWO LASER FIBER TIPS BROKE DURING INTRA-OPERATIVE USAGE.

Concomitant Medical Products:

Mfr Name: DIOMEDICS, INC.
Address: 2228 N CRESCENT DR
THE WOODLANDS, TX 77381
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
10-APR-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: DIOMETICS LASER FIBER
- **Device Type**: LASER FIBER
- **Device Type**: 600 M/800 M-ORB
- **Catalog**: MS-5501
- **Serial**: (*confidential*)
- **Lot**: 302969
- **Other ID**:

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: COHERENT MEDICAL DIVISION</th>
<th>Date Received: 16-May-1996</th>
</tr>
</thead>
</table>

**Event Date (B3):** 13-May-1996  
**Report Date (B4):** 14-May-1996  
**Report Date (F8):** 14-May-1996  
**Date Mfr Rec'd (G4):**  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):** HOSPITAL  
**Report Source (G3):**  
**Reporter Occupation (E3):** 500 - RISK MANAGER  
**Device Operator: HEALTH PROFESSIONAL**  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date: 31-Oct-2000**  
**Device Usage (H8):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  

**Event Description (B5):**  
User 07-JUN-1996: FIBER TIP DEFECTIVE: LIGHT HEATED METAL TUBE APPROX .5 TO 1 CM FROM TIP (THIS WAS BEING USED DURING AN ARTHROSCOPY). AS A RESULT, THE PT'S CONDITION SURFACE WAS BURNED SUPERFICIALLY.

**Concomitant Medical Products:**

**Mfr Name:** COHERENT MEDICAL, INC.  
**Address:** 3270 WEST BAYSHORE RD  
PALO ALTO, CA 94303  
UNITED STATES  
**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 07-JUN-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INFRATOME HANDPIECE
- **Device Type:** LASER
- **Device Type:** 30 DEGREE PROBE
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** 103195
- **Other ID:** NA

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

User Facility Report No:

Mfr Name: HERAEUS SURGICAL, INC.

Event Date (B3): 12-Apr-1996
Report Date (B4): 03-May-1996
Report Date (F8): 03-May-1996
Date Mfr Rec'd (G4):

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Report Date (B4): 03-May-1996
Report Date (F8): 002 - NURSE
Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Date Last Updated: 11/2/2010  9:17 AM
Recd: 29  Page: 57
Date Last Updated: 11/2/2010  9:17 AM

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 01-JUL-1996: PT SUSTAINED 8MM, THIRD DEGREE BURN TO RIGHT UPPER LIP DURING LASER PROCEDURE. IT APPEARS THAT THE SET SCREW HAD LOOSENED ALLOWING THE MIRROR TO SPIN.

Concomitant Medical Products:

Mfr Name: HERAEUS SURGICAL, INC.
Address: 575 COTTONWOOD DR
MILPITAS, CA 95035
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
01-JUL-1996:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: MICROMANIPULATOR
Device Type: LASER
Device Type: LS-11
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>EDAP TECHNOMED, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 12-Jun-1996</td>
<td>Event Report Type: INJURY</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 24-Jun-1996</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 24-Jun-1996</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 0 YR 60 DAYS (2 MO)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 19-AUG-1996:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 19-AUG-1996: PT WAS HAVING PULSED DYE LASER LITHOTRIPSY OF URETERAL CALCULUS. AN APPROX 1/2 INCH PIECE OF LASER FIBER BROKE OFF IN PT'S URETER DURING PROCEDURE. THE PIECE WAS REMOVED WITH A STONE BASKET. PRIOR USES: 5/1/96 PULSES 62, 5/15/96 PULSES 784, 5/28/96 PULSES 369, 5/30/96 PULSES 979. ON 6/12, 744 PULSES.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: PULSE PROBE
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: Fax:

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>19-Jan-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>24-Jan-1996</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 19-AUG-1996: DURING BRONCHOSCOPY, LASER TREATMENT OF TUMOR ATTEMPTED. FIRE ERRUPTED IN AIRWAY AFTER INITIAL FIRING OF LASER.

**Concomitant Medical Products:**

**Mfr Name:** LASERSCOPE

**Address:** 3052 ORCHARD
SAN JOSE, CA 95134
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
19-AUG-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LASERSCOPE - KTP 532
- **Device Type:** LASER
- **Device Type:** KTP-532
- **Catalog:** *
  - **Serial:** (*confidential*)
  - **Lot:** *
  - **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:**
  - **Fax:**

Date Last Updated: 11/2/2010 9:17 AM

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: CANDELA CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Date (B3):</strong></td>
<td>24-Jun-1996</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong></td>
<td>19-Aug-1996</td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td>19-Aug-1996</td>
</tr>
<tr>
<td><strong>Device Operator:</strong></td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td><strong>Device Usage (H8):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Event Description (B5):</strong></td>
<td>User 01-OCT-1996: LASER FIBER BROKE ABOVE THE GOLD TIP AS IT WAS INSERTED INTO THE ROPE DURING A CYSTOSCOPY, LEFT URETHROSCOPY, ATTEMPTED LASER LITHOTRIPSY AND ELECTROHYDRAULIC LITHOTRIPSY OF A LEFT DISTAL URETERAL STONE. X-RAY TAKEN. NO FOREIGN BODY NOTED. NO INJURY TO PT.</td>
</tr>
<tr>
<td><strong>Concomitant Medical Products:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Mfr Name:</strong> CANDELA</td>
<td></td>
</tr>
<tr>
<td><strong>Address:</strong> 530 BOSTON POST RD WAYLAND, MA 01778 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td><strong>Device Available for Evaluation:</strong> Y</td>
<td></td>
</tr>
<tr>
<td><strong>Device Evaluated by Manufacturer (H3):</strong> No Answer</td>
<td></td>
</tr>
<tr>
<td><strong>Remedial Action (H7):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Correction/Removal No (H9):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Additional Mfr Narrative (H10 &amp; H11):</strong> 01-OCT-1996:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 320 MICRON CANELA LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 8075-26-1300
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

**Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SHARPLAN LASERS, INC.</th>
<th>Date Received: 12-Sep-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 09-Sep-1996</td>
<td>Event Report Type: OTHER</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8): 12-Sep-1996</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 3 YR 0 DAYS (36 MO)</td>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
28-OCT-1996:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: *
Device Type: LASER 1055
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (b)
Address: (b) (b)

Health Professional: Yes

EMAIL: (b) (b)
Phone: (b) (b)
International: 
Fax: 

Occupation: 002 - NURSE

Recd: 33 
Page: 66 
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

CDRH

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 24-Oct-1996

Event Date (B3): 18-Oct-1996

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Report Date (B4): 24-Oct-1996

Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Report Date (F8): 24-Oct-1996

Report Source (G3): HEALTH PROFESSIONAL

Date Mfr Rec'd (G4):

Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-TUBE, SMOKE REMOVAL, ENDOSCOPIC (FCZ)

Device Evaluated by Manufacturer (H3): No Answer

Device Available for Evaluation: Y

Correction/Removal No (H9):

Event Location (F12): HOSPITAL

Report Date (F8): 24-Oct-1996

Event Description (B5):

User 12-NOV-1996: PT HAVING EGD WHEN LASER SMOKE EVACUATOR FAILED. PROCEDURE TERMINATED.

Concomitant Medical Products:

Mfr Name: LASE, INC.

Address: PO BOX 36158
CINCINNATI, OH 45236
UNITED STATES

Device Usage (H8): Single Use (H5):

Remedial Action (H7):

Additional Mfr Narrative (H10 & H11):

12-NOV-1996:
MAUDE EVENT REPORT (FOI)

Device Information:
- Brand: GERACI/MILLER SMOKE EVACUATION
- Device Type: LASER SMOKE EVACUATOR
- Device Type: SE11111 B11
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

Reporter Information:
- Name: [b] (b)
- Address: [b] (b)
- EMAIL: 
- Phone: (*)
- International: 
- Fax: 
- Occupation: 002 - NURSE

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.
Event Date (B3): 18-Sep-1996
Report Date (B4): 28-Sep-1996
Report Date (F8): 28-Sep-1996
Date Mfr Rec'd (G4):
Mfr Name: TRIMEDYNE, INC.

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: INVALID DATA

Adverse Event (B1):
Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3):

Date Received: 28-Sep-1996

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 12-NOV-1996: FORTY (40) YEAR OLD PT WITH INTERNAL DERANGEMENT WAS HAVING AN ARTHROSCOPY DONE WHEN THE HAND PIECE OF THE LASER AT THE CONNECTION MELTED. IT WAS REPLACED BY THE 60 DEGREE PROBE AND CASE CONTINUED. PHYSICIAN PREFERRED THE SIDE FIRE PROBE. IT IS NOT KNOWN AT THIS TIME WHAT ADVERSE OUTCOME PT MAY HAVE. THE PHYSICIAN STATES IT WILL BE APPROXIMATELY SIX (6) MONTHS BEFORE THIS IS KNOWN.

Concomitant Medical Products:

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-NOV-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TRIMEDYNE, INC.
- **Device Type:** LASER
- **Device Type:** 1210
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** TIP 228
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Sep-1996</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Sep-1996</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>28-Sep-1996</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Device Operator (G4):</td>
<td>INVALID DATA</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>28-Sep-1996</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 04-DEC-1996: FORTY (40) YEAR OLD PATIENT WITH INTERNAL DERANGEMENT WAS HAVING AN ARTHROSCOPY DONE WHEN THE HAND PIECE OF THE LASER AT THE CONNECTION MELTED. IT WAS REPLACED BY THE 60 DEGREE PROBE AND CASE CONTINUED. PHYSICIAN PREFERRED THE SIDE FIRE PROBE. IT IS NOT KNOWN AT THIS TIME WHAT ADVERSE OUTCOME PATIENT MAY HAVE. THE PHYSICIAN STATES IT WILL BE APPROXIMATELY SIX (6) MONTHS BEFORE THIS IS KNOWN</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE INC</td>
<td></td>
</tr>
<tr>
<td>Address: 2801 BARRANCA RD</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92606</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 04-DEC-1996:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TRIMEDYNE INC.
- **Device Type:** LASER
- **Device Type:** 1210
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** TIP 228
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** Yes

- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: CANDELA CORP.</th>
<th>Date Received: 26-Nov-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8): 21-Nov-1996</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 09-DEC-1996: PORTION OF LASER FIBER BROKE OFF INSIDE BLADDER. WAS SEEN FLOATING IN BLADDER WITH PIECES OF BLADDER STONES. AT END OF CASE NOT VISUALIZED. SURGEON FEELS THAT PIECE WAS IRRIGATED OUT WITH STONES.

**Concomitant Medical Products:**

**Mfr Name:** CANDELA LASER CORP
**Address:** 530 BOSTON POST RD
            WAYLAND, MA 01778
            UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
09-DEC-1996: 
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: RADIOGOLD LASER FIBERS
Device Type: LASER FIBER
Device Type: 8075-26-1300
Catalog: 8075-26-1300
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

[Redacted]

Health Professional: Yes

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SUMMIT TECHNOLOGY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 20-Aug-1996</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 20-Sep-1996</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8): 20-Sep-1996</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 10-APR-1997: DURING RESEARCH TREATMENT FOR MYOPIC ASTIGMATISM, EXCIMER LASER SHUT DOWN AFTER 64 OF ANTICIPATED 143 EXPOSURES. PT'S EYE WAS BANDAGED AND EYE APPEARED TO BE HEALING APPROPRIATELY BY POST-TREATMENT DAY 4, ALTHOUGH PT REPORTED MORE PAIN THAN IS USUAL. NO PERMANENT DAMAGE IS EXPECTED AND PROCEDURE MOST LIKELY WILL BE COMPLETED IN THE FUTURE.

Concomitant Medical Products:

Mfr Name: SUMMIT TECHNOLOGY
Address: 21 HICKORY DR.
WALTHAM, MA 02154
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-APR-1997:
CDRH

MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: APEX PLUS
Device Type: LASER
Device Type: APEX PLUS
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (b)
Email: [b] (6)
Phone: (*)
International: Fax:

Health Professional: No Information

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
<th>Date Received</th>
<th>21-Jun-1996</th>
</tr>
</thead>
</table>

#### Event Date (B3): 06-Feb-1996

#### Report Date (B4): 02-Apr-1996

#### Report Date (F8): 02-Apr-1996

#### Date Mfr Rec’d (G4):

#### Product Code: (OP)-LASER, OPHTHALMIC (HQF)

#### Device Age (F9): 1 YR 85 DAYS (15 MO)

#### Expiration Date:

### Event Description (B5):

User 25-APR-1997: PT HAD 3 FOCAL LASER TREATMENTS. 2/7/95 R #60 0.1 100 MICRONS 150-200 MV, 2/21/95 (L) #42 0.1 100 200 MV, 7/25/95 (L) #28 0.1 100 200 MV ON 6/13/95 C/O SOME DECREASE IN V/A L EYE. ON 9/19/95 C/O DECREASE IN V/ACUITY: ON 2/6/96 C/O MUCH WORSE VISION DIM AND BLURRING TOWARDS CENTER. ON 2/6/96 DIAGNOSED AS SUBRETINAL NEOVASCULARIZATION. STILL ATTEMPTING TO FOLLOW-UP 3 PTS.

### Concomitant Medical Products:

- Mfr Name: ALCON LABORATORIES
  - Address: 15800 ALTON PKWY
  - IRVINE, CA 92718
  - UNITED STATES

### Device Available for Evaluation: Y

### Device Evaluated by Manufacturer (H3): No Answer

### Remedial Action (H7):

### Correction/Removal No (H9): 25-APR-1997:

---

**Date Last Updated:** 11/2/2010 9:17 AM

---

Recd: 39

Page: 77
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** ALCON LASER
- **Device Type:** LASER
- **Device Type:** 532 LASER
- **Catalog:** --
- **Serial:** (*confidential*)
- **Lot:** --
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** [Redacted]

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 12-Mar-1997</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (F8): 18-Mar-1997</td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Expiration Date: 01-Nov-2000</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): User 25-APR-1997: FIBER TIP LOOSE</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: NA</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 2801 BARRANCA RD.</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92714</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 25-APR-1997:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OMNI TIP
Device Type: LASER FIBER
Device Type: 20475-HP
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: CANDELA CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 11-Apr-1997</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 23-Apr-1997</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 23-Apr-1997</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): User 09-MAY-1997: WHILE UNDERGOING CYSTOSCOPY WITH LASER LITHO, IT WAS NOTED THAT LASER FIBER APPEARED &quot;SHORT&quot;. LASER FIBER REMOVED FROM SCOPE WITH NO GOLD TIP PRESENT. UPON TAKING SCOPE OUT, A SEGMENT OF LASER FIBER WITH GOLD TIP WAS FOUND (APPROX 17 1/2&quot; SEGMENT).</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: CANDELA CORP.</td>
<td></td>
</tr>
<tr>
<td>Address: 530 BOSTON POST RD. WAYLAND, MA 01778 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 09-MAY-1997:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER FIBER 320 MICRON
- **Device Type:** LASER FIBER
- **Device Type:** 8075-26-1300
- **Catalog:** 8075-26-1300
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]

- **Health Professional:** Yes

- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>06-Oct-1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>12-Oct-1994</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>12-Oct-1994</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Problem (B1):** Y  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Event Location (F12):** HOSPITAL

**Event Description (B5):**  
User 22-MAY-1997: DURING LAPAROSCOPY LASER PROCEDURE-OVARIAN CYSTECTOMY, LASER TIP BROKE OFF. APPARENTLY IN PT'S ABDOMEN. SURGEON LOOKED FOR IT AND IRRIGATED CAVITY THOROUGHLY. TIP NOT LOCATED. CO NOTIFIED FOR INQUIRY ABOUT TIP. USED GRP-6, 10 WATTS. LASER TIME 6 MINUTES TOTAL. COOLANT CO2-LASER SET AT .2-.4.

**Concomitant Medical Products:**  

**Mfr Name:** SURGICAL LASER TECHNOLOGIES  
**Address:** 200 CRESSON BLVD.  
OAKS, PA 19456  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER TIP
- **Device Type:** LASER TIP
- **Device Type:** GRP-6
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** *

- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Jan-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>18-Feb-1997</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>24-Feb-1997</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>OUTPATIENT TREATMENT FACILITY</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR -95 DAYS ( 9 MO)</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>COHERENT</td>
</tr>
<tr>
<td>Address:</td>
<td>3270 WEST BAY SHORE DR P O BOX 10122 PALO ALTO, CA 94303 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>10-JUL-1997:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: NOVUS 2000
- Device Type: LASER
- Device Type: NOVUS2000
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Email: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
- Health Professional: Yes
- Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Device Operator</th>
<th>UNITED STATES MEDICAL CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>User 15-JUL-1997: PRESENTED TO SURGERY FOR CYSTO REMOVAL LT. JJ STENT URETEROSCOPIC CANDELA LASER LITHOTRIPSY W/VIDEO. ONCE THE CALCULUS WAS IDENTIFIED, A CANDELA LASER FIBER WAS PASSED THROUGH THE SCOPE &amp; AN ATTEMPT MADE TO FRAGMENT THE STONE. THE LASER FAILED TO WORK &amp; THE SURGEON WAS UNABLE TO FRAGMENT IT. THE STONE ENDED UP IN THE RENAL PELVIS. ANOTHER JJ URETERAL CATHETER WAS ADVANCED. SERVICE ENGINEER UNABLE TO REPAIR LASER. SERVICE ENGINEER FROM EQUIPMENT DEALER CONTACTED.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: UNITED STATES MEDICAL CORP.</td>
<td></td>
</tr>
<tr>
<td>Address: 7209 E KEMPER RD CINCINNATI, OH 45249 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 15-JUL-1997:</td>
<td></td>
</tr>
</tbody>
</table>

User Facility Report No: Mfr Name: UNITED STATES MEDICAL CORP.

| Event Date (B3): 04-Mar-1997 | Event Report Type: MALFUNCTION | Adverse Event (B1): Y |
| Event Date (F8): 13-Mar-1997 | Reporter Occupation (E3): 500 - RISK MANAGER | Event Location (F12): HOSPITAL |
| Date Mfr Rec'd (G4): | Device Operator: HEALTH PROFESSIONAL | Report Source (G3): |
| Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK) | Device Age (F9): | Manufacture Date (H4): |
| Expiration Date: | Single Use (H5): |
| Device Usage (H8): | |

Date Received: 30-Jun-1997
CDRH MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: CANDELLA LASER
Device Type: LASER
Device Type: LASER TRIPTER MDL 2000
Catalog: *
Serial: (*confidential*)
Lot: 7/87
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>LIFESTREAM INT'L, INC.</th>
<th>Date Received</th>
<th>26-Nov-1997</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 15-Oct-1997</td>
<td>Event Description (B5):</td>
<td>Event Location (F12): HOSPITAL</td>
<td>Event Location (F12):</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Reporter Occupation (F12): OTHER</td>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td>Event Outcome (B2):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
<th>Device Age (F9): 0 YR 150 DAYS (5 MO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiration Date:</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>Single Use (H5):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>User 04-DEC-1997: DURING EGD WITH LASER ABEILATION OF TUMOR, THE LASER FIBER TIP BROKE OFF. LASER FIBER TIP WAS RETRIEVED INTACT FROM ESOPHAGUS AREA USING A SNAKE LASER PROCEDURE TERMINATED FOLLOWING INCIDENT.</td>
<td>1997/10/08 GASTROSCOPE, OLYMPUS G1F29 (10/8/97 TO 10/8/97)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name: ENDEAVOR SURGICAL PRODUCTS</th>
<th>Address: *</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>UNKNOWN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation: Y</th>
<th>Device Evaluated by Manufacturer (H3): No Answer</th>
</tr>
</thead>
</table>

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 04-DEC-1997:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LIGHT TOUCH, MICROCONTACT LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 9S-5601
- **Serial:** (*confidential*)
- **Lot:** 238719
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b)(6)
- **Address:** (b)(6)
- **Health Professional:** No
- **Occupation:** OTHER

EMAIL: (b)(6)

Phone: (b)(6)

International: Fax:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

**Date Received:** 07-Nov-1997  
**Event Date (B3):** 07-Nov-1997  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y

**Mfr Name:** LIFESTREAM INT'L, INC.  
**Event Location (F12):** HOSPITAL

---

**User Facility Report No:**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

### Device Information

- **Device Operator:** HEALTH PROFESSIONAL  
- **Device Available for Evaluation:** R

### Event Description (B5):

User 29-DEC-1997: DURING ABLATION OF TUMOR IN ESOPHAGUS THE TIP BROKE OFF. UNABLE TO RETRIEVE TIP. NEW LASER FIBER USED TO COMPLETE PROCEDURE. YAG DIODE LASER SETTING WAS 20 WATTS. PT OUTCOME INDICATED NO ADVERSE EFFECTS FROM INCIDENT.

### Concomitant Medical Products:

- **YAG DIODE LASER (11/7/97 TO 11/7/97) (CONTIN)

---

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

---

**Date Last Updated:** 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVELOPMENT INFORMATION:

- **Brand:** LIGHT TOUCH MICROCONTACT LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 243216
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Health Professional: No

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3): USER</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 26-Jan-1998</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer Date (H4):</td>
<td>Manufacturing Date (H4):</td>
<td>Expiration Date:</td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 0 YR 180 DAYS (6 MO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 02-FEB-1998: DURING EGD WITH LASER ABLATION OF TUMOR, THE LASER FIBER TIP BROKE OFF. TIP WAS RETRIEVED. ANOTHER FIBER WAS USED AND THE TIP BROKE OFF. THE TIP WAS RETRIEVED. A THIRD FIBER WAS USED TO COMPLETE PROCEDURE. THE LOCAL SALES REP WAS CONTACTED AND THE FAILED FIBERS WERE SENT WITH HIM.

**Concomitant Medical Products:**
1997/12/12 2T100 OLYMPUS GASTROSCOPE (12/12/97 TO 12/12/97)

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
02-FEB-1998:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LIGHT TOUCH MICROCONTACT LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 9S-5609
- **Serial:** (*confidential*)
- **Lot:** 243216
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER

EMAIL:
Phone: [Redacted]
International:
Fax: [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</th>
<th>Date Received</th>
<th>28-Jan-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Report Date (B4): 25-Aug-1997</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Report Date (B8): 05-Sep-1997</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Report Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Event Date (B8):</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
</tbody>
</table>

Adverse Event (B1): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Problem (B1): Y

Event Location (F12): HOSPITAL

Date Mfr Rec'd (G4):

Device Operator: HEALTH PROFESSIONAL

Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9):

Manufacture Date (H4):

Single Use (H5):

Device Usage (H8):

Event Description (B5): User 03-MAR-1998: PT REC'D 3RD DEGREE BURN IN MOUTH DURING LASER TNA-UVULOPLASTY.

Concomitant Medical Products:

Mfr Name: SURGICAL LASER TECHNOLOGY
Address: 1 GREAT VALLEY PKWY.
MALVERN, PA 19355
UNITED STATES

Device Available for Evaluation: Y

Device Available by Manufacturer (H3): No Answer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

03-MAR-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER, SLT YAG
Device Type: LASER, YAG
Device Type: CLMD/ 110-40
Catalog: UNK
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 401 - BIOMEDICAL ENGINEER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>15-Jan-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>06-Mar-1998</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>11-Feb-1998</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 11-MAR-1998: ACCORDING TO THE HOSPITAL, A PT WAS UNDERGOING LASER BRONCHOSCOPY FOR A MALIGNANT ENDOBRONCHIAL TUMOR. THE EVENT OCCURRED AFTER CONSECUTIVELY USING THREE FREE BEAM FIBERS. DURING THE USE OF THE THIRD FIBER WHICH WAS A 1.0 MM BARE FIBER, A FLARE WAS SEEN FOLLOWED BY AN AIRWAY FIRE, FOLLOWED BY A &quot;LOUD BANG, POSSIBLE AN EXPLOSION&quot;. THE PT SUFFERED SOME CHARRING IN THE LEFT BRONCHUS WHICH LATER BEGAN TO HEAL. THE PT SUBSEQUENTLY DIED, AS A RESULT OF THE CANCER, AS OPPOSED TO THE COMPLICATIONS RELATED TO THE EVENT.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>FLEXIBLE BRONCHOSCOPE &amp; ENDOTRACH TUBE</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>SHARPLAN LASERS, INC.</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LASER INDUSTRIES, LTD</td>
</tr>
<tr>
<td>Address:</td>
<td>ATIDIM SCIENCE BASED PARK</td>
</tr>
<tr>
<td>Address:</td>
<td>TEL AVIV, ISRAEL</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>11-MAR-1998:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SHARPLAN FREE BEAM BARE FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 24625
- **Catalog:** AA2010900
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *(b) (b)*
- **Address:** *(b) (b)*
- **Email:** *(b) (b)*
- **Phone:** *(b) (b)*
- **International:** *(b) (b)*
- **Fax:** *(b) (b)*

- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>07-Jul-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>25-Jun-1998</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Jul-1998</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>02-Jul-1998</td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 08-JUL-1998: LENS OF SCOPE SHATTERED INTO PT OPERATIVE SITE DUE TO USER ERROR WITH HOLMIUM LASER V566. SITE IRRIGATED BY SURGEON, NO PARTICLES REMAINED.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>TRIMEDYNE CORP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>2801 BARRANZA RD</td>
</tr>
<tr>
<td>IRVINE, CA 92914</td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

| Device Available for Evaluation: | N |
| Device Evaluated by Manufacturer (H3): | No Answer |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 08-JUL-1998: |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** HOLMIUM #V566
- **Device Type:** LASER - OMNIPULSE
- **Device Type:** V566 OMNIPULSE
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** 80W HOLMIUM DESIGN

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:** (b) (6)
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: CANDELA CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jun-1998</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Jul-1998</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Event Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 27-JUL-1998: PT HAD URETEROSCOPY WITH LASER UREROTRIPSY AND INSERTION OF A DOUBLE-J URETERAL STENT. DURING CANDELA LASER USE ON URERAL STONE CANDELA LASER FIBER BROKE AT THE ENTRY POST INTO THE ACMI URERAL SCOPE. (LASER FIBER BROKE TWICE. MAXIMUM SETTING WAS 100 WATTS OF POWER.) FIBER RETRIEVED FROM PT (IT IS BELIEVED THAT ALL WAS REMOVED AND TREAT NO INJURY WAS SUSTAINED.) STONE FRAGMENTS REMOVED VIA BASKET.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: CANDELA CORP.</td>
<td></td>
</tr>
<tr>
<td>Address: 530 BOSTON POST RD. WAYLAND, MA 01778 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: CANDELA LASER FIBER
Device Type: LASER FIBER OPTIC CABLE ASSY
Device Type: 8075-26-1300
Catalog: 8075-26-1300
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: Mfr Name: ETHICON ENDO-SURGERY, INC.

- **Event Date (B3):** 15-Jun-1998
- **Event Report Type:** MALFUNCTION
- **Adverse Event (B1):** Problem (B1): Y
- **Event Outcome (B2):**
- **Report Date (B4):** Omitted
- **Event Location (F12):** INVALID DATA
- **Report Date (F8):**
- **Reporter Occupation (E3):** OTHER
- **Event Description (B5):**
  User 21-AUG-1998: FIBER BROKE DURING CASE. "DIFFUSER FAULT."
- **Device Operator:** HEALTH PROFESSIONAL
- **Device Age (F9):** Manufacture Date (H4):
- **Expiration Date:** 01-Jan-2002
- **Single Use (H5):**
- **Device Usage (H8):**

**Concomitant Medical Products:**

- **Mfr Name:** INDIGO MEDICAL
- **Address:** 10123 ALLIANCE RD
  CINCINNATI, OH 45242
  UNITED STATES
- **Device Available for Evaluation:** R
- **Device Evaluated by Manufacturer (H3):** No Answer
- **Remedial Action (H7):**
- **Correction/Removal No (H9):**
- **Additional Mfr Narrative (H10 & H11):**
  21-AUG-1998:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INDIGO
Device Type: LASER FIBER
Device Type: LF001
Catalog: *
Serial: (*confidential*)
Lot: K48R6T
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *
Address: [redacted]

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>INDIGO MEDICAL, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 17-Aug-1998</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 17-Aug-1998</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 01-May-2003</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 21-AUG-1998: SHAVING FROM LASER FIBER RETAINED IN BLADDER DURING LASER ABLATION PROSTATE-SHAVING WAS RETRIEVED - NO INJURY TO PT - PER SURGEON.

**Concomitant Medical Products:**

NA

**Mfr Name:** INDIGO MEDICAL LASER FIBEROPTICS
**Address:** 10123 ALLIANE RD
CINCINNATI, OH 42524
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 21-AUG-1998:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: TEMPERATURE SENSING DIFFUSER TIP
- **Device Type**: LASER FIBER
- **Device Type**: LF001
- **Catalog**: NA
- **Serial**: (*confidential*)
- **Lot**: LA4AA2A
- **Other ID**: *

**Reprocessed & Reused**: N/A

REPORTER INFORMATION:

**Name**: [Redacted]
**Address**: [Redacted]
**Email**: [Redacted]
**Phone**: [Redacted]
**International**: [Redacted]
**Fax**: [Redacted]

**Health Professional**: Yes
**Occupation**: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>23-Nov-1998</th>
</tr>
</thead>
</table>

**User Facility Report No:**

| Event Date (B3): 13-Nov-1998 | Event Report Type: OTHER |
| Report Date (F8): 23-Nov-1998 | Reporter Occupation (E3): OTHER |
| Date Mfr Rec'd (G4): | Device Operator: HEALTH PROFESSIONAL |

**Product Code:** (OB)-LASER, NEODYMIUM:YAG FOR GYNECOLOGIC USE (LLW)

**Device Age (F9): 5 YR 1 DAYS (5 YR)**

**Expiration Date:**

**Device Usage (H8):**

**Event Description (B5):**


**Concomitant Medical Products:**

| Mfr Name: LASERSCOPE |
| Address: * |
| * |
| UNKNOWN |

**Device Available for Evaluation:** *

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 04-DEC-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** *
- **Device Type:** LASER YAG
- **Device Type:** KTP 532
- **Catalog:** 10-0612 - FIBREOPTIC
- **Serial:** (*.confidential*)
- **Lot:** 10-0612-838
- **Other ID:** GOOD TILL 9-2000

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **Health Professional:** Yes

- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**

- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**User Facility Report No:**

**Mfr Name:** ALCON LABORATORIES

**Event Date (B3):** 22-Apr-1999
**Report Date (B4):** 07-May-1999
**Report Date (F8):** 07-May-1999
**Date Mfr Rec'd (G4):**

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)
**Device Operator:** HEALTH PROFESSIONAL
**Event Report Type:** OTHER
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
**Adverse Event (B1):** Y
**Problem (B1):** N
**Report Date (B4):** 07-May-1999
**Event Location (F12):** HOSPITAL
**Reporter Occupation (E3):** 002 - NURSE
**Device Age (F9):**
**Expiration Date:**
**Device Usage (H8):**

**Event Description (B5):**
User 24-JUN-1999: PHYSICIAN REPORTRED POST-OP THAT PT SUFFERED POSSIBLE SCLERAL BURN. UPON NOTIFICATION SURGERY SUPERVISION NOTIFIED ALCON SURGICAL. AMBULATORY CATARACT SURGERY, RT EYE IN 1999 WITH IOL INSERT. DURING EARLY "SCALPING" OF THE CATARACT, A SMALL THERMAL BURN OCCURRED ON THE ANTERIOR WOUND. THIS WAS IMMEDIATELY RECOGNIZED. THERE WAS NO ELEVATION OF THE PROBE PRIOR TO INCIDENT, DISTORTION OF THE WOUND FROM EVENT. MILD THERMAL BURN TO WOUND.

**Concomitant Medical Products:**

**Mfr Name:** ALCON IRVINE CONSUMER AFFAIRS
**Address:** 15800 ALTON PKWY
IRVINE, CA 92718
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer
**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
24-JUN-1999:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** ULTRASONIC HANDPIECE
- **Device Type:** LASER TIP
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

**EMAIL:**

**Phone:**

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Mfr Name: INDIGO MEDICAL, INC.

Event Date (B3): 15-Jun-1999  19-Jun-1999
Report Date (F8): 17-Jun-1999  19-Jun-1999
Date Mfr Rec'd (G4): 19-Jun-1999

Event Report Type: MALFUNCTION
Adverse Event (B1): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Problem (B1): Y

Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 01-Mar-2004
Single Use (H5):
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INDIGO MEDICAL INC.
Address: 10123 ALLIANCE RD
CINCINNATI, OH 45242
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-JUL-1999:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 1CM TEMP-SENSING DIFFUSER TIP FIBEROPTIC
Device Type: LASER FIBER
Device Type: LF001
Catalog: LF001
Serial: (*confidential*)
Lot: M4E08E
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

EMAIL: 
Phone: (*)
International: 
Fax: 

Health Professional: Yes
Occupation: 002 - NURSE
Event Description (B5):
User 09-AUG-1999: THE SURGEON WAS USING A SHAPLAN LASER TO PERFORM AN ADENODECTOMY. THE SHEATH THAT THE WAVEGUIDE WENT THROUGH BECAME VERY HOT WHEN IT CAME INTO CONTACT WITH THE PT'S LIP IT BURNED IT.

Concomitant Medical Products:

Mfr Name: SHARPLAN
Address: 1 PEARL COURT
          ALLENDALE, NJ 07401
          UNITED STATES

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
09-AUG-1999:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: CO2 LASER
- Device Type: LASER
- Device Type: 1041
- Catalog: 2
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: [redacted]
- Address: [redacted]
- EMAIL: [redacted]
- Phone: (*)
- International: [redacted]
- Fax: [redacted]

Health Professional: Yes

Occupation: 401 - BIOMEDICAL ENGINEER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>XINTEC CORPORATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 01-Sep-1999</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4) 15-Nov-1999</td>
<td>Event Outcome (B2):</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (F8) 15-Nov-1999</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 30-NOV-1999: LASER BEAM ACTIVATED INAPPROPRIATELY DURING PROCEDURE. IT'S USE WAS IMMEDIATELY DISCONTINUED.

Concomitant Medical Products:

Mfr Name: XINTEC CORPORATION
Address: 900 ALICE STREET
OAKLAND, CA 94607
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
30-NOV-1999:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMIUM LASER YAG
- **Device Type:** LASER YAG
- **Device Type:** ODYSSEY
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: UNKNOWN</th>
<th>Date Received: 20-Jan-2000</th>
</tr>
</thead>
</table>

**Event Date (B3):** 18-Jan-2000  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Reporter Occupation (E3):** 002 - NURSE  
**Device Operator:** HEALTH PROFESSIONAL  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Date Mfr Rec'd (G4):** 20-Jan-2000  
**Report Source (G3):** HEALTH PROFESSIONAL  
**Report Date (F8):** 19-Jan-2000  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  

**Event Description (B5):**  
User 28-JAN-2000: APPROX 30 MIN INTO PROCEDURE HOLMIUM LASER OVERHEATED AND PROCEDURE COULD NOT BE COMPLETED. PT WILL NEED TO UNDERGO GENERAL ANESTHESIA FOR FUTURE PROCEDURE.

**Concomitant Medical Products:**

Mfr Name: FORTEC MEDICAL  
Address: 2458 EDISON BLVD.  
TWINSBURG, OH 44087  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
28-JAN-2000:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMIUM
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 18-Aug-2000</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (B4): 27-Sep-2000</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8): 27-Sep-2000</td>
<td>Adverse Event (B1): Y Problem (B1): Y</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td></td>
<td>Report Source (G3):</td>
</tr>
</tbody>
</table>

**Product Code:** (OB)-LASER, SURGICAL, GYNECOLOGIC (HHR)

**Device Available for Evaluation:** Y

**Device Available for Evaluation by Manufacturer (H3):** No Answer

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Event Description (B5):**

User 06-OCT-2000: MD REPORTED PT SUSTAINED VULVAR BURNS DURING LASER CONIZATION OF CERVIX PERFORMED.

**Concomitant Medical Products:**

NA

**Mfr Name:** SURGICAL LASER TECHNOLOGIES

**Address:** 200 CRESSO BLVD
PO BOX 880
OAKS, PA 19456
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

06-OCT-2000:
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand: SURGICAL LASER TECHNOLOGY
   Device Type: LASER FIBER
   Device Type: SSRH7
   Catalog: UNK
   Serial: (*confidential*)
   Lot: 828101
   Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

   Name: [b] (b)
   Address: [b] (b)
   EMAIL: [b] (b)
   Phone: (*)
   International: [b] (b)
   Fax: [b] (b)

   Health Professional: Yes
   Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

User Facility Report No: Mfr Name: ALCON LABORATORIES

Event Date (B3): 04-Aug-2000 Event Report Type: OTHER
Date Mfr Rec’d (G4): Device Operator: HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INFINITECH
Address: 6201 SOUTH FREeway
FORT WORTH, TX 76134
UNITED STATES

Device Available for Evaluation: Y Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-OCT-2000:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INFINITECH
Device Type: ASPIRATING LASER PROBE
Device Type: 10-0612
Catalog: *
Serial: (*confidential*)
Lot: UNK
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Blacked out]
Address: [Blacked out]
Health Professional: Yes

EMAIL: [Blacked out]
Phone: [Blacked out]
International: [Blacked out]
Fax:

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 22-Jan-2001</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 22-Jan-2001</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 29-JAN-2001: THE FIRST KIT - UNABLE TO LOAD RINGS. THE SECOND KIT UNABLE TO RELEASE RING ONTO TUBE. MD CONVERTED TO BIPOLAR. NO HARM OCCURRED TO PT.

Concomitant Medical Products:

Mfr Name: CIRCON CABOT
Address: 3037 MT. PLEASANT ST
RACINE, WI 53405
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 29-JAN-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** *
- **Device Type:** LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 744320J
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes

**EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

**Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: SHARPLAN LASERS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received: 27-Apr-2001</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 07-Mar-2001</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 25-Apr-2001</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 25-Apr-2001</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
</tr>
<tr>
<td>Expiration Date:</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
</tr>
</tbody>
</table>

Event Description (B5):
User 01-MAY-2001: LASER BEAM SCATTERED AND OFF TO LEFT DURING PROCEDURE.

Concomitant Medical Products:

Mfr Name: SHARPLAN LASER
Address: 1 PEARL COURT
ALENDALE, NJ 07401
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
01-MAY-2001:
CDRH

MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SHARPLAN CO2 LASER
- **Device Type:** LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: BIOLITEC, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received: 04-May-2001</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 19-Apr-2001</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 23-Apr-2001</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 23-Apr-2001</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
</tbody>
</table>

| Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): | Manufacture Date (H4): |
| Expiration Date: | Single Use (H5): |
| Device Usage (H8): | |

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>User 11-MAY-2001: HOLMIUM LASER FIBER TIP BROKE OFF DURING PROCEDURE. NOTED IN PT RIGHT URETER. TOO SMALL TO REMOVE OR IDENTIFY ON X-RAY.</td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

Mfr Name: BIOLITEC
Address: 515 SHAKER RD
EAST LONGMEADOW, MA 01028
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
11-MAY-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: CENAMOPTIC
- Device Type: LASER FIBER
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *
- Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: [Redacted]
- Address: [Redacted]
- Health Professional: Yes
- Occupation: 002 - NURSE
- EMAIL: [Redacted]
- Phone: [Redacted] (b) (6)
- International: Fax: [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: DIOMED, LTD.</th>
<th>Date Received: 26-Jul-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 12-Jun-2001</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8): 22-Jun-2001</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 1 YR 0 DAYS (1 YR)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
User 31-JUL-2001: PT INCURRED AIRWAY FIRE INJURY DURING PHOTODYNAMIC THERAPY. APPROX 3 MINUTES INTO THE PDT TREATMENT THE PDT FIBER APPEARED TO MELT. THE FIBER WAS IMMEDIATELY REMOVED AND IN DOING SO, AN AIRWAY FIRE WAS NOTED. THE FIRE WAS IMMEDIATELY EXTINGUISHED.

Concomitant Medical Products:
OPTIGUIDE FIBER OPTIC FOR PDT.

Mfr Name: DIOMED INC.
Address: 1 DUNDEE PARK
ANDOVER, MA 01810
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
31-JUL-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DIOMED
Device Type: LASER
Device Type: T2USA
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)
Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Details

**Event Date (B3):** 15-May-2002  
**Report Date (B4):** 05-Jun-2002

**Event Report Type:** INJURY  
**Event Outcome (B2):**

**Adverse Event (B1):** Y  
**Problem (B1):** N

**Report Date (B8):**

**Event Location (F12):** INVALID DATA

**Reporter Occupation (E3):** 002 - NURSE  
**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):** 6 YR -182 DAYS (5.5 YR)  
**Manufacture Date (H4):**

**Expiration Date:** Single Use (H5):  
**Device Usage (H8):**

**Event Description (B5):**

User 22-JUL-2002: PT UNDERWENT LASER TREATMENT SESSION #1. CONTACT LENS FELL OUT ON MORE THAN ONE OCCASION. SOME LASER SPOTS WERE DIVERTED TO CENTRAL VISUAL AREA CAUSING DIMINISHED VISION.

### Concomitant Medical Products:

Mfr Name: HGM INC (LUMENIS)  
Address: 3959 WEST 1820 SOUTH  
SALT LAKE CITY, UT 84104  
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

22-JUL-2002:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** HGM INC
- **Device Type:** LASER
- **Device Type:** E 50-3-K05-2-02
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** SPECTRUM K5

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received</td>
<td>07-Oct-2002</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>27-Aug-2002</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>04-Sep-2002</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>04-Sep-2002</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 16-OCT-2002: DURING A CYSTOSCOPY, URETEROSCOPY PROCEDURE WITH A HOLMIUM LASER FOR A LITHOTRIPSY IN THE RIGHT RENAL CALCULUS, THE LASER FIBER FRACTURED THROUGH (OUTSIDE OF PT AND URETEROSCOPE). THE SCRUB TECH WAS TOUCHED BY THE ACTIVE FIBER AS IT &quot;WHIP-LASHED&quot; BY THEM. ALL SAFETY PRECAUTIONS WERE IN PROCESS; NO INJURY TO PT. WHITE MARK APPEARED ON SCRUB TECH'S ARM. THE LASER MACHINE WAS SHUT DOWN IMMEDIATELY BY THE LASER REP.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 15091 BAKE PKWY.</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 16-OCT-2002:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: TRIMEDYNE, INC
- Device Type: LASER FIBER
- Device Type: B365
- Catalog: UNK
- Serial: (*confidential*)
- Lot: UNK
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: [REDACTED]
- Address: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]
- Occupation: 002 - NURSE

Recd: 67
Page: 134
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Date Received</th>
<th>Mfr Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-Oct-2001</td>
<td>INJURY</td>
<td>Y</td>
<td>26-Dec-2002</td>
<td>LUMENIS, INC.</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 11-Oct-2001  
**Event Report Type:** INJURY  
**Adverse Event (B1):** Y  
**Date Received:** 26-Dec-2002  
**Mfr Name:** LUMENIS, INC.

**Event Date (B3):** 11-Oct-2001  
**Event Report Type:** INJURY  
**Adverse Event (B1):** Y  
**Date Received:** 26-Dec-2002  
**Mfr Name:** LUMENIS, INC.

**Event Description (B5):**  

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>COHERENT</td>
<td>2400 CONDENSA STREET</td>
</tr>
<tr>
<td></td>
<td>SANTA CLARA, CA 95051</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-JAN-2003:

DEVICE INFORMATION:

Brand: HOLMIUM VERSA PULSE SELECT
Device Type: LASER
Device Type: SELECT 80
Catalog: NOT KNOWN
Serial: (*confidential*)
Lot: NOT KNOWN
Other ID: NOT KNOWN

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

EMAIL: 
Phone: (*)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: 05-Feb-2003
Mfr Name: LUMENIS, INC.

Event Date (B3): 03-Feb-2003
Report Date (B4): 03-Feb-2003
Report Date (F8): 03-Feb-2003
Date Mfr Rec'd (G4):

Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): * - INVALID DATA
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): N
Event Location (F12): HOSPITAL
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 03-MAR-2003: DURING LEFT URETEROSCOPY & HOLMURM LASER OF LEFT RENAL CALCULI THE HOLMURM LASER PROBE TIP WAS BROKEN OFF. THE TIP WAS SEEN THROUGH THE SCOPE BUT NOT FOUND OR RETRIEVED.

Concomitant Medical Products:
HOLMUIM LASER.

Mfr Name: COHERENT
Address: 5100 PATRICK HENRY DR
SANTA CLARA, CA 95054
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
03-MAR-2003:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SLIMLINE
- **Device Type:** LASER PROBE
- **Device Type:** 365
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 100800
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Email:**
- **Phone:** (b) (6)
- **Health Professional:** No
- **Occupation:** * - INVALID DATA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
<th>Date Received</th>
<th>28-Jul-2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Nov-2002</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Dec-2002</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: INVALID DATA</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 04-AUG-2003: THE LASER FIBER DID NOT LIGHT AIMING BEAM, A NEW FIBER WAS OPENED. THE IMPLANT WIRE WOULD NOT OPEN FOR PLACEMENT, A NEW IMPLANT WAS OPENED.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Mfr Name:** LASERSCOPE SURGICAL SYSTEMS  
**Address:** 3052 ORCHARD DR  
SAN JOSE, CA 95134  
UNITED STATES

**Device Available for Evaluation:** *  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
04-AUG-2003:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: ACCUSTAT
- **Device Type**: LASER FIBER; IMPLANT WIRE
- **Catalog**: 10-3032-205
- **Serial**: (*confidential*)
- **Lot**: 10-3032-205
- **Other ID**: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name**: [redacted]
- **Address**: [redacted]
- **Phone**: (*)
- **International**: [redacted]
- **Fax**: [redacted]

- **Email**: [redacted]

**Health Professional**: No Information

**Occupation**: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**
User 02-OCT-2003: LASERSCOPE NIAGARA 80 WATT KTP LASER IN USE. PT UNDERGOING PROSTATE VAPORIZATION PROCEDURE. LASER BEING OPERATED BY LASER TECHNICIAN. THE SURGICAL TECH MOVED IN FRONT OF THE MACHINE AND "NUDGED" THE FILTER. THE FIBER SNAPPED AT THE BASE WHERE IT CONNECTS TO THE MACHINE. FIBER MELTED AT BASE AND "SNAPPED" APART. LASER LIGHT ESCAPED, FILLED THE ROOM. ALL PERSONS IN THE ROOM WERE WEARING EYE PROTECTION. SURGICAL TECH SUSTAINED 3RD DEGREE BURN 1/8" TO THE LEFT LEG. LASER OPERATOR IMMEDIATELY HIT THE EMERGENCY OFF BUTTON WHICH PREVENTED FURTHER INJURY.

**Concomitant Medical Products:**
NA

**Device Available for Evaluation:** R

**Remedial Action (H7):**

**Mfr Name:** LASERSCOPE
**Address:** 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

**Device Evaluated by Manufacturer (H3):** No Answer

**Device Available for Evaluation:** R

**Correction/Removal No (H9):** No Answer

**Additional Mfr Narrative (H10 & H11):**
02-OCT-2003:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASERSCOPE GREEN LIGTH PV ADDSTAT
- **Device Type:** LASER FIBER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 10-2079-319C-139
- **Other ID:** 0114-9221 REV C

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

User Facility Report No: Mfr Name: BAUSCH & LOMB SURGICAL, INC.

<table>
<thead>
<tr>
<th>Event Date (B3): 01-Jun-2003</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 01-Aug-2003</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
</table>
User 08-JAN-2004: THIS PROCEDURE WAS A LASER VAPORIZATION OF RIGHT URETERAL CALCULI USING A 7 FR FLEXIBLE (STORZ) URETEROSCOPE ALONG WITH A LASER FIBER. THE STAFF SAW A "RED FLASH" ON THE VIDEO. THE LASER BROKE IN 2 PLACES (6" EACH) THEREFORE, BREAKING THE FIBEROPTICS INSIDE THE FLEXIBLE URETEROSCOPE. THE LASER BROKE INSIDE THE SCOPE. THE ENTIRE FIBER WAS RETRIEVED AND THE PATIENT WAS NOT EFFECTED BY EVENT.

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNK</td>
</tr>
</tbody>
</table>

| Mfr Name: BAUSCH LOMB SURGICAL, INC. |
| Address: 180 VIA VERDE |
| SAN DIMAS, CA 91773 |
| UNITED STATES |

| Device Available for Evaluation: R |
| Device Evaluated by Manufacturer (H3): No Answer |

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Correction/Removal No (H9):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Additional Mfr Narrative (H10 &amp; H11): 08-JAN-2004:</th>
</tr>
</thead>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Device Information:

- **Brand:** KARL STORZ
- **Device Type:** LASER FIBER 7FR FLEX WRERTOSCOPE
- **Device Type:** 11274AAU
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

### Reprocessed & Reused:

- **N**

### Reporter Information:

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>No Information</td>
</tr>
<tr>
<td>Occupation</td>
<td>OTHER</td>
</tr>
</tbody>
</table>

**EMAIL:**

**Phone:** (*)

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date Received: 26-Mar-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 17-Mar-2004</td>
<td>Event Report Type: OTHER</td>
<td>Adverse Event (B1): Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (B4): 26-Mar-2004</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 26-Mar-2004</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: INVALID DATA</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>User 30-MAR-2004: LASER TESTING DONE AND PASSED BEFORE CASE. WHEN SURGEON USED LASER @ 3000 JOULES INSIDE LEFT KNEE FIBEROPTIC FIRED OUT OF FIBER ONTO MAYO STAND AND THROUGH DRAPE AND GOWN OF SCRUB TECH BURNING LEFT ARM CAUSING A 2MM BURN/WOUND.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name: TRIMEDYNE</th>
<th>Address: 1509 BAKE PARKWAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRVINE, CA 92618</td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 30-MAR-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** TRIMEDYN
- **Device Type:** LASERSCOPE FIBER
- **Device Type:** 20470-HP
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 30600-8
- **Other ID:** *

- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>12-Mar-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>DEATH</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>SPECTRANETICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>96 TALAMINE COURT COLORADO SPRINGS, CO 80907 UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: Y

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

06-APR-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM
- **Device Type:** LASER - GEN 4.OR
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** No

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [*]
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:  Date Received  26-May-2004
Mfr Name: ACMI CORPORATION

| Event Date (B3): 05-May-2004 | Event Report Type: MALFUNCTION | Adverse Event (B1): Y
| Report Date (F8): 21-May-2004 | Reporter Occupation (E3): 500 - RISK MANAGER | Event Location (F12): HOSPITAL
| Date Mfr Rec'd (G4): | Device Operator: HEALTH PROFESSIONAL | Report Source (G3): |

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 01-Mar-2007
Single Use (H5):
Device Usage (H8):

Event Description (B5):
User 25-JUN-2004: THE PT WAS UNDERGOING A LEFT LASER LITHOTRIPSY OF LOWER POLE STONE WHEN THE LASER TIP BROKE OFF IN THE BLADDER. THE SURGEON RETRIEVED THE LASER TIP. THERE WAS NO INJURY TO THE PT.

Concomitant Medical Products:

Mfr Name: ACMI CORPORATION
Address: 136 TURNPIKE RD.
SOUTHBOROUGH, MA 01772
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-JUN-2004:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMIUM
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSH
- **Catalog:** 200MICRON
- **Serial:** (*confidential*)
- **Lot:** A1204-01S
- **Other ID:** *

Reprocessed & Reused: N

REPORER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** (*)
- **International:**
- **Fax:**

Health Professional: No Information

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 22-Jul-2004
Report Date (B4): 11-Aug-2004
Report Date (F8): 11-Aug-2004
Date Mfr Rec'd (G4):

Event Description (B5):

Concomitant Medical Products:
PT. DISCHARGED FROM HOSP IN 7/2004.

Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.

Adverse Event (B1): Problem (B1): N
Event Report Type: INJURY
Event Outcome (B2): HOSPITALIZATION
Report Date (B4):eline 2004
Report Date (F8): 500 - RISK MANAGER
Event Location (F12): HOSPITAL
Reporter Occupation (E3): HEALTH PROFESSIONAL
Event Date: 16-Aug-2004

Device Operator: Date Mfr Rec'd (G4):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-AUG-2004:

Mfr Name: *
Address: 147 KEYSTONE DR.
MONTGOMERYVILLE, PA 18936
UNITED STATES

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SURGICAL LASER TECHNOLOGIES
- **Device Type:** LASER PROBE SMTR 1.5
- **Device Type:** SMTR 1.5
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**
User 07-OCT-2004: PATIENT IN CATHETERIZATION LAB HAVING INFECTED ICD, IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, AND LEADS REMOVED. WHEN REMOVING THE FINAL LEAD USING A LASER LEAD EXTRACTOR THE PATIENT HAD SUDDEN DROP IN BLOOD PRESSURE. WAS GIVEN MEDICATIONS AND FLUIDS AND LOCAL PRESSURE WAS USED FOR HEMOSTASIS BUT WITHOUT SUCCESS. ECHO, ECHOCARDIOGRAM, DONE SHOWED LARGE PERICARDIAL EFFUSION AND THE PATIENT WAS TAKEN EMERGENTLY TO OPERATING ROOM AND EXPIRED. A 6CM (ANOTHER STATEMENT SAYS 6MM) LACERATION WAS FOUND IN THE SUPERIOR VENA CAVA THAT EXTENDED TO THE JUNCTION OF THE INTERPERICARDIAL SUPERIOR VENA CAVA TO THE JUNCTION OF THE RIGHT ATRIUM.

**Concomitant Medical Products:**
NO OTHER THERAPIES

**Mfr Name:** SPECTRANETICS CORPORATION
**Address:** 96 TALAMINE COURT
COLORADO SPRINGS, CO *
UNITED STATES

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
07-OCT-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASER SHEATH SLS II
- **Device Type:** LASER CARDIAC LEAD REMOVAL DEVICE
- **Device Type:** 500-013
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** Y

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No Information
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 500 - RISK MANAGER

Mfr Name:  MACKIN MEDICAL INC.

Event Date (B3):  23-Sep-2004
Report Date (B4):  07-Oct-2004
Report Date (F8):  07-Oct-2004
Date Mfr Rec'd (G4):  REPORT DATE (F4):

Event Report Type:  MALFUNCTION
Adverse Event (B1):
Problem (B1):  Y
Event Outcome (B2):
Event Location (F12):  HOSPITAL
Report Source (G3):  HEALTH PROFESSIONAL

Product Code:
(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator:  HEALTH PROFESSIONAL

Device Age (F9):
Manufacture Date (H4):
Expiration Date:
Single Use (H5):
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:

Mfr Name:  MACKIN MEDICAL
Address:  *
BRYN MAWR, PA 19010
UNITED STATES

Device Available for Evaluation:  R
Device Evaluated by Manufacturer (H3):  No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
20-OCT-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: HOLMIUM LASER
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: M02220
Other ID: HMA1040F

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: No

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received

User Facility Report No: Mfr Name: XINTEC CORPORATION

Event Date (B3): 01-Nov-2004 Event Report Type: MALFUNCTION Adverse Event (B1): Problem (B1): Y
Report Date (B4): 08-Nov-2004 Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8): 08-Nov-2004 Reporter Occupation (E3): 500 - RISK MANAGER Event Location (F12): HOSPITAL
Date Mfr Rec'd (G4): Device Operator: HEALTH PROFESSIONAL Report Source (G3):
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Single Use (H5):
Expiration Date: Device Usage (H8):

Event Description (B5):
User 18-NOV-2004: PT ADMITTED WITH CALCULUS OF KIDNEY. UTI HTN, DM2, AND NUMBNESS. PT UNDERWENT A CYSTO. LEFT STENT REMOVAL, BILATERAL RETROGRAD PYELOGRAM, RIGHT UTERETERSCOPY WITH LASER LITHOTRIPSY DURING THIS PORTION OF THE SURGERY THE VERY TIP OF THE FIBER BROKE OFF INTO THE RIGHT COLLECTING SYSTEM. SEVERAL ATTEMPTS WERE MADE TO REMOVE THE FRAGMENT USING 3-PRONG GRASERS AND A COMPRASS BASKET. HOWEVER, DUE TO LARGE AMOUNT OF DEBRIS THE FRAGMENT WAS NO LONGER VISIBLE. ESTIMATED SIZE 1 MM IN LENGTH AND 200 MICROS IN DIAMETER. A LARGE STENT WAS PLACED.

Concomitant Medical Products:

Mfr Name: CONVERGENT & LASER TECH
Address: 900 ALICE STREET
          OAKLAND, CA 94607
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-NOV-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** CONVERGENT - LASER
- **Device Type:** LASER SHEATH
- **Device Type:** ODYSSEY
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Occupation:** 500 - RISK MANAGER
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>24-Nov-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>15-Dec-2004</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>HOSPITALIZATION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 12-JAN-2005: IT WAS REPORTED THAT THE PT WAS TO HAVE A LASER COAGULATION OF THE PROSTATE; HOWEVER, THE LASER WOULD NOT HEAT TO 80 DEGREES SO THE PROCEDURE COULD NOT BE PERFORMED. THE PT HAD TO UNDERGO A TURP PROCEDURE WHICH REQUIRED OVERNIGHT HOSPITALIZATION. THE DEVICE WILL BE RETURNED FOR ANALYSIS.</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>12-JAN-2005:</td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**
- LASER FIBER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO LASER INTERSTITIAL TREATMENT SYSTEM
- **Device Type:** LASER-SURGERY DEVICES - REUSABLE
- **Catalog:** LS83E
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Phone:**
- **Fax:**
- **EMAIL:**
- **International:**
- **Occupation:** 002 - NURSE
- **Health Professional:** Yes
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| User Facility Report No: | Mfr Name: LASER PERIPHERALS LLC. | Event Date (B3): 02-Dec-2004 | Event Report Type: MALFUNCTION | Adverse Event (B1): Problem (B1): Y
| Event Date (F8): 28-Dec-2004 | Reporter Occupation (E3): 500 - RISK MANAGER | Event Location (F12): HOSPITAL | Event Location (F12): |
| Date Mfr Rec’d (G4): | Device Operator: HEALTH PROFESSIONAL | Report Source (G3): |

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4):

**Expiration Date:** Single Use (H5):

**Device Usage (H8):**

**Event Description (B5):**

User 12-JAN-2005: WHEN USING 200 FIBER FOR LASER IN FLEXIBLE DUR-8 ELITE URETEROSCOPE, ABOUT 1-1/2 TO 2 INCHES OF FIBER BROKE OFF. PIECE WAS RETRIEVED WITH ALLIGATOR FORCEP. AFTER CASE SCOPE OUTER CASING FOUND TO HAVE SMALL HOLE BUT DOES NOT APPEAR TO HAVE DAMAGE TO OPTICS.

**Concomitant Medical Products:**

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 12-JAN-2005:

Report Date (B4): 10-Jan-2005
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER PERIPHERALS
- **Device Type:** LASER FIBER
- **Device Type:** HBLF-200
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** E0447
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
  - Fax:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>07-Dec-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>13-Dec-2004</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>13-Dec-2004</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>-</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 24-JAN-2005: COHERENT LASER PRETESTING COMPLETED. LASER WAS WARMED UP AND FUNCTIONAL. WHEN PHYSICIANS WERE ABOUT TO USE LASER, IT SHUT DOWN BY ITSELF. ATTEMPTS TO RE-START WERE UNSUCCESSFUL. CLINICAL ENGINEERING CHECKED AND WILL REPAIR. FOLLOW UP REVEALS: STUCK EMERGENCY POWER SWITCH WAS THE PROBLEM.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>COHERENT, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>5100 PATRICK HENRY DRIVE</td>
</tr>
<tr>
<td>SANTA CLARA, CA 95054</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>24-JAN-2005:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: COHERENT LASER
- Device Type: LASER
- Device Type: VP SELECT
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [REDACTED]
- Address: [REDACTED]
- EMAIL: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]
- Health Professional: No Information
- Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**


**Concomitant Medical Products:**

OLYMPUS FLEXIBLE URETEROSCOPE, TYPE P2.

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

27-JAN-2005:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: HOLMIUM LASER  
Device Type: LASER FIBER
Device Type: UNK
Catalog: *  
Serial: (*confidential*)
Lot: UNK  
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**
User 24-FEB-2005: THE CO2 LASER WOULD NOT FUNCTION IN THE SUPER PULSE MODE, SO IT WAS SWITCHED TO CONTINUOUS. IT CONTINUED TO FIRE EVEN AFTER THE PEDAL WAS RELEASED.

**Concomitant Medical Products:**
NOT KNOWN

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
24-FEB-2005:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SHARPLAN
Device Type: LASER, SURGICAL, CO2
Device Type: 1055
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: No Information

EMAIL: 
Phone: (b) (6)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: Mfr Name: HGM, INC.

Event Date (B3): 28-Feb-2005 Event Report Type: MALFUNCTION Adverse Event (B1): Problem (B1): Y
Report Date (B4): 03-Mar-2005 Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8): 03-Mar-2005 Reporter Occupation (E3): 500 - RISK MANAGER Event Location (F12): HOSPITAL
Date Mfr Rec'd (G4): Device Operator: HEALTH PROFESSIONAL Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:

Mfr Name: HGM
Address: *
SALT LAKE CITY, UT *
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-MAR-2005:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** PC-EDO
- **Device Type:** LASER
- **Device Type:** E02-A-A01-2
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** JD
- **Address:**
- **Health Professional:** Yes

**Email:**

**Phone:**

**International:**

**Fax:**

**Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date Received: 18-Jun-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 28-Apr-2004</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 18-May-2004</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 18-May-2004</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: INVALID DATA</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3): INVALID DATA</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 30-MAR-2005: WHILE THE SURGEON WAS USING THE LASER FIBER TO DO A PARTIAL LATERAL MENISCETOMY, THE FIBER EXPLODED, CHARRING TISSUE. ANOTHER FIBER WAS USED TO FINISH THE PROCEDURE. BOTH LASER FIBERS HAD BEEN RE-STERILIZED.

**Concomitant Medical Products:**

HOLMIUM YAG LASER.

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 15091 BAKE PKWY.

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

30-MAR-2005:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: TRIMEDYNE
Device Type: DISPOSABLE LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: 307005
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: No

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 28-Mar-2005</td>
<td>Event Outcome (B2):</td>
<td>Report Date (B4): 04-Apr-2005</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: INVALID DATA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date: Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
14-APR-2005:
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

  Brand: KTP LASER FIBER
  Device Type: LASER FIBER
  Device Type: *
  Catalog: *
  Serial: (*confidential*)
  Lot: 10-2079-503A-0454
  Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

  Name: (b)(6)
  Address: (b)(6)
  EMAIL: (b)(6)
  Phone: (b)(6)
  International: (b)(6)
  Fax:
  Occupation: -

  Health Professional: No Information
**MAUDE EVENT REPORT (FOI)**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received</td>
<td>23-Aug-2005</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 12-Aug-2005  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y

**Report Date (B4):** 23-Aug-2005  
**Event Outcome (B2):**  
**Report Date (F8):** 23-Aug-2005

**Date Mfr Rec'd (G4):**  
**Report Source (G3):** INVALID DATA

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Operator:** INVALID DATA

**Event Description (B5):**
User 07-SEP-2005: PATIENT WAS SCHEDULED TO HAVE AN INDIGO PROSTATECTOMY, BUT THE INDIGO OPTIMA LASER MALFUNCTIONED AND WOULD NOT TURN ON. THE MACHINE HAD BEEN TESTED BY THE BIOMEDICAL ENGINEER PRIOR TO ITS USE AND IT WAS DETERMINED TO BE FUNCTIONING.

**Concomitant Medical Products:** NOT KNOWN

**Mfr Name:** ETHICON ENDO SURGERY

**Address:** 4545 CREEK ROAD  
CINCINNATI, OH 45242  
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
07-SEP-2005:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INDIGO OPTIMA
Device Type: LASER BEAM MACHINE
Device Type: LS83F
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: No Information

Email: [redacted]
Phone: [redacted]
International: [redacted]
Fax:

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 18-Apr-2005</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 09-Sep-2005</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 09-Sep-2005</td>
<td>Reporter Occupation (E3):</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: INVALID DATA</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

**Concomitant Medical Products:**
NOT APPLICABLE

**Mfr Name:** LASERSCOPE
**Address:** 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

**Device Available for Evaluation:** R
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 16-SEP-2005:

**Adverse Event (B1):** Problem (B1): Y
**Event Location (F12):** HOSPITAL
**Report Source (G3):** INVALID DATA

Date Received: 09-Sep-2005
Date Last Updated: 11/2/2010  9:17 AM Recd: 89 Page: 177
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** GREENLIGHT PV ADDSTAT
- **Device Type:** LASER FIBER
- **Device Type:** 10-2079-506A-0159
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No Information
- **Occupation:** -
<table>
<thead>
<tr>
<th>Date Received</th>
<th>30-Dec-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Dec-2005</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>30-Dec-2005</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>30-Dec-2005</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td></td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>-</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>-</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Mfr Name: LASERSCOPE</td>
<td></td>
</tr>
<tr>
<td>Address: 3070 ORCHARD DRIVE</td>
<td></td>
</tr>
<tr>
<td>SAN JOSE, CA 95134</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 28-JAN-2006:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT PV
- **Device Type:** LASER, ND:YAG (KTP)
- **Device Type:** GREEN LIGHT PU
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *(b) (6)*
- **Address:** *(b) (6)*

Health Professional: No Information

- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:**
- **Fax:**

Occupation: -
### Event Description (B5):

User 28-JAN-2006: A PATIENT WAS BROUGHT TO THE OR FOR A BRONCHOSCOPY AND KTP LASER ABLATION OF AIRWAY GRANULOMA. THE KTP LASER WAS INSPECTED AND TESTED PER PROTOCOL PRIOR TO THE PROCEDURE STARTING. A 3.5 VENTILATING BRONCHOSCOPY WAS PLACED WITH THE KTP LASER FIBER BEING PASSED THROUGH THE SIDE PORT OF THE BRONCHOSCOPE. ONCE THE FIBER ENTERED THE AIRWAY, IT FRACTURED. THERE WERE THREE PIECES NOTED IN THE AIRWAY. A PARSON'S LARYNGOSCOPE WAS USED TO EXPOSE THE LARYNX WHILE OPTICAL FORCEPS WERE USED TO REMOVE THE THREE PIECES OF THE SHATTERED FIBER. THE ORIGINAL PLANNED PROCEDURE WAS THEN COMPLETED. THERE WAS NO INJURY TO THE PATIENT WHO WAS DISCHARGED HOME FOUR DAYS LATER.

### Concomitant Medical Products:

- NO OTHER THERAPIES

### Mfr Name: MEDICAL ENERGY INC

#### Address:

- 225 EAST ZARAGOZA STREET
- PENSACOLA, FL 32501
- UNITED STATES

#### Device Available for Evaluation: Y

#### Device Evaluated by Manufacturer (H3): No Answer

#### Remedial Action (H7):

#### Correction/Removal No (H9):

#### Additional Mfr Narrative (H10 & H11):

28-JAN-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER POWERTOUCH
Device Type: LASER FIBER QUARTZ CONTACT DELIVERY SYSTEM
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: 1904
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: No Information

EMAIL: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
### Event Description (B5):


### Concomitant Medical Products:

NOT KNOWN

### Mfr Name: COHERENT INC.

**Address:**
5100 PATRICK HENRY DRIVE
SANTA CLARA, CA 95054
UNITED STATES

### Device Available for Evaluation:

Y

### Device Evaluated by Manufacturer:

No Answer

### Remedial Action:

No Answer

### Additional Mfr Narrative:

01-MAR-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ULTRAPULSE
- **Device Type:** LASER, HANDPIECE
- **Device Type:** UP5000C
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No Information
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>26-Jan-2006</th>
<th>Event Report Type:</th>
<th>INJURY</th>
<th>Adverse Event (B1):</th>
<th>Y</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>31-Mar-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Event Location (F12):</td>
<td>AMBULATORY SURGICAL FACILITY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(OP)-EXCIMER LASER SYSTEM (LZS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 03-MAY-2006: DURING LASER LASIK TREATMENT OF PATIENT'S EYE, TRACKING MECHANISM DISENGAGED AND WOULD NOT ALLOW SURGEON TO RE-ACQUIRE THE EYE TRACKING AND CONTINUE SURGERY. SURGERY ABORTED AT 88% COMPLETE. PATIENT HAD TO RETURN AND HAVE SURGERY AGAIN. ALCON FIELD REP REPRODUCED REPORTED PROBLEM OF TRACKER. UNABLE TO MAINTAIN TRACKING STABILITY DURING TRACKER TESTING PROCEDURE. REPLACED GALVO BOX AND ANALOG BOX. VERIFIED TRACKER OPERATIONS. REPLACED DSP CARD AS A PREVENTATIVE MEASURE. COMPLETED SYSTEM VERIFICATION AND DEVICE WAS RETURNED TO SERVICE.

**Concomitant Medical Products:**

**Mfr Name:** ALCON LABORATORIES, INC.  
**Address:** 6201 SOUTH FREEWAY  
MAIL STOP S3-14  
FT. WORTH, TX 76134  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**  
03-MAY-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LADARVISION
- **Device Type:** LASER SYSTEM, EYE TRACKING DEVICE
- **Device Type:** 4000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: PHOTOMEDEX, INC.</th>
<th>Date Received: 05-May-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 05-May-2006</td>
<td>Event Report Type: OTHER</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 05-May-2006</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 05-May-2006</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 05-Dec-2010</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 12-MAY-2006: WHILE DOING A RIGHT LASER LITHOTRIPSY WITH A DORNIER HOLMIUM H2O-155. THE LASER TIP BROKE OFF WHICH IN USE. SURGEON RETRIEVED BROKEN FIBER WITH A STONE BASKET.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 12-MAY-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>DORNIER HOLMIUM H2O</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>272 MICRON FIBER</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>H2O-155</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N</td>
</tr>
</tbody>
</table>

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>Yes</td>
</tr>
<tr>
<td>EMAIL:</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Phone:</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>International:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Occupation:</td>
<td>OTHER</td>
</tr>
</tbody>
</table>

Recd: 94   Page: 188   Date Last Updated: 11/2/2010 9:17 AM
Event Date (B3): 23-May-2006  
Report Date (B4): 05-Jun-2006  
Report Date (F8): 05-Jun-2006  
Date Mfr Rec’d (G4):  

Event Report Type: MALFUNCTION  
Adverse Event (B1): Problem (B1): Y  
Event Outcome (B2):  
Reporter Occupation (E3): 500 - RISK MANAGER  
Device Operator: INVALID DATA  
Event Location (F12): HOSPITAL  
Report Source (G3):  

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)  
Device Age (F9):  
Expiration Date:  
Device Usage (H8):  

Event Description (B5):  
User 21-JUN-2006: LASER FIBER BROKE AT 37,000 JOULES AND BLACKENED GLOVE OF SURGEON WHEN FIBER BROKE DURING BLADDER NECK CONTRACTURE REPAIR. EVENT DID NOT REACH PATIENT. LASER FIBER "TOSSED" AT TIME OF EVENT AND REPLACED BY REPRESENTATIVE.  

Concomitant Medical Products:  
NOT KNOWN  

Mfr Name: TRIMEDYNE, INC.  
Address: 15091 BAKE PARKWAY  
IRVINE, CA 92618  
UNITED STATES  

Device Available for Evaluation: N  
Device Evaluated by Manufacturer (H3): No Answer  

Remedial Action (H7):  
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11): 21-JUN-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMES
- **Device Type:** LASER, FIBER
- **Device Type:** 20440
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>Date Received</th>
<th>29-Jun-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 01-May-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 28-Jun-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 28-Jun-2006</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: ()-()</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 30-JUN-2006: NEXTMED GREENLIGHT LASER WOULD NOT FIRE DURING CASE. PATIENT HAD ALREADY HAD ANESTHESIA WHEN PROBLEM WAS DISCOVERED. THE GREEN LIGHT KTP LASER FIBER WAS ENGAGED AND MET WITH FALSING SIGNALS. THE TECHNICIAN DISCOVERED A FATAL FIBEROPTIC INJURY THAT COULD NOT BE REPAIRED. THERE WAS NO REPLACEMENT MACHINE AND ENDOSCOPIC WAS NOT PERFORMED, AS THE PATIENT WAS NOT CONSENTED FOR ANY OTHER PROCEDURE, OTHER THAN THE GREEN LIGHT TURP. CASE WILL BE RESCHEDULED.

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
30-JUN-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** NEXTMED GREENLIGHT KTP LASER
- **Device Type:** LASER
- **Device Type:** GREENLIGHT
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>03-Aug-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 18-Jul-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 28-Jul-2006</td>
<td>Reporter Name:</td>
<td>Device Operator: INVALID DATA</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
</tr>
</tbody>
</table>

User 23-AUG-2006: HOLMIUM LASER FIBER B365 BROKE DURING LASER LITHOTRIPSY WHILE BEING USED BY SURGEON. THE STONE WAS PARTIALLY EMBEDDED INTO THE WALL OF THE URETER. FIBER WAS REPLACED DURING THE PROCEDURE. NO INJURY TO PATIENT. SURGEON NOTED THAT HE TORQUED THE DEVICE, POTENTIALLY CONTRIBUTING TO FIBER BREAKAGE.

Concomitant Medical Products:
NOT KNOWN

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer: No Answer

Remedial Action: No Answer
Correction/Removal No: No Answer
Additional Mfr Narrative: 23-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** B365
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 403039
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**User Facility Report No:**

<table>
<thead>
<tr>
<th>Event Date (B3): 27-Jul-2006</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 01-Aug-2006</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Report Date (F8): 01-Aug-2006</td>
<td>Reporter Occupation (E3): -</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Event Description (B5):**
User 05-SEP-2006: DURING A LASER TREATMENT OF THE PROSTATE, THE TIP OF THE LASER FIBER BLEW APART. THERE WAS NO HARM TO THE PATIENT.

**Concomitant Medical Products:** NOT KNOWN

**Mfr Name:** LASERSCOPE

**Address:** 3070 ORCHARD DRIVE SAN JOSE, CA 95134 UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 05-SEP-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ADDSTAT
Device Type: LASER FIBER
Device Type: GREENLIGHT PV
Catalog: 10-2080
Serial: (*confidential*)
Lot: 10-2080-612Q
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b] [b] [b] [b]
Address: [b] [b] [b] [b] [b]

Health Professional: No Information

EMAIL: [b] [b]
Phone: [b] [b]
International: [b] [b]
Fax: [b] [b]

Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>25-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>27-Sep-2006</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 17-OCT-2006: DURING A PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE USING GREENLIGHT LASER, THE LASER MALFUNCTIONED. MID PROCEDURE THE LASER READ PROBLEM 43, AND WENT BACK TO THE SELF TEST SCREEN. IT ATTEMPTED TO GO THRU SELF TEST AGAIN UNSUCCESSFULLY AND READ PROBLEM 90. WE ATTEMPTED TO REBOOT AND THE SAME PROBLEM OCCURRED. A CALL WAS PLACED TO LASERSCOPE WHO INFORMED US WE WOULD BE UNABLE TO COMPLETE THE CASE. DOCTOR FINISHED THE PROCEDURE BY PERFORMING A TRANSURETERAL RESECTION OF THE PROSTATE.

Concomitant Medical Products:
NOT KNOWN

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
         SAN JOSE, CA 95134
         UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-OCT-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: GREENLIGHT LASER
Device Type: LASERSCOPE
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
Name: (b) (6)
Address: (b) (6)

Health Professional: No Information

EMAIL: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Occupation: -
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE, INC.</th>
<th>Date Received: 22-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 15-Aug-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 22-Sep-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 22-Sep-2006</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 19-OCT-2006: PHYSICIAN PERFORMING KTP (POTASSIUM TITANYL PHOSPHATE) VAPORIZATION OF PATIENT'S PROSTATE FOR ONE HOUR UNTIL THE CHANNEL WAS WIDE OPEN. PHYSICIAN MADE DECISION TO SWITCH TO A RETROSCOPE TO COMPLETE REMOVAL OF OBSTRUCTING TISSUE. PHYSICIAN NOTED THE TIP OF THE LASER BROKE OFF. PHYSICIAN LOCATED THE TIP AND CHECKED IT AGAINST THE MAIN FIBER AND EVERYTHING MATCHED UP. PATIENT TOLERATED THE PROCEDURE WELL AND THERE WERE NO COMPLICATIONS. THE LASER FIBER IS A SINGLE-USE ITEM. UNFORTUNATELY STAFF DID NOT RETAIN THE LASER FIBER/BROKEN TIP. A RENTAL AGENCY PROVIDES THIS FACILITY WITH THE LASERSCOPES AND ACCESSORIES.

**Concomitant Medical Products:**

NOT APPLICABLE

**Mfr Name:** LASERSCOPE
**Address:** 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

19-OCT-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** KTP LASER FIBER
- **Device Type:** LASER, FIBEROPTICS
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:  Mfr Name: LASERSCOPE

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-Oct-2006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (B4):</th>
<th>Event Outcome (B2):</th>
<th>Event Location (F12):</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-Oct-2006</td>
<td></td>
<td>HOSPITAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (F8):</th>
<th>Reporter Occupation (E3):</th>
<th>Date Mfr Rec’d (G4):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>PHYSICIAN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Age (F9):</th>
<th>Expiration Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>User 10-NOV-2006: GREEN LIGHT PVP LASER BROUGHT IN FROM A RENTAL COMPANY FOR A PROSTATECTOMY CASE. BIOMED CHECKED LASER PRIOR TO USE, IT WAS GOOD TO GO. AFTER LASER FIBER CONNECTED TO LASER MACHINE THE SELF CHECK FAILED. AFTER ADJUSTMENTS AND REBOOTING, ANOTHER FIBER WAS OPENED, THIS ALSO DID NOT PASS THE SELF CHECK. AFTER MORE ADJUSTMENTS THE LASER WENT INTO STANDBY MODE READY FOR USE. AFTER USING PART WAY THROUGH PROCEDURE DELIVERING 24, 109 JOULES OF POWER, BUT BEFORE PROCEDURE WAS COMPLETE THE LASER SHUT DOWN. SINCE IT WAS COMPANY POLICY NOT TO ISSUE MORE THAN TWO LASER FIBERS THE PROCEDURE WAS FINISHED WITHOUT USE OF THE LASER VIA TRANSURETHRAL RESECTION OF THE PROSTATE. THIS ADDED LENGTH TO THE PROCEDURE TIME AND THE PATIENT INCURRED THIS ADDITIONAL EXPENSE.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOT KNOWN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name: LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: 3070 ORCHARD DRIVE</td>
</tr>
<tr>
<td>SAN JOSE, CA 95134</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Evaluated by Manufacturer (H3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Answer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Correction/Removal No (H9):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Mfr Narrative (H10 &amp; H11):</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-NOV-2006:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>GREENLIGHT PVP LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER, GREENLIGHT PVP</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>Address</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>Yes</td>
</tr>
<tr>
<td>EMAIL</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Phone</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
</tbody>
</table>

Occupation: 002 - NURSE
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**User Facility Report No:**

<table>
<thead>
<tr>
<th>Event Date (B3): 30-Oct-2006</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 22-Nov-2006</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: UNKNOWN</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Code:**

<table>
<thead>
<tr>
<th>Device Age (F9):</th>
<th>Manufacture Date (H4):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 21-DEC-2006: PATIENT WAS BEING TREATED FOR ROSACEA ON THE FACE. WHEN I ATTEMPTED TO TREAT AN AREA WITH FINE VASCULATURE WITH INCREASED POWER SETTINGS, THE FILTER WAS NOT PULLED AWAY FAR ENOUGH AND THE SKIN ABSORBED THE LIGHT MORE INTENSELY THAN INTENDED. SOME ERYTHEMA ENSUED AS WELL AS DARKENING OF THE SKIN. ICE APPLIED IMMEDIATELY AS WELL AS CREAM. PATIENT WAS COMFORTABLE AND NOT IN ANY PAIN.

**Concomitant Medical Products:**

NOT APPLICABLE

**Mfr Name:** LUMENIS, INC.

**Address:**

2400 CONDENSIA STREET
SANTA CLARA, CA 95051
UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

21-DEC-2006:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EPILIGHT
Device Type: LASER, COSMETIC
Device Type: UNK
Catalog: UNK
Serial: (*confidential*)
Lot: UNK
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b]
Address: [b] [b]

Health Professional: No Information

EMAIL: [b] [b]
Phone: [b] [b]
International: [b] [b]
Fax: [b] [b]

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: BOSTON SCIENTIFIC CORP.</th>
<th>Date Received: 05-Dec-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 05-Dec-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 05-Dec-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 05-Dec-2006</td>
<td>Reporter Occupation (E3): -</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: INVALID DATA</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NOT KNOWN

**Mfr Name:** BOSTON SCIENTIFIC CORP.
**Address:** ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
26-DEC-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Device Information</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>*</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Catalog</td>
<td>840804</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>TRF2056A</td>
</tr>
<tr>
<td>其他ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Reporter Information</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Professional</td>
<td>No Information</td>
</tr>
<tr>
<td>Name</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

| EMAIL:                          | |
| Phone                           | (b) (6) |
| International                   |  |
| Fax                             |  |

Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**User Facility Report No:**
**Mfr Name:** SURGICAL LASER TECHNOLOGIES, INC.
**Date Received:** 28-Nov-2006

**Event Date (B3):** 16-Nov-2006
**Event Report Type:** MALFUNCTION
**Adverse Event (B1):**
**Problem (B1):** Y

**Report Date (B4):** 28-Nov-2006
**Event Outcome (B2):**
**Reporter Occupation (E3):** 500 - RISK MANAGER
**Device Operator:** PHYSICIAN

**Date Mfr Rec'd (G4):**
**Device Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
**Report Source (G3):**

**Product Code:**
**Device Age (F9):**
**Expiration Date:**
**Device Usage (H8):**

**Event Description (B5):**

**Concomitant Medical Products:**
NOT APPLICABLE

**Mfr Name:** SURGICAL LASER TECHNOLOGIES, INC.
**Address:** 147 KEYSTONE DRIVE
MONTGOMERYVILLE, PA 18936
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
27-DEC-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** FIBER DELIVERY SYSTEM
- **Device Type:** LASER, FIBER
- **Catalog:** TCRH7
- **Serial:** (*confidential*)
- **Lot:** 521303
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

**Health Professional:** No Information

**Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
<th>Event Date (B3): 07-Dec-2006</th>
<th>Event Report Type: *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>LASERSCOPE</td>
<td>Event Date (B3): 07-Dec-2006</td>
<td>Event Report Type: *</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>3070 ORCHARD DRIVE</td>
<td>Event Date (B3): 07-Dec-2006</td>
<td>Event Report Type: *</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SAN JOSE, CA 95134</td>
<td>Event Date (B3): 07-Dec-2006</td>
<td>Event Report Type: *</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td>Event Date (B3): 07-Dec-2006</td>
<td>Event Report Type: *</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
User 17-JAN-2007: AN 80-WATT KTP LASER FIBER INTRODUCER TO BEGIN VAPORIZATION OF THE PROSTATE. THE LASER FIBER RUPTURED AND HAD TO BE RETRIEVED. A SECOND LASER FIBER INTRODUCED AND IT RUPTURED AND AGAIN WAS RETRIEVED.

Concomitant Medical Products:
NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT PVP LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** GREENLIGHT PV
- **Catalog:** 10-2080
- **Serial:** (*confidential*)
- **Lot:** 10-2080-620N
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *(b) (b)*
- **Address:** *(b) (b)*
- **Health Professional:** No Information

- **EMAIL:** *(b) (b)*
- **Phone:** *(b) (b)*
- **International:** *(b) (b)*
- **Fax:** *(b) (b)*

- **Occupation:** 500 - RISK MANAGER
User Facility Report No:  

Mfr Name: LASERSCOPE  

**Event Date (B3):** 26-Dec-2006  
**Report Date (B4):** 09-Jan-2007  
**Report Date (F8):** 09-Jan-2007  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** MALFUNCTION  

**Adverse Event (B1):** Problem (B1): Y  
**Event Outcome (B2):**  

**Event Location (F12):** HOSPITAL  
**Report Source (G3):**  

**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:** Single Use (H5):  
**Device Usage (H8):**  

**Event Description (B5):**  
User 17-JAN-2007: DURING TRANSURETHRAL RESECTION OF PROSTATE, A SECTION OF THE LASER FIBER BROKE OFF IN PATIENT'S BLADDER AND HAD TO BE RETRIEVED.  

**Concomitant Medical Products:**  
NO OTHER THERAPIES  

Mfr Name: LASERSCOPE  
Address: 3070 ORCHARD DRIVE  
SAN JOSE, CA 95134  
UNITED STATES  

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
17-JAN-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT PV FIBEROPTIC
- **Device Type:** LASER FIBER
- **Device Type:** LIMIT 275 KJ
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 10-2080-632X
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 27-Nov-2006</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 21-Dec-2006</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 21-Dec-2006</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 21-Dec-2006</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3): -</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Device Operator: OTHER</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
</tbody>
</table>


Concomitant Medical Products:

NO OTHER THERAPIES

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DR
          SAN JOSE, CA 95134
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-JAN-2007:

MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** GREENLIGHT PV ADDSTAT
- **Device Type:** LASER, GREEN
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 10-2079-6302
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** (b)(6)
- **Address:** (b)(6)

Health Professional: No Information

EMAIL: (b)(6)
Phone: (b)(6)
International: Fax:

Occupation: -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:  
Mfr Name: LASERSCOPE  

Event Date (B3): 29-Dec-2006  
Report Date (B4): 24-Jan-2007  
Report Date (F8): 24-Jan-2007  
Date Mfr Rec'd (G4):  

Event Report Type: INJURY  
Event Outcome (B2): REQUIRED INTERVENTION  
Reporter Occupation (E3): -  
Device Operator: PHYSICIAN  

Adverse Event (B1): Y  
Problem (B1): N  
Event Location (F12): HOSPITAL  
Report Source (G3):  

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
Device Age (F9):  
Expiration Date:  
Device Usage (H8):  

Event Description (B5):  
User 25-JAN-2007: DOCTOR WAS PERFORMING LASER SURGERY IN PATIENT LUNGS IN AN OXYGEN ENRICHED ENVIRONMENT, WHICH RESULTED IN BURNS TO THE PATIENT AS WELL AS THE BRONCHOSCOPE, LASER FIBER, AND TRACHEAL TUBE.

Concomitant Medical Products:  
NOT KNOWN  

Mfr Name: LASERSCOPE  
Address: 3070 ORCHARD DRIVE  
SAN JOSE, CA 95134  
UNITED STATES  

Device Available for Evaluation: Y  
Device Evaluated by Manufacturer (H3): No Answer  

Remedial Action (H7):  
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11):  
25-JAN-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVELOPE INFORMATION:

Brand: KTP/ YAG LASER
Device Type: LASER SYSTEM
Device Type: 813
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: No Information

EMAIL: [b] (6)
Phone: [b] (6)
International:
Fax:

Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>BIOLITEC, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 04-Jan-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 09-Jan-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 09-Jan-2007</td>
<td>Reporter Occupation (E3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: INVALID DATA</td>
<td></td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 26-JAN-2007: BIOLITEC LASER WAS BEING USED ON A PATIENT WHEN THE TIP OF LASER WIRE BROKE OFF INSIDE PATIENT DURING AN URETEROSCOPY PROCEDURE. PHYSICIAN WAS ABLE TO RETRIEVE TIP AND THERE WAS NO HARM TO THE PATIENT.

**Concomitant Medical Products:**
NOT KNOWN

**Mfr Name:** BIOLITEC, INC.
**Address:** 515 SHAKER ROAD
EAST LONGMEADOW, MA 01028
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 26-JAN-2007:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: BIOLITEC
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: No Information

EMAIL: [b] (6)
Phone: [b] (6)
International: Fax:

Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: XINTEC CORPORATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 09-Jan-2007</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 12-Jan-2007</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 12-Jan-2007</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: CONVERGENT LASER TECHNOLOGIES
Address: 1660 SOUTH LOOP ROAD
ALAMEDA, CA 94502
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
08-FEB-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ODYSSEY 30B
- **Device Type:** LASER, HOLMIUM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

  Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER

  EMAIL: (b) (6)
  Phone: (b) (6)
  International: 
  Fax: 

Recd: 110  Page: 220  Date Last Updated: 11/2/2010 9:17 AM
User Facility Report No:  
Mfr Name: LASERSCOPE  

---

**Event Date (B3):** 08-Feb-2007  
**Report Date (B4):** 20-Feb-2007  
**Report Date (F8):** 20-Feb-2007  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Report Date (B4):** 20-Feb-2007  
**Event Location (F12):** HOSPITAL  
**Date Last Updated: 11/2/2010  9:17 AM**  
**Recd: 111**  

**Concomitant Medical Products:**  
NO OTHER THERAPIES  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):**  

**User 07-MAR-2007:** DURING A GREENLIGHT LASER PROCEDURE, THE TIP OF THE LASER FIBER EXPLODED INTO MULTIPLE PIECES WITHIN THE BLADDER. DUE TO THE SURGEON RETRIEVING FRAGMENTS FROM THE BLADDER, THE SURGERY TIME WAS EXTENDED APPROXIMATELY 45 MINUTES.  

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 07-MAR-2007:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

    Brand: IQ FIBEROPTICS
    Device Type: LASER FIBER
    Device Type: 10-2090-B
    Catalog: 10-2090-B
    Serial: (*confidential*)
    Lot: 10-2090-650S
    Other ID: *

    Reprocessed & Reused: N/A

REPORTER INFORMATION:

    Name: [b] (b)
    Address: [b] (b)

    EMAIL: [b] (b)
    Phone: [b] (b)
    International: [b] (b)
    Fax: [b] (b)

    Health Professional: No Information
    Occupation: 500 - RISK MANAGER
User Facility Report No: | Mfr Name: LASERSCOPE
---|---

**Event Date (B3):** 28-Dec-2006  
**Report Date (B4):** 28-Feb-2007  
**Report Date (F8):** 28-Feb-2007  
**Date Mfr Rec’d (G4):**  

**Device Operator:** PHYSICIAN  
**Report Source (G3):**  
**Report Date (F8):**  
**Event Location (F12):** HOSPITAL  
**Report Date (B4):** 28-Feb-2007  
**Event Outcome (B2):**  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Date Received:** 02-Nov-2010

### Event Description (B5):

### Concomitant Medical Products:
NOT APPLICABLE

**Mfr Name:** LASERSCOPE  
**Address:** 3070 ORCHARD DRIVE  
SAN JOSE, CA 95134  
UNITED STATES

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
29-MAR-2007:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT PVP
- **Device Type:** LASER, SURGICAL
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

- **Health Professional:** No Information
- **Occupation:** -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:  
Mfr Name: SSI LASER ENGINEERING, INC.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Mar-2007</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>02-Mar-2007</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>02-Mar-2007</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Mar-2007</td>
<td>Reporter Occupation (E3): PHYSICIAN</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

User 02-APR-2007: OPERATING ROOM WAS SET UP PREOPERATIVELY; CO2 LASER UNIT IN ROOM AND CONNECTED WITH MICROSCOPE MICROMANIPULATOR LASER UNIT FOR FUNCTION AND ALIGNMENT OF AIMING BEAM. LASER TESTED. TEST DEMONSTRATED CO2 LASER WAS FUNCTIONING PROPERLY. INTRAOPERATIVELY, SAFETY MEASURES WERE MET, SALINE MOISTENED GAUZE ON EYES OF THE PATIENT, SALINE MOISTENED GREEN TOWELS ON AND AROUND HEAD, NECK AND FACE (THE OPERATIVE FIELD). TIME OUT WAS PERFORMED. INTRAOPERATIVELY, LASER STATUS (READY AND STAND-BY) WAS VERBALLY COMMUNICATED BY SCRUB TECHNICIAN. AT 0827 A FLARE OCCURRED AT THE SITE OF THE ENDOTRACHEAL TUBE THAT WAS IN THE TRACHEAL STOMA SITE. THE FLARE WAS EXTINGUISHED IMMEDIATELY BY PHYSICIAN. ENDOTRACHEAL TUBE REMOVED AND AIRWAY IRRIGATED WITH SALINE; NEW ENDOTRACHEAL TUBE PLACED FOLLOWED BY REPEAT BRONCHOSCOPY. THE ENDOTRACHEAL TUBE WAS FOUND TO BE A RUSH 4,5 TUBE REF#103600 SIZE I.D.MM 4,5 LOT#04491 EXP 2009-10. THE TUBE WAS SEQUESTERED. THE SSI LASER ENGINEERING ULTRA MD40 (MODEL MD 40) LASER MACHINE WAS TAKEN OUT OF SERVICE AND PLACED IN LOCKED CONSIGNMENT AREA AND WILL BE CHECKED FOR FUNCTIONALITY BY CLINICAL ENGINEERING AND/OR MANUFACTURER. PER CLINICAL ENGINEERING, THE LASER COMPANY WILL NEED TO SEND SOMEONE OUT TO CHECK THE LASER. PATIENT WAS EXTUBATED PRIOR TO LEAVING THE OR, HAD A TRACH TUBE IN PLACE, AND MOVING AT WILL. BREATHING ON OWN AND TRANSPORTED TO THE PACU.

Concomitant Medical Products: 
NOT APPLICABLE

Mfr Name: LASER ENGINEERING
Address: A DIVISION OF SSI, INC.
1650 ELM HILL PIKE SUITE 5
NASHVILLE, TN 37210
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-APR-2007:

DEVICE INFORMATION:

Brand: ULTRA MD40
Device Type: LASER, CO2
Device Type: ULTRA MD40 (MODEL MD 40)
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6) [b] (6)
Address: [b] (6) [b] (6)

EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Health Professional: No Information
Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
<th>Date Received: 16-Mar-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 08-Mar-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8): 16-Mar-2007</td>
<td>Reporter Occupation (E3): -</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: OTHER</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 10-APR-2007: DURING CYSTOSCOPY CASE THE GREENLIGHT LASER SHUT DOWN INDICATING LACK OF WATER PRESSURE. IT WAS DETERMINED THAT THE PROBLEM WAS RELATED TO THE LASER AND NOT TO LACK OF WATER PRESSURE.

**Concomitant Medical Products:**

NO OTHER THERAPIES

**Mfr Name:** LASERSCOPE  
**Address:** 3070 ORCHARD DRIVE  
SAN JOSE, CA 95134  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

10-APR-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: GREENLIGHT
Device Type: LASER, KTP
Device Type: 0010-0070
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

EMAIL: [b] (b)
Phone: [b] (b)
International: 
Fax: 

Health Professional: No Information

Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LUMENIS, INC.</th>
<th>Date Received: 07-Mar-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 26-Jan-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 07-Mar-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 07-Mar-2007</td>
<td>Reporter Occupation (E3): -</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: NURSE</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LUMENIS, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 2400 CONDENSA STREET SANTA CLARA, CA 95051 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 12-APR-2007:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>SHARPLAN LASER 150XJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER, SURGICAL</td>
</tr>
<tr>
<td>Device Type</td>
<td>XJ-150</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] (6)</td>
</tr>
</tbody>
</table>

Health Professional: No Information

EMAIL: [b] (6)

Phone: [b] (6)

International: -

Fax: -

Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 29-Jan-2007</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8): 21-Mar-2007</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3): -</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Device Operator: INVALID DATA</td>
</tr>
</tbody>
</table>

User 13-APR-2007: COULD NOT INSERT FIBER IN LASER APERTURE THEREBY RENDERING LASER INOPERABLE. PATIENT WAS NOT ABLE TO HAVE PROCEDURE AND HAD TO BE RESCHEDULED A MONTH LATER. GREENLIGHT PVP LASER RENTED FROM A CO WHO ALSO PROVIDES ACCESSORIES FOR OPERATION.

Concomitant Medical Products: NOT APPLICABLE

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
        SAN JOSE., CA 95134
        UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-APR-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SURGICAL LASER
Device Type: LASER, PROSTATE
Device Type: GRENNLIGHT PVP
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

EMAIL: [b] (b)
Phone: [b] (b)
International: 
Fax: 

Health Professional: No Information
Occupation: 

Date Last Updated: 11/2/2010 9:17 AM
# MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: XINTEC CORPORATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received</td>
<td>20-Mar-2007</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 09-Mar-2007  
**Report Date (B4):** 20-Mar-2007  
**Report Date (F8):** 20-Mar-2007  
**Mfr Name:** XINTEC CORPORATION  
**Event Report Type:** MALFUNCTION  
**Event Description (B5):**


**Concomitant Medical Products:**

NOT APPLICABLE

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

18-APR-2007:

---

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Event Outcome (B2):**

**Reporter Occupation (E3):** 500 - RISK MANAGER  
**Device Operator:** PHYSICIAN  
**Event Location (F12):** HOSPITAL  
**Report Source (G3):**

**Report Date (F8):** 20-Mar-2007  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Report Date (F8):** 20-Mar-2007  
**Event Location (F12):** HOSPITAL
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ODYSSEY 30
Device Type: LASER, HOLMIUM
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:

[Redacted]

Email: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Health Professional: No Information

Occupation: 500 - RISK MANAGER
**MAUDE EVENT REPORT (FOI)**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE</th>
<th>Date Received: 23-Jan-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 15-Dec-2005</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 13-Jan-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 13-Jan-2006</td>
<td>Reporter Occupation (E3): -</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NOT APPLICABLE

**Mfr Name:** LASERSCOPE

**Address:**

3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

03-MAY-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>*</td>
</tr>
<tr>
<td>Catalog</td>
<td>10-2079</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>10-2079-5251158</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

| Name:          | (b) (b)                          |
| Address:       | (b) (b)                          |

Health Professional: No Information

EMAIL: (b) (b)

Phone: (b) (b)

International: Fax: (b) (b)

Occupation: -
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 19-Apr-2007

User Facility Report No: 
Mfr Name: BOSTON SCIENTIFIC CORP.

Event Date (B3): 12-Mar-2007
Report Date (B4): 19-Apr-2007
Report Date (F8): 19-Apr-2007
Date Mfr Rec'd (G4): 

Event Report Type: MALFUNCTION
Event Outcome (B2): 
Reporter Occupation (E3): -
Device Operator: PHYSICIAN

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): 

Event Description (B5):

Concomitant Medical Products:
UNKNOWN

Mfr Name: BOSTON SCIENTIFIC CORP.
Address: 1 BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
04-MAY-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>HOLMIUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>365</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

Name: [Redacted]
Address: [Redacted]
EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Health Professional: No Information

Occupation: -
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LASER PERIPHERALS LLC.</th>
<th>Date Received: 04-May-2007</th>
</tr>
</thead>
</table>

**Event Date (B3):** 20-Mar-2007  
**Report Date (B4):** 04-May-2007  
**Report Date (F8):** 04-May-2007  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Reporter Occupation (E3):** -  
**Device Operator:** PHYSICIAN  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):** HOSPITAL  
**Report Source (G3):**  

**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Device Available for Evaluation:** Y  
**Manufacture Date (H4):**  
**Single Use (H5):**  
**Device Usage (H8):**  

**Event Description (B5):**  

**Concomitant Medical Products:**  
NOT APPLICABLE  

**Mfr Name:** LASER PERIPHERALS  
**Address:** 1000 BOONE AVE NORTH  
SUITE 300  
GOLDEN VALLEY, MN 55427  
UNITED STATES  

**Correction/Removal No (H9):**  
**Remedial Action (H7):**  
**Additional Mfr Narrative (H10 & H11):** 14-MAY-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMIUM BARE SINGLE-USE LASER ACCESSORY
- **Device Type:** LASER FIBER
- **Device Type:** HB-200
- **Catalog:** HB-200
- **Serial:** (*confidential*)
- **Lot:** LP-414
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>17-May-2007</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4)</td>
<td>23-May-2007</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8)</td>
<td>23-May-2007</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Device Name:</td>
<td>AMERICAN MEDICAL SYSTEMS, INC.</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NOT APPLICABLE

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

08-JUN-2007:
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- **Brand:** ADDSTAT GREENLIGHT HPS FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 10-2090
- **Serial:** (*confidential*)
- **Lot:** 716N220L
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LUMENIS, INC.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 05-Feb-2007</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8): 18-May-2007</td>
<td>Reporter Occupation (E3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 12-JUN-2007: THE PROBLEM IS THAT THE AIMING BEAM WAS DIM. BIOMED SENT THE DEVICE TO THE MFR FOR REPAIR AS IT IS UNDER WARRANTY. THE MFR ALIGNED THE LASER AND RETURNED IT TO OUR FACILITY A FEW WEEKS LATER. IT WAS RETURNED TO SERVICE. THERE WAS NO PATIENT HARM.

**Concomitant Medical Products:**

NOT APPLICABLE

**Mfr Name: LUMENIS INC.**

**Address:** 2400 CONDENSA STREET

SANTA CLARA, CA 95051

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

12-JUN-2007:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALMIC ARGON LASER
- **Device Type:** LASER
- **Device Type:** NOVUS SPECTRA
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **Fax:** [REDACTED]

- **Health Professional:** No Information
- **Occupation:** * - INVALID DATA

Date Last Updated: 11/2/2010 9:17 AM

Page: 244
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 15-Jun-2007

Event Date (B3): 14-Jun-2007
Report Date (B4): 15-Jun-2007
Report Date (F8): 15-Jun-2007
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2): -
Reporter Occupation (E3): PHYSICIAN

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 13-JUL-2007: HOLMIUM LASER WAS BEING USED ON PATIENT TO RELEASE LEFT URETERO PELVIC JUNCTION STRicture. LASER WAS IN USE FOR 5 MINUTES. THERE WAS A TOTAL OF 1326 PULSES. FIRING NOISE OF LASER BECAME LOW AT ONE POINT. THE OR TECHNICIAN HAD BEEN SUPPORTING LASER FIBER WITH HIS RIGHT HAND. THE OR TECHNICIAN FELT THE LASER FIBER SLIP THROUGH HIS HAND. THE FIBER HAD BROKEN. THE OR TECHNICIAN FELT PAIN ON THE LATERAL SIDE OF HIS RIGHT HAND. A HOLE HAD BURNT IN HIS GLOVES. BLACKENED AREA THE SIZE OF A PENCIL POINT TIP. SURROUNDED BY APPROXIMATELY 1/4" AREA OF WHITENED TISSUE. NOTED ON OR TECHNICIAN'S LATERAL SIDE OF RIGHT HAND, SMALL AREA OF MELTED DRAPE. NO PATIENT INJURY.

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: INNOVA QUARTZ
Address: 23030 N. 15TH AVE
PHOENIX, AZ 85027
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ACCU FLEX
- **Device Type:** LASER FIBER
- **Device Type:** 840802
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** TRF 3486S
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [b] (6)
- **EMAIL:**
- **Phone:** [b] (6)
- **International:**
- **Fax:**

Health Professional: No Information

Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 05-Jun-2007

Event Date (B3): 05-Jun-2007
Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y
Event Outcome (B2):

Event Location (F12): HOSPITAL

Date Mfr Rec’d (G4):
Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-JUL-2007:

Date Last Updated: 11/2/2010 9:17 AM

Recd: 124 Page: 247
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ENDOPROBE
- **Device Type:** LASER ENDOPROBE
- **Catalog:** 10562-1
- **Serial:** (*confidential*)
- **Lot:** 012216
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No Information
- **Occupation:** -
- **International:** [Redacted]
- **Fax:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>07-May-2007</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>INVALID DATA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 19-JUL-2007: LASER TURNED ITSELF OFF DURING THE MIDDLE OF A LITHOTRIPSY AND WOULD NOT TURN BACK ON. LASER WAS TAKEN AWAY FROM THE FIELD. AN ELECTROHYDRAULIC LITHOTRIPTOR WAS USED IN ITS PLACE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT KNOWN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>NEW STAR LASERS, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9085 FOOTHILLS BLVD. ROSEVILLE, CA 95747 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>19-JUL-2007:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: NEW STAR LASER
Device Type: LASER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Health Professional: No Information
Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>30-May-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>14-Jun-2007</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>14-Jun-2007</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y

**Event Outcome (B2):**

**Event Location (F12):** HOSPITAL

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):**

**Event Location (F12):** HOSPITAL

**Date Mfr Rec'd (G4):** 14-Jun-2007

---

**Event Description (B5):**
User 02-AUG-2007: THERE WAS AN EQUIPMENT FAILURE WITH TWO LASER FIBERS. THE FIBERS BROKE WHEN THEY WERE BEING USED IN THE URETEROSCOPES, WHILE IN USE ON THE PATIENT. THE FIBERS THAT BROKE IN THE URETEROSCOPE WHERE REMOVED FROM THE PATIENT.

**Concomitant Medical Products:**
NOT KNOWN

**Mfr Name:** FIBERTECH USA, LLC

**Address:**
4111 EAST VALLEY AUTO DRIVE
SUITE 104
MESA, AZ 85206
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
02-AUG-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** QUANTA BAREFIBER
- **Device Type:** LASER FIBER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 0603024
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No Information
- **occupation:** 500 - RISK MANAGER

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 27-Jun-2007

Event Date (B3): 18-Jan-2007

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Event Outcome (B2):

Event Location (F12): HOSPITAL

Reporter Occupation (E3): 500 - RISK MANAGER

Device Operator: INVALID DATA

Device Age (F9):

Device Evaluated by Manufacturer (H3): No Answer

Manufacture Date (H4):

Device Usage (H8):

Device Available for Evaluation: Y

Concomitant Medical Products:

NO OTHER THERAPIES

Event Description (B5):


Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

06-AUG-2007:
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HL2
- **Device Type:** LASER, CO2
- **Device Type:** HL2
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE</th>
<th>Date Received: 26-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 26-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 26-Jul-2007</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: OTHER</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 30-AUG-2007: THE LASER KEPT PUTTING ITSELF INTO A STANDBY MODE WITH DEVICE INDICATING "PORT-OVERHEAT." THIS OCCURRED MULTIPLE TIMES. OPERATOR CALLED COMPANY AND WAS TOLD TO FILL A RESERVOIR WITH STERILE WATER. PROBLEM DID NOT RESOLVE. REPLACED LASER FIBER WITH FRESH LASER FIBER WHICH WORKED FOR SHORT TIME BEFORE MACHINE SHUT ITSELF DOWN AND COULD NOT BE RESTARTED.

**Concomitant Medical Products:**

NOT APPLICABLE

**Mfr Name:** LASERSCOPE  
**Address:** 3070 ORCHARD DRIVE  
SAN JOSE, CA 95134  
UNITED STATES

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 30-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** GREENLIGHT PV LASERSCOPE
- **Device Type:** LASER, GREENLIGHT
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 10-2080-6470-1840
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received</td>
<td>21-Aug-2007</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 08-Aug-2007</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 21-Aug-2007</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: NURSE</td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 06-SEP-2007: WHILE USING THE GREEN LIGHT LASER DURING A PVP (PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE), THE WATTAGE DECREASED FROM 80 WATTS TO 65 WATTS AUTOMATICALLY. PHYSICIAN NOTIFIED, AND THE CASE CONTINUED WITH THE LOWER WATTAGE. ERROR CODE 44 ON SCREEN OF MACHINE. COMPANY NOTIFIED AND BIO-MED AWARE. MAINTENANCE FROM LASERSCOPE TO COME IN TO SERVICE THE LASER.

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
         SAN JOSE, CA 95134
         UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-SEP-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASERSCOPE
Device Type: LASER, KTP, UROLOGIC
Device Type: 7107
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

EMAIL: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Health Professional: No Information

Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: BOSTON SCIENTIFIC CORP.</th>
<th>Date Received: 11-Sep-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 04-Sep-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 11-Sep-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 11-Sep-2007</td>
<td>Reporter Occupation (E3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 17-OCT-2007: THE SURGEON WAS INSERTING THE PROBE THROUGH AN ADAPTER. TWO FIBERS IN THE PROBE BROKE DURING INSERTION. NO HARM TO THE PATIENT.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT KNOWN</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: BOSTON SCIENTIFIC CORPORATION</td>
<td>Address: ONE BOSTON SCIENTIFIC PLACE NAMICK, MA 01760 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 17-OCT-2007:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** *
- **Device Type:** LASER FIBER, HOLMIUM
- **Catalog:** M0068408931
- **Serial:** (*confidential*)
- **Lot:** 48801206
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No Information
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** Fax:
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Date (B3):** 17-Oct-2007  
**Report Date (B4):** 02-Nov-2007  
**Report Date (F8):** 02-Nov-2007  
**Date Mfr Rec'd (G4):**  

**Mfr Name:** LUMENIS, INC.  
**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)  
**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Event Report Type:** MALFUNCTION  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Event Outcome (B2):**  
**Event Location (F12):** AMBULATORY SURGICAL FAC  
**Event Location (F12):** AMBULATORY SURGICAL FAC  
**Report Source (G3):**  

**Device Operator:** PHYSICIAN  
**Reporter Occupation (E3):** 500 - RISK MANAGER  
**Report Date (B4):** 02-Nov-2007  
**Report Date (F8):** 02-Nov-2007  
**Date Mfr Rec'd (G4):**  

**Event Description (B5):**  

**Concomitant Medical Products:**
NOT KNOWN

**Mfr Name:** LUMENIS, INC.  
**Address:** 2400 CONDENSA STREET  
SANTA CLARA, CA 95051  
UNITED STATES  

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 27-NOV-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: LUMENIS DUOTOME SIDELITE 550
- Device Type: LASER FIBER
- Device Type: 840-846
- Catalog: *
- Serial: (*confidential*)
- Lot: 58190607
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [b] (6)
- Address: [b] (6)

- Health Professional: No Information

- EMAIL: [b] (6)
- Phone: [b] (6)
- International: [b] (6)
- Fax: [b] (6)

- Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 28-Dec-2007

User Facility Report No: 

Mfr Name: FORTEC MEDICAL, INC

Event Date (B3): 27-Nov-2007
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 28-Dec-2007
Event Outcome (B2):
Reporter Occupation (E3): 500 - RISK MANAGER

Event Location (F12): HOSPITAL

Date Mfr Rec'd (G4): 

Device Operator: PHYSICIAN
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: FORTEC MEDICAL, INC.
Address: 10125 WELLMAN ROAD
STREETSBORO, OH 44241
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
28-JAN-2008:
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- **Brand:** FORTEC FIBERS
- **Device Type:** LASER, GENERATOR
- **Catalog:** DHBFSF230-DO
- **Serial:** (*confidential*)
- **Lot:** C0070218B CRM073002
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

User Facility Report No: Mfr Name: BOSTON SCIENTIFIC CORP.

Event Date (B3): 27-Dec-2007
Report Date (B4): 07-Jan-2008
Report Date (F8): 07-Jan-2008
Date Mfr Rec'd (G4): 

Event Report Type: *
Report Date (F8): -
Event Location (F12): HOSPITAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: PHYSICIAN

Device Evaluated by Manufacturer (H3): No Answer

 correction/Removal No (H9): 29-JAN-2008:
Additional Mfr Narrative (H10 & H11):

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: BOSTON SCIENTIFIC
Address: ONE BOSTON SCIENTIFIC PLACE
        NATICK, MA 01760
        UNITED STATES

Device Available for Evaluation: Y

Remedial Action (H7):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INNOVAQUARTZ ACCUFLEX
- **Device Type:** LASER FIBER
- **Device Type:** 840802
- **Catalog:** 840802
- **Serial:** (*confidential*)
- **Lot:** TRF34865
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No Information

**EMAIL:** (b) (6)
**Phone:** (b) (6)
**International:** 
**Fax:** 

**Occupation:** -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:  
Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE  
Date Received: 11-Jan-2008

Event Date (B3): 07-Jan-2008  
Report Date (B4): 11-Jan-2008  
Report Date (F8): 11-Jan-2008  
Date Mfr Rec'd (G4):  
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
Device Operator: PHYSICIAN  
Report Source (G3): PHYSICIAN  
Event Report Type: MALFUNCTION  
Event Outcome (B2):  
Reporter Occupation (E3): 500 - RISK MANAGER  
Event Location (F12): HOSPITAL  
Event Description (B5): 

Concomitant Medical Products: UNKNOWN  
Device Available for Evaluation: N  
Device Evaluated by Manufacturer (H3): No Answer  
Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 14-FEB-2008: 

Mfr Name: LASERSCOPE, INC.  
Address: 3070 ORCHARD DRIVE  
SAN JOSE, CA 95134  
UNITED STATES  
Adverse Event (B1): Problem (B1): Y
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- Brand: GREENLIGHT PVP
- Device Type: LASER, GENERATOR
- Device Type: UNK
- Catalog: UNK
- Serial: (*confidential*)
- Lot: 10-2079-714D
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [b] (b)
- Address: [b] (b)
- EMAIL: [b] (b)
- Phone: [b] (b)
- International: [b] (b)
- Fax: [b] (b)
- Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 28-Jan-2008</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 04-Feb-2008</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 04-Feb-2008</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: NOT KNOWN</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LASERSCOPE</td>
<td></td>
</tr>
<tr>
<td>Address: 3070 ORCHARD DRIVE</td>
<td></td>
</tr>
<tr>
<td>SAN JOSE, CA 95134</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 13-MAR-2008:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** ENDOSTAT LASER
- **Device Type:** LASER FIBER
- **Device Type:** L66D
- **Catalog:** 16-8319-81
- **Serial:** (*confidential*)
- **Lot:** 16-8319-635
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>05-Mar-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 17-MAR-2008: THE HOLMIUM LASER 100 WATT MACHINE WAS BEING FIRED WHEN THE SHEATH ON LASER FIBER SHREDDED. SOME OF THE LASER FIBERS WERE MISSING FROM THE SHEATH. THE FIBERS WERE UNABLE TO BE VISUALIZED IN THE PATIENT.

**Concomitant Medical Products:**
NOT KNOWN

**Mfr Name:** BOSTON SCIENTIFIC CORPORATION
**Address:** 1 BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
17-MAR-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** SLIMLINE EZ 200
- **Device Type:** LASER FIBER
- **Device Type:** PRODUCT #: M0068408920
- **Catalog:** 840-892
- **Serial:** (*confidential*)
- **Lot:** 66871207
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
Event Date (B3): 09-Feb-2008
Report Date (B4): 07-Mar-2008
Report Date (F8): 07-Mar-2008
Date Mfr Rec'd (G4): -
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-MAR-2008:

Event Description (B5):
User 25-MAR-2008: A PATIENT WAS ADMITTED WITH RIGHT URETERAL CALCULUS. SHE UNDERWENT CYSTOSCOPY, RIGHT FLEXIBLE AND RIGID URETEROSCOPY WITH LASER LITHOTRIPSY. DURING THE LASER LITHOTRIPSY, THE LASER FIBER TIP BROKE OFF. THE SURGEON WAS ABLE TO RETRIEVE THE TIP UTILIZING A BASKET. LASER LITHOTRIPSY PROCEEDED AND WAS COMPLETED WITH A NEW LASER FIBER. NO PATIENT INJURY WAS NOTED.

Concomitant Medical Products:
NO OTHER THERAPIES

Mfr Name: CONVERGENT LASER TECHNOLOGIES
Address: 1660 SOUTH LOOP ROAD
ALAMEDA, CA 94502
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-MAR-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** *
- **Device Type:** LASER FIBER
- **Device Type:** *
- **Catalog:** SMH1020F
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: Y

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No Information
- **Occupation:** -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 17-May-2008

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
</table>

**Event Date (B3):** 01-Feb-2008
**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y

**Event Date (B4):** 17-May-2008
**Event Outcome (B2):**

**Report Date (F8):** 17-May-2008
**Reporter Occupation (E3):**

**Device Operator:** PHYSICIAN

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Concomitant Medical Products:** NOT APPLICABLE

**Mfr Name:** PRI MEDICAL TECHNOLOGIES, INC.
**Address:** 10939 PENDLETON STREET
SUN VALLEY, CA 91352
UNITED STATES

**Device Age (F9):**
**Manufacture Date (H4):**

**Expiration Date:**
**Single Use (H5):**
**Device Usage (H8):**

**Event Description (B5):**
User 02-JUN-2008: DIOD LASER FIBER WAS BEING USED BY THE SURGEON DURING A TURP. THE 2 FIBERS BROKE INSIDE THE PATIENT BLADDER. THE SURGEON WAS ABLE TO RETRIEVE THE FRAGMENTS. NO PATIENT HARM OR DELAY IN SURGERY.

**Device Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Date Last Updated:** 11/2/2010 9:17 AM
Recd: 138 Page: 275
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SURE-FLEX
- **Device Type:** LASER FIBER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 06-May-2008</th>
<th>Event Report Type: *</th>
<th>Adverse Event (B1): Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 02-Jul-2008</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): AMBULATORY SURGICAL FAC</td>
</tr>
<tr>
<td>Report Date (F8): 02-Jul-2008</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 15-JUL-2008: SIX PATIENTS UNDERGOING LASIK RECEIVED AN OVER-CORRECTION DUE TO MACHINE SOFTWARE GENERATING INAPPROPRIATE TREATMENT TABLES. THE MANUFACTURER HAS SENT US AN URGENT DEVICE CORRECTION NOTICE, AND HAS PROVIDED US WITH UPGRADED SOFTWARE (VERSION 3.92)

**Concomitant Medical Products:**

- NOT KNOWN

**Mfr Name:** ADVANCED MEDICAL OPTICS

**Address:** 1700 E ST ANDREW PLACE
SANTA ANA, CA 92795
UNITED STATES

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer:** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 15-JUL-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** VISX EXCIMER LASER WAVESCAN SOFTWARE 3.9/3.901
- **Device Type:** LASER, OPTHALMIC
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 18-Jun-2008 | Event Report Type: | MALFUNCTION | Adverse Event (B1): | Problem (B1): | Y |
| Report Date (B4): | 19-Jun-2008 | Event Outcome (B2): | | | | |
| Report Date (F8): | 19-Jun-2008 | Reporter Occupation (E3): | 002 - NURSE | Event Location (F12): | HOSPITAL | |
| Date Mfr Rec'd (G4): | | Device Operator: | PHYSICIAN | Report Source (G3): | | |

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

15-JUL-2008:

**Event Description (B5):**


**Concomitant Medical Products:**

NO OTHER THERAPIES

**Mfr Name:** BIOLITEC, INC.

**Address:**

515 SHAKER ROAD

EAST LONGMEADOW, MA 01028

UNITED STATES
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

Brand: SIDEFIBER
Device Type: LASER FIBER
Device Type: *
Catalog: SF-980-DL
Serial: (*confidential*)
Lot: E08-0261-B
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Health Professional: Yes

Occupation: 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: Report Date (B4): 09-Jul-2008
Mfr Name: ADVANCED MEDICAL OPTICS, INC. Report Date (B8): 09-Jul-2008

Event Date (B3): 08-Jul-2008 Event Report Type: MALFUNCTION
Report Date (F8): 09-Jul-2008 Adverse Event (B1): Problem (B1): Y
Report Date (F12): 09-Jul-2008

Event Description (B5):
User 15-JUL-2008: DURING THE TREATMENT FOR LASIK, THE MACHINE AUTOMATICALLY SHUT OFF AND WOULD NOT RESTART. THE PROCEDURE HAD TO BE ABORTED WHEN ONLY 50% COMPLETE.

MANUFACTURER RESPONSE FOR EXCIMER LASER, VISX S4 IR
THEY ARE SERVICING THE MACHINE TODAY, 7/9/08. THEY REPORTED ON THE PHONE THEY HAD NOT SEEN SUCH A PROBLEM.

Concomitant Medical Products:
NONE

Mfr Name: ADVANCE MEDICAL OPTICS, INC.
Address: 1700 EAST SAINT ANDREW PLACE
SANTA ANA, CA 92705
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 15-JUL-2008:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VISX S4 IR
- **Device Type:** LASER, OPHTALMOLOGY
- **Device Type:** S4 IR
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No Information
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER
Event Date (B3): 02-Jun-2008
Report Date (B4): 24-Jun-2008
Report Date (F8): 24-Jun-2008
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: PHYSICIAN

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
UNKNOWN

Mfr Name: BOSTON SCIENTIFIC
Address: ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
18-JUL-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DUOTOME SIDE LITE 550 (LUMENIS)
- **Device Type:** LASER FIBER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 67541207
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**

**Health Professional:** No Information

**Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: BOSTON SCIENTIFIC CORP.</th>
<th>Date Received</th>
<th>10-Jul-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 27-Jun-2008</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 10-Jul-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 10-Jul-2008</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date: Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: UNKNOWN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: BOSTON SCIENTIFIC CORPORATION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: ONE BOSTON SCIENTIFIC PLACE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NATICK, MA 01760</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 28-JUL-2008:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: HOLMIUM LASER FIBER
Device Type: LASER, FIBER
Device Type: *
Catalog: 840803
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b) [b] (b) [b] (b) [b] (b)
Address: [b] (b) [b] (b) [b] (b) [b] (b)

Health Professional: No Information

EMAIL: [b] (b) [b] (b) [b] (b) [b] (b)
Phone: [b] (b) [b] (b) [b] (b) [b] (b)
International: [b] (b) [b] (b) [b] (b) [b] (b)
Fax: [b] (b) [b] (b) [b] (b) [b] (b)

Occupation: 500 - RISK MANAGER
Event Date (B3): 10-Jul-2008
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Date Mfr Rec'd (G4): 16-Jul-2008
Device Operator: PHYSICIAN
Event Location (F12): HOSPITAL

Event Description (B5):

Concomitant Medical Products: UNKNOWN

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
         SAN JOSE, CA 95134
         UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
31-JUL-2008:

DEVICE INFORMATION:

Brand: GREENLIGHT LASER
Device Type: LASER, SURGICAL
Device Type: KTP 803
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: No Information

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: -
### MAUDE EVENT REPORT (FOI)
#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>User Facility Report No:</th>
<th>Mfr Name: FORTEC MEDICAL, INC</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-Jul-2008</td>
<td>Event Date (B3): 07-Jul-2008</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>15-Jul-2008</td>
<td>Report Date (F8):</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td></td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td></td>
<td>Device Operator: PHYSICIAN</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td></td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td></td>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOT KNOWN</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mfr Name: FORTEC MEDICAL, INC</td>
<td>Address: 10125 WELLMAN RD STREETSBORO, OH 44241 UNITED STATES</td>
</tr>
<tr>
<td></td>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
</tr>
<tr>
<td></td>
<td>Correction/Removal No (H9):</td>
<td>Remedial Action (H7):</td>
</tr>
<tr>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11): 06-AUG-2008:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** FORTEC FIBERS SMA 365 BARE FIBER ASSY, FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** C08-0177-B
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: 08-Sep-2008

Mfr Name: SPECTRANETICS CORP.

Event Date (B3): 08-Aug-2008
Report Date (B4): 08-Sep-2008
Report Date (F8): 08-Sep-2008
Date Mfr Rec'd (G4):

Event Description (B5):

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: SPECTRANETICS CORPORATION
Address: 96 TALAMINE COURT
COLORADO SPRINGS, CO 80907
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-SEP-2008:

Report Date (B4): 08-Sep-2008
Event Report Type: MALFUNCTION
Adverse Event (B1):
Problem (B1): Y
Event Outcome (B2):
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: PHYSICIAN
Event Location (F12): HOSPITAL
Report Source (G3):
Product Code: (CV)-PACER LEAD (MFA)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Page: 291
Date Last Updated: 11/2/2010  9:17 AM
Recd: 146
Date Received: 08-Sep-2008
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LLD #2
- **Device Type:** LASER, CARDIAC LEAD REMOVAL SYSTEM
- **Catalog:** 518-019
- **Serial:** (*confidential*)
- **Lot:** 070522
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
User Facility Report No: 

Mfr Name: SPECTRANETICS CORP.

Event Date (B3): 31-Jul-2008
Report Date (B4): 21-Aug-2008
Report Date (F8): 21-Aug-2008
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: PHYSICIAN

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3):

Product Code: (CV)-PACER LEAD (MFA)
Device Available for Evaluation: Y

Device Age (F9):
Expiration Date:
Device Usage (H8):

Manufacture Date (H4):

Event Description (B5):
User 10-SEP-2008: THE CARDIOLOGIST WAS USING SPECTRANETICS LASER LEAD REMOVAL EQUIPMENT LLD#1 AND EXPERIENCED THE SAME PROBLEM WITH THE FIRST THREE DEVICES. EACH CAME APART OR BROKE WHILE IN USE AND WERE NO LONGER FUNCTIONAL AS THE LOCK FAILED TO HOLD TOGETHER. THE DOCTOR ALSO ATTEMPTED THE LEAD REMOVAL WITH A SPECTRANETICS LLD E LASER LEAD REMOVAL DEVICE. THIS DEVICE FAILED TO UNLOCK AND A SMALL PORTION OF IT HAD TO BE LEFT IN THE PATIENT WITHIN THE LEAD.

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: SPECTRANETICS
Address: 96 TALAMINE COURT
COLORADO SPRINGS, CO 80907
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-SEP-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>LLD #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER, CARDIAC LEAD REMOVAL SYSTEM</td>
</tr>
<tr>
<td>Catalog</td>
<td>518-018</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>LLD080514B</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] [6]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] [6]</td>
</tr>
<tr>
<td>EMAIL</td>
<td>[b] [6]</td>
</tr>
<tr>
<td>Phone</td>
<td>[b] [6]</td>
</tr>
<tr>
<td>International</td>
<td>[b] [6]</td>
</tr>
<tr>
<td>Fax</td>
<td>[b] [6]</td>
</tr>
<tr>
<td>Occupation</td>
<td>500 - RISK MANAGER</td>
</tr>
</tbody>
</table>

Health Professional: No Information
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>31-Jul-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Facility Report No:</td>
<td>Mfr Name: IRIDEX CORP.</td>
</tr>
<tr>
<td>Event Date (B3): 25-Jul-2008</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 31-Jul-2008</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 31-Jul-2008</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: INVALID DATA</td>
</tr>
<tr>
<td>Product Code: (OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>User 15-SEP-2008: DURING PROCEDURE, IT WAS NOTED THAT THE LASER FIBER WAS NOT FUNCTIONING. RN NOTICED A RED &quot;HOT SPOT&quot; TOWARDS END OF LASER FIBER. ALL PERSONNEL IN ROOM WERE WEARING APPROPRIATE LASER GOGGLES. NEW FIBER OBTAINED AND FUNCTIONING PROPERLY. MALFUNCTIONING PROBE WILL BE RETURNED TO MANUFACTURER FOR EVALUATION.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Mfr Name: IRIDEX CORP.</td>
<td></td>
</tr>
<tr>
<td>Address: 1212 TERRA BELLA AVE MOUNTAINVIEW, CA 94043 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 15-SEP-2008:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** ADJUSTABLE AND INTUITIVE
- **Device Type:** LASER PROBE, OPTHALMIC
- **Serial:** (*confidential*)
- **Lot:** 8010462
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No Information
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** Fax:
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th></th>
<th>Mfr Name: MACKIN MEDICAL INC.</th>
<th></th>
<th>Date Received</th>
<th>25-Aug-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 16-Jul-2008</td>
<td>Event Report Type: *</td>
<td>Adverse Event (B1): Problem (B1): N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 23-Jul-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 23-Jul-2008</td>
<td>Reporter Occupation (E3): -</td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td>Report Source (G3):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 22-SEP-2008: AFTER USING THE LASER TO BREAK UP URETERAL STONE SURGEON NOTED A PIECE OF 'BLUE' AMONGST YELLOW STONE PIECES.

**Concomitant Medical Products:**

NO OTHER THERAPIES

**Mfr Name:** MACKIN MEDICAL INC.  
**Address:** 945 E. HAVERFORD ROAD  
SUITE B  
BRYN MAWR, PA 19010  
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

22-SEP-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: *
Device Type: LASER FIBER
Device Type: *
Catalog: HOL1040F
Serial: (*confidential*)
Lot: M04845
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Email: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Health Professional: No Information

Occupation: -
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>18-Aug-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>08-Sep-2008</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>08-Sep-2008</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>-</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 24-SEP-2008: BOSTON SCIENTIFIC HOLMIUM LASER FIBER 273 MICRON, ACCUFLEX SNAPPED IN HALF DURING USE. FIBER BROKE APPROXIMATELY 6" FROM MACHINE (NOT IN CONTACT WITH PATIENT). THE LASER WAS TURNED OFF AND REMOVED FROM THE FIELD. ANOTHER FIBER USED WITHOUT INCIDENT. NO HARM TO PATIENT. THE HOLMIUM LASER WAS CHECKED BY CLINICAL TECH, AND NO PROBLEMS WERE NOTED WITH IT.

**Concomitant Medical Products:**

NOT APPLICABLE

| Mfr Name: | BOSTON SCIENTIFIC CORP. (UROLOGY) |
| Address: | ONE BOSTON SCIENTIFIC PLACE |
| | NATICK, MA 01760 |
| | UNITED STATES |

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11): 24-SEP-2008:
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Information:

Brand: ACCUFLEX (273 MICRON)
Device Type: LASER FIBER
Catalog: 840803
Serial: (*confidential*)
Lot: TRF2957F
Other ID: *

Reprocessed & Reused: N/A

Reporter Information:

Name: [REDACTED]
Address: [REDACTED]

Health Professional: No Information

Email: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: -
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Date Mfr Rec'd (G4): 22-Sep-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>HOYA PHOTONICS, INC.</td>
</tr>
<tr>
<td>Event Date (B3): 04-Apr-2008</td>
<td></td>
</tr>
<tr>
<td>Event Report Type: INJURY</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: Single Use (H5): Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): User 25-SEP-2008: DURING A LASER SURGICAL PROCEDURE TO REMOVE LESIONS FROM THE PATIENT'S FACE, A FIRE ERUPTED AND THE PATIENT'S NASAL CANNULA BEGAN TO BURN AROUND THE PATIENT'S NOSE. THE SURGEON REMOVED THE BURNING NASAL CANNULA FROM THE PATIENT AND THREW IT ON THE FLOOR.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: NOT KNOWN</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: HOYA CONBIO MEDICAL AND DENTAL LASERS</td>
<td></td>
</tr>
<tr>
<td>Address: 47733 FREMONT BLVD FREMONT, CA 94538 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: N</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 25-SEP-2008:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** ND:YAG LASER
- **Device Type:** LASER, SURGICAL
- **Device Type:** MEDLITE IV
- **Catalog:** N/A
- **Serial:** (*confidential*)
- **Lot:** N/A
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]

Health Professional: No Information

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 15-Sep-2008

User Facility Report No:

Mfr Name: BOSTON SCIENTIFIC CORP.

Event Date (B3): 04-Sep-2008
Event Report Type: MALFUNCTION

Adverse Event (B1):
Problem (B1): Y

Report Date (B4): 15-Sep-2008
Event Outcome (B2):

Report Date (F8): 15-Sep-2008
Reporter Occupation (E3): -

Device Evaluated by Manufacturer (H3): No Answer

Date Mfr Rec'd (G4): 15-Sep-2008
Device Operator: PHYSICIAN

Device Available for Evaluation: Y

Mfr Name: BOSTON SCIENTIFIC CORP. (UROLOGY)
Address: ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

Event Description (B5):

Concomitant Medical Products:
NOT APPLICABLE

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
01-OCT-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ACCUFLEX
- **Device Type:** LASER FIBER
- **Device Type:** UPN M0068408040
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** TRF 036F
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: AMERICAN MEDICAL SYSTEMS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 29-Aug-2008</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 09-Sep-2008</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 09-Sep-2008</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3): -</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Operator: PHYSICIAN</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>User 08-OCT-2008: FIRST: GREENLIGHT LASER PROBE WAS PLUGGED IN - IT SAID IT WAS EXPIRED, ALTHOUGH THE OUTSIDE OF THE BOX STATED IT WAS OK. SECOND: GREEN LIGHT LASER PROBE BROKE DURING USE.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: AMERICAN MEDICAL SYSTEMS, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 10700 BREN ROAD WEST MINNETONKA, MN 55343 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 08-OCT-2008:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: GREENLIGHT
Device Type: LASER FIBER, KTP
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: 10/2079 714D
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: No Information

Occupation: -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

User Facility Report No:  Mfr Name:  AMERICAN MEDICAL SYSTEMS, INC.
21-Oct-2008

Event Date (B3):  Event Report Type:  MALFUNCTION  
Report Date (B4):  Adverse Event (B1):  
Report Date (F8):  Problem (B1):  Y
Date Mfr Rec'd (G4):  
Product Code:  (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) 
Device Operator:  PHYSICIAN

Event Description (B5):
User 28-OCT-2008: LASER MACHINE FAILED TO OPERATE PROPERLY. WHEN FOOT PEDAL WAS INITIATED IT WORKED WELL AND SUDDENLY STOPPED WORKING. PROCEDURE TERMINATED WITH ARRANGEMENTS FOR FOLLOW UP WAVE LITHOTRIPSY. BIOMEDICAL ENGINEERING ASSESSMENT OF PROBLEM: LASER FAILED TO FUNCTION DURING CASE. CONTRACTED EQUIPMENT OWNER/OPERATOR IDENTIFIED PROBLEM AS THE FOOT SWITCH CABLE. 
RECOMMENDATION: CONNECTOR ON THE FOOTSWITCH CABLE (WHERE IT CONNECTS TO THE LASER) WAS DAMAGED. BIOMED HAD DONE A SAFETY INSPECTION OF THE LASER PRIOR TO THE CASE, BUT THE DAMAGED CONNECTOR WAS NOT SEEN. IT IS THE VENDOR'S RESPONSIBILITY TO CHECK THE FUNCTIONALITY OF THEIR EQUIPMENT PRIOR TO A CASE.

Concomitant Medical Products:

NOT APPLICABLE

Mfr Name:  AMERICAN MEDICAL SYSTEMS, INC.  
Address:  10700 BREN ROAD WEST MINNETONKA, MN 55343 UNITED STATES

Device Available for Evaluation:  R  
Device Evaluated by Manufacturer (H3):  No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
28-OCT-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** STONELIGHT
- **Device Type:** LASER, HOLMIUM, UROLOGICAL
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No Information
- **Occupation:** -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AMS INNOVATIVE CENTER-SAN JOSE</td>
<td>05-Aug-2008</td>
<td>MALFUNCTION</td>
<td>Problem (B1): Y</td>
<td>06-Aug-2008</td>
</tr>
</tbody>
</table>

Date Mfr Rec'd (G4): 06-Aug-2008

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Operator: PHYSICIAN

Event Description (B5):

Concomitant Medical Products:
NOT KNOWN

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
          SAN JOSE, CA 95134
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
28-OCT-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: *
Device Type: LASER, FIBER
Device Type: 10-2079-B
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

EMAIL: (b) (b)
Phone: (b) (b)
International: 
Fax: 

Health Professional: No Information
Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received: 12-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 11-Nov-2008</td>
<td>Event Report Type: *</td>
<td>Adverse Event (B1): Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (B4): 12-Nov-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 12-Nov-2008</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 18-NOV-2008: CYSTOSCOPY LEFT URETEROSCOPY LASER LITHOTRIPSY URETERAL STENT PLACEMENT LEFT RETROGRADE PYELOGRAM-HOLMIUM LASER. LASER NOT WORKING PROPERLY-ONLY ABLE TO COMPLETE CYSTOSCOPY. STENT PLACED AND STONE WAS RELEASED. THEREFORE, NO HARM TO PT AND PT DOES NOT NEED TO RETURN FOR ANOTHER PROCEDURE.

**Concomitant Medical Products:**
NOT KNOWN

**Mfr Name:** DORNIER MED TECH AMERICA, INC.
**Address:** 1155 ROBERTS BOULEVARD
KENNESAW, GA 30144
UNITED STATES

**Device Available for Evaluation:** R
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
18-NOV-2008:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>MEDILAS H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER, HOLMIUM</td>
</tr>
<tr>
<td>Device Type</td>
<td>MEDILAS H</td>
</tr>
<tr>
<td>Catalog</td>
<td>UNK</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>[b] (b)</td>
<td>[b] (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>[b] (b)</td>
<td>[b] (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>International:</th>
<th>Fax:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Health Professional: No Information

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: PHOTOMEDEX, INC.</th>
<th>Date Received</th>
<th>07-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 10-Oct-2008</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4): 07-Nov-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 07-Nov-2008</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
User 18-NOV-2008: WHILE LASERING THROUGH SOFT TISSUE, THE ERP2 TIP (GENERAL PURPOSE) BROKE OFF IN THE BRAIN. THE SURGEONS WERE USING THE MICROSCOPE, SO ALL OF THE TIP WAS ABLE TO BE SEEN AND REMOVED. THIS OCCURRED WITH TWO TIPS.

**Concomitant Medical Products:**
NOT APPLICABLE

**Mfr Name:** PHOTOMEDEX  
**Address:** 147 KEYSTONE DRIVE  
MONTGOMERYVILLE, PA 18936  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
18-NOV-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SLT CONTACT LASER
- **Device Type:** CONTACT LASER SCALPEL TIP
- **Device Type:** ERP2
  - **Catalog:** *
  - **Serial:** (*confidential*)
  - **Lot:** 806501
  - **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>21-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>User Facility Report No:</td>
<td>Mfr Name: TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Event Date (B3): 21-Nov-2008</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 21-Nov-2008</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 21-Nov-2008</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: PHYSICIAN</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 05-DEC-2008: HOLMIUM LASER WAS BEING USED TO BREAK DOWN A BLADDER STONE. THE 1,000UM FIBER WAS SELECTED AND INSERTED INTO THE LASER BY THE RN LASER OPERATOR. THE WATTS WERE INCREASED TO 80, AND THE PPS WAS SET TO 13 AS REQUESTED BY THE SURGEON. THE 1,000 MICRON LASER FIBER WAS INTRODUCED THROUGH A RIGID CYSTOSCOPE AFTER VISUALIZATION OF THE STONE. WHEN THE SURGEON WAS ATTEMPTING TO USE THE LASER, IT WAS NOTED THAT THE LASER WAS NOT PUTTING OUT PROPER ENERGY. THE LASER BEAM AND AIMING BEAM WOULD NOT WORK. THE LASER WAS USED FOR A TOTAL OF 7 MINUTES. THE NURSE MANAGER FOR OR UROLOGY SERVICES WAS CALLED AND ASKED TO COME TO THE OR SUITE. AT THAT TIME THE SURGEON WAS ASKED IF THE RN LASER OPERATOR COULD CHANGE THE FIBER AND TRY A NEW ONE TO SEE IF THE NEW FIBER WOULD WORK. THE LASER WAS PLACED ON STAND-BY AND A NEW FIBER INSERTED BY THE MANAGER. SHE WAS UNABLE TO ADJUST THE AIMING BEAM AND THE WATTS. SHE TURNED THE LASER OFF AND BACK ON. AFTER TURNING IT BACK ON, THE LASER STARTED SMOKING, WAS SHUT OFF, UNPLUGGED AND MOVED OUT OF THE BUILDING. A FIRE EXTINGUISHER WAS USED ON THE MACHINE. NO FLAME WAS SEEN.

**Concomitant Medical Products:**

NO OTHER THERAPIES

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DRIVE
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

05-DEC-2008:

DEVICE INFORMATION:

- **Brand:** HOLMIUM LASER
- **Device Type:** LASER, SURGICAL, HOLMIUM
- **Device Type:** 1210-VHP
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

03-Dec-2008

Mfr Name: SYNERGETICS USA

Event Date (B3): 20-Nov-2008
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Event Location (F12): HOSPITAL
Report Source (G3): PHYSICIAN

User Facility Report No:

Date Mfr Rec'd (G4): 03-Dec-2008

Reporter Occupation (E3): 500 - RISK MANAGER

Event Description (B5):
User 12-DEC-2008: LASER PROBE TIP BROKE OFF IN PATIENT'S EYE. IT WAS RETRIEVED AND THERE WAS NO PATIENT HARM.

Concomitant Medical Products:

UNKNOWN

Mfr Name: SYNERGETICS, INC.
Address: 3845 CORPORATE CENTRE DRIVE
SAINT CHARLES, MO 63304
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-DEC-2008:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 23G INVERTED EXTENDABLE DIRECTIONAL LASER PROBE
- **Device Type:** LASER PROBE, OPHTHALMIC
- **Catalog:** 55.36.23E
- **Serial:** (*confidential*)
- **Lot:** 7020135
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No Information
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 500 - RISK MANAGER
## Event Description (B5):

User 17-DEC-2008: LASER FIBER WAS PLACED AT THE 5 O'CLOCK AND 7 O'CLOCK POSITION, TURNED ON, RESECTING THE TISSUE AND OPENING THE NECK OF THE BLADDER WHEN THE TIPS BROKE OFF. TIPS REMOVED WITH GRASPING FORCEPS.

## Concomitant Medical Products:

- CARDIAC DRUGS

## Device Information:

- **Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
- **Device Operator:** PHYSICIAN
- **Device Available for Evaluation:** Y
- **Device Evaluated by Manufacturer (H3):** No Answer

## Mfr Name:

- BOSTON SCIENTIFIC CORP.

## Address:

ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

## Remedial Action (H7):

17-DEC-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LUMENIS DUOTOME SIDELITE 550
- **Device Type:** LASER FIBER
- **Device Type:** 550
- **Catalog:** 840-846
- **Serial:** (*confidential*)
- **Lot:** 60590707
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** *(b)(6)*
- **Address:** *(b)(6)*
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER

**EMAIL:** *(b)(6)*

**Phone:** *(b)(6)*

**International:**

**Fax:**

**Date Last Updated:** 11/2/2010 9:17 AM
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: BOSTON SCIENTIFIC CORP.</th>
</tr>
</thead>
</table>

| Event Date (B3):          | 29-Sep-2008                       |
| Event Report Type:        | MALFUNCTION                       |
| Adverse Event (B1):       | Problem (B1): Y                  |
| Report Date (B4):         | 15-Dec-2008                       |
| Event Outcome (B2):       |                                   |
| Reporter Occupation (E3): | -                                 |
| Event Location (F12):     | HOSPITAL                          |
| Date Mfr Rec'd (G4):      |                                   |
| Device Operator:          | PHYSICIAN                         |
| Report Date (F8):         |                                   |
| Event Description (B5):   | User 13-JAN-2009: THE LASER FIBER TIP DEGRADED DURING LASER PROSTATE PROCEDURE. POWER SETTING WAS 2 JOULES AND 50 HERTZ FOR A TOTAL OF 100 WATTS. FIBER WAS REMOVED FROM USE AND A NEW ONE OPENED. MANUFACTURER REP WAS PRESENT DURING PROCEDURE AND WITNESSED OCCURRENCE. NO HARM TO PATIENT. PATIENT WAS DISCHARGED THE FOLLOWING DAY WITH NO COMPLICATIONS FROM INCIDENT. |
| Product Code:             | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9):          | Manufacture Date (H4):            |
| Expiration Date:          | Single Use (H5):                  |
| Device Usage (H8):        |                                   |

**MANUFACTURER RESPONSE FOR FIBER DELIVERY DEVICE, DUOTOME SIDELITE 550**

MANUFACTURER REP WAS PRESENT AT THE TIME OF THE EVENT, UNKNOWN AT THIS TIME WHAT THEIR RESPONSE WAS.

**Concomitant Medical Products:**

NO OTHER THERAPIES

<table>
<thead>
<tr>
<th>Mfr Name: BOSTON SCIENTIFIC CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: ONE BOSTON SCIENTIFIC PLACE</td>
</tr>
<tr>
<td>NATICK, MA 01760</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | No Answer |

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

13-JAN-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LUMENIS DUOTOME SIDELITE 550
- **Device Type:** LASER FIBER
- **Device Type:** M0068408460
- **Catalog:** 840-846
- **Serial:** (*confidential*)
- **Lot:** 70930208
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** -
## MAUDE EVENT REPORT (FOI)

### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Sep-2008</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>03-Jan-2009</td>
<td>Event Outcome (B2):</td>
<td>-</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>03-Jan-2009</td>
<td>Reporter Occupation (E3):</td>
<td>-</td>
<td>Report Source (G3):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>Single Use (H5):</td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Event Description (B5):


### Concomitant Medical Products:

UNKNOWN

Mfr Name: AMERICAN MEDICAL SYSTEMS, INC.
Address: 10700 BREN ROAD WEST
MINNETONKA, MN 55343
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
16-JAN-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** GREENLIGHT
- **Device Type:** LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [b] (b)
- **Address:** [b] (b)
- **Health Professional:** No Information
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:**
  - Fax: [b] (b)
- **Occupation:** -
User Facility Report No: 

Date Received: 02-Nov-2010

Mfr Name: MEDTRONIC INC., CARDIAC RHYTHM DISEASE MANAGEMENT

Event Date (B3): 06-Jan-2009
Event Report Type: MALFUNCTION
Event Outcome (B2):

Report Date (B4): 03-Feb-2009
Adverse Event (B1):

Date Mfr Rec'd (G4):

Event Location (F12): HOSPITAL

Product Code: (CV)-IMPLANTABLE CARDOVERTER DEFIBRILLATOR (NON-CRT) (LWS)

Device Operator: INVALID DATA

Device Age (F9): Manufacture Date (H4):

Expiration Date:

Device Evaluated by Manufacturer (H3): No Answer

Address: CARDIAC RHYTHM DISEASE MANAGEM
8200 CORAL SEA STREET NE
MOUNDS VIEW, MN 55112
UNITED STATES

Device Available for Evaluation: Y

Concomitant Medical Products: NOT APPLICABLE

Mfr Name: MEDTRONIC INC.

Date Last Updated: 11/2/2010 9:17 AM

Event Description (B5):


Recd: 163

Page: 325

Date Last Updated: 11/2/2010 9:17 AM
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-FEB-2009:

DEVICE INFORMATION:

Brand: SPRINT FIDELIS
Device Type: LEAD, ICD
Device Type: 6949
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
EMAIL: [b] (6)
Phone: [b] (6)
International:
Fax:

Health Professional: No Information

Occupation: 500 - RISK MANAGER
User Facility Report No: Mfr Name: LUMENIS, INC.

Event Date (B3): 14-Jan-2009
Report Date (B4) 18-Feb-2009
Report Date (F8): 18-Feb-2009
Report Date (B4): 18-Feb-2009
Date Mfr Rec'd (G4): 

Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Event Date (B3): 14-Jan-2009
Report Date (B4) 18-Feb-2009
Event Outcome (B2):
Event Location (F12): HOSPITAL
Event Report Type: MALFUNCTION
Report Date (B4): 18-Feb-2009
Event Location (F12): HOSPITAL

Report Source (G3):

Device Operator: PHYSICIAN

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):

User 24-FEB-2009: PATIENT UNDERGOING EXTRACTION OF AN URETERAL STONE WITH HOLMIUM LASER. DURING THE PROCEDURE THE LASER FIBER MADE AN AUDIBLE "POP" NOISE AND FLASHED. ALL STAFF AND THE PATIENT WERE WEARING EYE PROTECTION. THERE WAS NO EVIDENCE OF LASER CONTACT TO SKIN (OF PATIENT OR STAFF). THE LASER UNIT AND FIBER WERE REMOVED FROM SERVICE AND INSPECTED BY A BIOMEDICAL ENGINEER. THE LASER UNIT WAS TESTED WITH A TEST FIBER AND FOUND TO BE FUNCTIONING PROPERLY. THE BLAST SHIELD WAS REPLACED BECAUSE IT WAS "DAMAGED." (THE BLAST SHIELD ACTS AS A "FUSE" AND PROTECTS THE LASER'S INTERNAL COMPONENTS IN THE EVENT OF A FIBER FAILURE.) THE LASER WAS PLACED BACK IN SERVICE. THE ENGINEER DID NOT INSPECT THE FIBER, BUT IT WAS RETAINED IN THE EVENT THE MANUFACTURER REQUESTS TO INSPECT IT. THE LASER FIBER IS A REUSABLE ITEM. WE DO KEEP TRACK OF HOW MANY TIMES THEY ARE USED/STERILIZED. THEY CAN BE USED UP TO TEN TIMES, BUT USUALLY DO NOT ACHIEVE THAT NUMBER. THEY ARE INSPECTED AND TRIMMED WITH A TOOL AFTER EACH USE.

THE FIBERS CAN BE USED UP TO 10 TIMES. WE KEEP TRACK OF THE TIMES THE FIBER HAS BEEN USED/STERILIZED BY MARKING THE CONTAINER THE FIBER IS STERILIZED IN. WE HAVE A CUTTING/TRIMING TOOL FOR THE FIBERS ACCORDING TO SIZE. THE REUSEABLE FIBERS ARE DISCARDED FOR THE FOLLOWING REASONS:

1. THE FIBER IS TRIMED TO THE POINT THAT IT'S TOO SHORT TO REACH FROM THE LASER TO THE STERILE FIELD.
2. THE FIBER HAS BEEN USED 10 TIMES.
3. AFTER EACH TRIM, THE FIBER IS CHECKED WITH AN INSPECTION SCOPE TO CHECK FOR DAMAGED FIBERS. IF THERE ARE DAMAGED FIBERS THAT CAN'T BE TRIMMED, THE FIBER WILL BE DISCARDED.
4. THERE IS A BLAST SHIELD ON THE LASER. IF THIS NEEDS TO BE REPLACED DURING A CASE, THE FIBER THAT IS BEING USED IS DICARDED BECAUSE YOU CAN'T BE SURE THAT THE FIBER HAS CAUSED THIS.

FIBER FAILURE CAN CAUSE INJURY TO STAFF/PATIENT, BUT IN THIS CASE THERE WAS NO ADVERSE OUTCOME.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Concomitant Medical Products:

Mfr Name: LUMENIS, INC.
Address: 2400 CONDENSA STREET
SANTA CLARA, CA 95051
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
24-FEB-2009

DEVICE INFORMATION:

Brand: VERSAPULSE POWERSUITE
Device Type: LASER, HOLMIUM
Device Type: POWERSUITE-20W
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)  
Address: [b] (b)  

Health Professional: No Information

EMAIL: [b] (b)  
Phone: [b] (b)  
International: [b] (b)  
Fax: 

Occupation: 500 - RISK MANAGER

Recd: 164  Page: 328  Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

Event Date (B3): 05-Mar-2009
Report Date (B4): 09-Mar-2009
Report Date (F8): 09-Mar-2009
Event Report Type: MALFUNCTION
Event Description (B5):
User 18-MAR-2009: DURING LASER LITHOTRIPSY, LASER FIBER BROKE INTO TWO PIECES OUTSIDE THE PATIENT. ALL FIBER PARTS ABLE TO BE REMOVED BY PHYSICIAN. USED NEW FIBER TO COMPLETE THE CASE. NO PATIENT HARM.

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: FIBERTECH USA, INC.
Address: 4111 EAST VALLEY AUTO DR.
SUITE 104
MESA, AZ 85206
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-MAR-2009:

Report Date (B4): 09-Mar-2009
Report Date (F8): 09-Mar-2009
Event Outcome (B2):
Event Location (F12): HOSPITAL
Event Description (B5):
User 18-MAR-2009: DURING LASER LITHOTRIPSY, LASER FIBER BROKE INTO TWO PIECES OUTSIDE THE PATIENT. ALL FIBER PARTS ABLE TO BE REMOVED BY PHYSICIAN. USED NEW FIBER TO COMPLETE THE CASE. NO PATIENT HARM.

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: FIBERTECH USA, INC.
Address: 4111 EAST VALLEY AUTO DR.
SUITE 104
MESA, AZ 85206
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-MAR-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** *
- **Device Type:** LASER FIBER
- **Device Type:** BARE FIBER FT IR200/220ST-3/SM-F
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 0703044
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No Information
- **Occupation:** -
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
Event Date (B3): 09-Mar-2009
Report Date (B4): 11-Mar-2009
Report Date (F8): 11-Mar-2009
Date Mfr Rec'd (G4): 

Event Report Type: MALFUNCTION
Event Date (B3): 09-Mar-2009
Event Outcome (B2): 
Report Date (F8): 11-Mar-2009
Report Location (F12): HOSPITAL

Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: PHYSICIAN

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): 

Event Description (B5):

Concomitant Medical Products:

Mfr Name: LUMENIS, INC.
Address: 2400 CONDENSA STREET
          SANTA CLARA, CA 95051
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
18-MAR-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DUOTOME SIDELITE 550 FIBER DELIVERY DEVICE
- **Device Type:** LASER FIBER
- **Catalog:** 840-846
- **Serial:** (*confidential*)
- **Lot:** 62010807
- **Other ID:** *
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>09-Apr-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>17-Apr-2009</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Apr-2009</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>-</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>-</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

User 27-APR-2009: BOSTON SCIENTIFIC ACCUFLEX HOLMIUM LASER FIBER BROKE DISTAL TO INSERTION IN PATIENT DURING THE PROCEDURE. ANOTHER FIBER WAS USED TO COMPLETE THE PROCEDURE WITHOUT INCIDENT. NO HARM TO THE PATIENT.

**Concomitant Medical Products:**

NOT APPLICABLE

**Mfr Name:** BOSTON SCIENTIFIC CORP.

**Address:** ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

27-APR-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ACCUFLEX
- **Device Type:** LASER FIBER, HOLMIUM, SINGLE-USE
- **Device UPN:** M0068408040
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** TRF 1358E
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>22-Apr-2009</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>23-Apr-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>23-Apr-2009</td>
<td>Reporter Occupation (E3):</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

**Concomitant Medical Products:**
NOT APPLICABLE

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTER DRIVE
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 05-MAY-2009:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: *
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)
EMAIL: [b] (b)
Phone: [b] (b)
International: (b) (b)
Fax: (b) (b)

Health Professional: No Information

Occupation: -
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 22-Apr-2009

User Facility Report No: | Mfr Name: NEW STAR LASERS, INC. | Date Received: 22-Apr-2009
---|---|---

**Event Date (B3):** 09-Apr-2009  
**Report Date (B4):** 22-Apr-2009  
**Report Date (F8):** 22-Apr-2009  
**Date Mfr Rec'd (G4):** 22-Apr-2009

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Report Date (F8):** 500 - RISK MANAGER  
**Event Location (F12):** HOSPITAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):**

**Event Description (B5):**
User 07-MAY-2009: WHILE A PATIENT WAS UNDERGOING CYSTO/URETEROSCOPY AND LASER LITHOTRIPSY, ATTEMPTS TO FIRE THE NEW STAR LASER WERE UNSUCCESSFUL, AND AN "ERROR 17" WAS DISPLAYED, WHICH MEANS "LOW LASER OUTPUT". THE SURGEON WAS ABLE TO PROCEED WITH THE PROCEDURE USING AN ELECTRO-LITHOTRIPTOR. THE LASER WAS CALIBRATED AND TESTED BY THE THIRD PARTY COMPANY WHICH IS CONTRACTED TO PROVIDE MAINTENANCE SERVICE ON THE LASER.

THE SURGEON NOTED THAT THERE WAS NO ADVERSE IMPACT TO THE PATIENT.

**Concomitant Medical Products:**
NOT KNOWN

**Mfr Name:** NEW STAR LASERS, INC.  
**Address:** 9085 FOOTHILLS BLVD  
ROSEVILLE, CA 95747  
UNITED STATES

**Device Available for Evaluation:**
No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
07-MAY-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** *
- **Device Type:** LASER, HO:YAG, GENERAL PURPOSE
- **Device Type:** NS1500
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:美洲医疗系统, 公司.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 02-Mar-2009 | **Event Report Type:** MALFUNCTION | **Adverse Event (B1):** Problem (B1): Y |
**Report Date (B4):** 05-May-2009 | **Event Outcome (B2):** | |
**Report Date (F8):** 05-May-2009 | **Report Date (F8):** | |
**Date Mfr Rec'd (G4):** | **Event Location (F12):** HOSPITAL | |

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) | **Device Operator:** PHYSICIAN |
**Device Available for Evaluation:** N |
**Device Evaluated by Manufacturer (H3):** No Answer |
**Remedial Action (H7):** |
**Correction/Removal No (H9):** |
**Additional Mfr Narrative (H10 & H11):** 15-MAY-2009 |

**Event Description (B5):**
User 15-MAY-2009: PATIENT UNDERGOING PHOTOVAPORIZATION OF PROSTATE WITH GREENLIGHT LASER. DURING THE PROCEDURE THE LASER FIBER TIP BROKE OFF WHILE IN THE PATIENT. THE SURGEON WAS ABLE TO RETRIEVE THE TIP WITHOUT INJURY TO THE PATIENT. THE REPRESENTATIVE FROM THE CONTRACTED LASER PROVIDER TOOK THE BROKEN FIBER TIP WITH HIM TO INCLUDE WITH HIS REPORT TO HIS COMPANY.

**Concomitant Medical Products:**
NO OTHER THERAPIES

**Mfr Name:** 美洲医疗系统, 公司.  | **Address:** 10700 BREN ROAD WEST MINNETONKA, MN 55343 UNITED STATES |

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT HPS BPA
- **Device Type:** LASER FIBER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 10-2090-851R-3056
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No Information
- **PHONE:** [Redacted]
- **INTERNATIONAL:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 500 - RISK MANAGER
User Facility Report No: Mfr Name: BIOLITEC, INC.

Event Date (B3): 18-May-2009
Report Date (B4): 22-May-2009
Event Report Type: MALFUNCTION
Event Outcome (B2):

Adverse Event (B1): Problem (B1): Y

Reporter Occupation (E3): Device Operator: PHYSICIAN

Event Location (F12): HOSPITAL
Report Source (G3):

Date Mfr Rec’d (G4):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Code:
Device Age (F9):
Expiry Date:
Device Usage (H8):

Event Description (B5): User 12-JUN-2009: PATIENT WAS TO UNDERGO OUTPATIENT PHOTOVAPORIZATION OF THE PROSTATE. THE EVOLVE 150 LASER WAS CHECKED BY BIOMED PRIOR TO THE PROCEDURE, THEN BROUGHT INTO THE OR. THE LASER TECHNICIAN TURNED ON THE LASER TO PERFORM A SELF CHECK AND THE LASER PASSED. THE STERILE FIBER WAS GIVEN TO THE SURGEON; THE FIBER WAS PLACED THROUGH THE LASER BRIDGE. THE LASER WAS THEN SET ON STANDBY UNTIL THE SURGEON IS READY FOR THE LASER TO FIRE. SHORTLY AFTER JUST A SMALL AMOUNT OF TISSUE VAPORIZATION, THE LASER STOPPED AND A "FIBER PORT OVERHEATED" MESSAGE DISPLAYED ON THE SCREEN. THE LASER TECH WAITED FOR THE LASER TO COOL AND ATTEMPTED TO RE-ENABLE IT. THIS WAS REPEATED SEVERAL TIMES WITH DIFFERENT FIBERS WITH THE SAME END RESULT. THE PROCEDURE WAS ABORTED AND THERE WAS NO HARM TO THE PATIENT. THE BIOLITEC TECHNICIAN SENT THE LASER TO THE FACTORY THE SAME DAY OF THIS PROCEDURE TO PERFORM A TEST TO DETERMINE IF THE BLAST SHIELD WAS DAMAGED. RESULTS WERE REPORTED BACK TO THE FACILITY THAT THE CAUSE FOR THE DISPLAYED MESSAGE WAS DUE TO A DEFECTIVE FIBER. THE PATIENT IS RESCHEDULED FOR THIS PROCEDURE.

Concomitant Medical Products:

Mfr Name: BIOLITEC, INC.
Address: 515 SHAKER ROAD
EAST LONGMEADOW, MA 01028
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
CDRH
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
12-JUN-2009:

DEVICE INFORMATION:
- Brand: EVOLVE 150
- Device Type: LASER, PVP
- Device Type: *
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: [REDACTED]
- Address: [REDACTED]
- EMAIL: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]
- Health Professional: No Information
- Occupation: -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: GYRUS MEDICAL INC., SUB. OF GYRUS ACMI, INC.</th>
</tr>
</thead>
</table>

Event Date (B3): 04-Jun-2009
Report Date (B4): 05-Jun-2009
Report Date (F8): 05-Jun-2009
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3):
Device Operator: PHYSICIAN

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3):

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LINK)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
UNKNOWN

Mfr Name: GYRUS MEDICAL, INC.
Address: 6655 WEDGEWOOD ROAD, SUITE 160
           MAPLE GROVE, MN 55311
           UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
24-JUN-2009:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** *
- **Device Type:** LASER FIBER, 1000 MICRON
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** LD2707S
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No.</th>
<th>Mfr Name: UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 26-Jun-2009</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Mfr Name: FORTEC FIBERS</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Address: 10125 WELLMAN ROAD STREETSBORO, OH 44241 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>Event Report Type (G3):</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>Event Description (B5):</td>
</tr>
<tr>
<td>Device Operator: PHYSICIAN</td>
<td>User 13-JUL-2009: LASER FIBER WIRE DEFECTIVE. OPENED NEW ONE AND IT WORKED FINE.</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 01-Jul-2009</td>
<td>Concomitant Medical Products:</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>NOT KNOWN</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 13-JUL-2009:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** *
- **Device Type:** LASER FIBER, FLAT TIP, HOLMIUM
- **Device Type:** DHBFSF230-DO
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *(b) (6)*
- **Address:** *(b) (b)*
- **Health Professional:** No Information
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:**
- **Fax:**
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| User Facility Report No: | Mfr Name: | Date Received | Date Mfr Rec’d (G4): | Product Code: | Device Operator: | Event Report Type: | Event Date (B3): | Report Date (B4): | Report Date (F8): | Event Outcome (B2): | Reporter Occupation (E3): | Adverse Event (B1): | Problem (B1): | Event Location (F12): | Event Description (B5): |
|-------------------------|-----------|---------------|----------------------|---------------|------------------|-------------------|-----------------|------------------|------------------|--------------------|---------------------|----------------|-------------------|-------------------|
|                         |           |               |                      |               |                  |                   |                 |                  |                  |                    |                     |                     |                  |                   |                    |
|                         |           |               |                      |               |                  |                   |                 |                  |                  |                    |                     |                     |                  |                   |                    |

Recd: 174
Page: 347
User 13-JUL-2009: AN ADOLESCENT PATIENT WAS ADMITTED TO THE HOSPITAL WITH THREE-MONTH HISTORY OF PERSISTENT PNEUMONIA. CT SCAN SHOWED CALCIFIED MASS OBSTRUCTING THE RIGHT MIDDLE LOBE TAKEOFF INTRALUMINALLY. A SURGICAL PROCEDURE WAS SCHEDULED FOR DIRECT LARYNGOSCOPY, BRONCHOSCOPY AND BIOPSY OF MASS WITH KTP LASER.

PATIENT WAS INITIALLY INTUBATED AND A FLEXIBLE ADULT FIBER OPTIC BRONCHOSCOPE WAS PLACED THROUGH ETT. BIOPSIES WERE OBTAINED USING A FLEXIBLE BIOPSY FORCEPS THROUGH THE BRONCHOSCOPE. THE KTP LASER WAS USED TO CONTROL BLEEDING. THE PATIENT HAD INITIALLY BEEN VENTILATED WITH 21% FIO2 AT THE START OF THE CASE BUT WITH CONTINUED DESATURATIONS SECONDARY TO AIRWAY LEAK AROUND THE BRONCHOSCOPE THE FIO2 WAS INCREASED TO 100%. THE SURGEON WAS UNABLE TO REMOVE THE MASS SO THE FLEXIBLE BRONCHOSCOPE WAS REMOVED.

A RIGID BRONCHOSCOPE WAS THEN PLACED AND ATTEMPTS TO REMOVE THE MASS WERE UNSUCCESSFUL. RIGID BRONCHOSCOPE WAS REMOVED AND PATIENT WAS REINTUBATED. SEVERAL MORE SPECIMENS WERE OBTAINED USING THE FLEXIBLE BRONCHOSCOPE THROUGH THE ETT. BLEEDING WAS STOPPED USING THE KTP LASER. ATTEMPTS WERE ALSO MADE TO ABLATE THE MASS WITH THE KTP.


A FLEXIBLE BRONCHOSCOPE WAS PASSED THROUGH THE ETT TO EXAMINE THE AIRWAY. THIS EXAMINATION REVEALED EVIDENCE OF MELTED PLASTIC VERSES VAPORIZED PLASTIC FROM THE END OF THE FLEXIBLE BRONCHOSCOPE. THE PATIENT WAS TRANSFERRED FROM THE OPERATING ROOM TO THE PEDIATRIC INTENSIVE CARE UNIT. THE PATIENT REMAINED INTUBATED UNTIL 2 DAYS AFTER THE PROCEDURE, WHEN SHE WAS SUCCESSFULLY EXTUBATED. THE PATIENT REMAINS HOSPITALIZED AND IS SCHEDULED TO RETURN TO THE OPERATING ROOM FOR REMOVAL OF THE MASS.

Concomitant Medical Products:

NO OTHER THERAPIES

Mfr Name: AMERICAN MEDICAL SYSTEMS, INC.
Address: 10700 BREN ROAD WEST
MINNETONKA, MN 55343
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

Sorted by

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
13-JUL-2009:

**DEVICE INFORMATION:**

- **Brand:** AURA XP
- **Device Type:** LASER, KTP
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th></th>
<th>Mfr Name: CANDELA LASER CORP.</th>
<th></th>
</tr>
</thead>
</table>

| Event Date (B3): 11-Jun-2009 | Event Report Type: MALFUNCTION | Adverse Event (B1): Problem (B1): Y |
| Report Date (B4): 07-Aug-2009 | Event Outcome (B2): | |
| Report Date (F8): 07-Aug-2009 | Reporter Occupation (E3): 500 - RISK MANAGER | Event Location (F12): HOSPITAL |
| Date Mfr Rec'd (G4): | Device Operator: PHYSICIAN | Report Source (G3): |

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Event Description (B5):**


**Concomitant Medical Products:**

NOT KNOWN

**Mfr Name:** CANDELA CORPORATION

**Address:** 530 BOSTON POST ROAD WAYLAND, MA 01778 UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

19-AUG-2009:
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: V-BEAM PERFECTA
Device Type: LASER, DERMATOLOGIC
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *(b) (6)*
Address: *(b) (6)*

EMAIL: *(b) (6)*
Phone: *(b) (6)*
International: 
Fax: 

Health Professional: No Information

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Event Date (B3):</td>
<td>12-Aug-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Report Date (F8):</td>
<td>24-Aug-2009</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 02-SEP-2009: SURGEON PRESSED ON THE HOLMIUM LASER PEDAL AT 0.6 JOULES; LASER DID NOT TURN ON. A FEW SECONDS LATER, STAFF HEARD A POP SOUND FROM THE MACHINE, WITH SMELL OF SMOKE. THE FIRST FIBER WAS A USED FIBER WITH LOT # 82191208. PATIENT AND DRAPE CHECKED FOR BURNS; NONE FOUND. ABOUT 20 MINUTES LATER, SURGEON USED THE LASER AGAIN, WITH A NEW LASER FIBER (LOT # 81601108). THE POWER WAS RAISED TO 0.8, THEN TO 2.1. SURGEON REPORTED MACHINE NOT WORKING. STAFF HEARD ANOTHER POP SOUND FROM THE MACHINE.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS, INC.</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>3959 WEST 1820 SOUTH</td>
<td></td>
</tr>
<tr>
<td>SALT LAKE CITY, UT 84104</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>02-SEP-2009:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VP SELECT
Device Type: LASER, HOLMIUM
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:
Email: (b) (6)
Phone: (b) (6)
International:
Fax:

Health Professional: No Information

Occupation: -
Event Description (B5):
User 16-SEP-2009: LASER FIBER TIP CAME APART IN PATIENT'S BLADDER WITH THE FIRST PULSE - TIP WAS REMOVED COMPLETELY.

Concomitant Medical Products:
NOT KNOWN

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-SEP-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DUOTOME SIDELITE
- **Device Type:** LASER FIBER
- **Device Type:** 550
- **Catalog:** 840-846
- **Serial:** (*confidential*)
- **Lot:** 85750209
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No Information
- **Occupation:** -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: AMERICAN MEDICAL SYSTEMS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>13-Aug-2009</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Sep-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>15-Sep-2009</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>PHYSICIAN</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>User 28-SEP-2009: GREENLIGHT HPS LASER FIBER PROBE FRACTURED AS IT WAS BEING USING DURING GREENLIGHT LASER TUR-P. ALL PIECES WERE RETRIEVED PER DR. FIBER WILL BE RETURNED TO THE COMPANY. PROCEDURE WAS STARTED WITH THE LASER, THEN CONVERTED BY THE SURGEON TO ESU THEN BACK TO LASER FOR COMPLETION OF CASE. FIBER BROKE AT 120 WATTS. END OF TIP EXTRACTED VIA CYSTOSCOPY PER DR. GLAND VOLUME WAS 60 ML, 12.5 MINUTES EXPENDED, ENERGY EXPENDED 62418 JOULES.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>28-SEP-2009:</td>
</tr>
</tbody>
</table>

Date Received: 15-Sep-2009
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT HPS BPH FIBEROPTIC
- **Device Type:** LASER FIBER
- **Device Type:** 10-2090
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 10-2090-927L
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** -
MAUDE EVENT REPORT (FOI)


<table>
<thead>
<tr>
<th>Event Date (B3): 08-Oct-2009</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 12-Oct-2009</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4):
Expiry Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: BOSTON SCIENTIFIC CORPORATION
Address: ONE BOSTON SCIENTIFIC PLACE
NATICK, MA 01760
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
23-OCT-2009:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ACCUFLEX
Device Type: LASER FIBER
Device Type: *
Catalog: 840802
Serial: (*confidential*)
Lot: TRF1837P
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: No Information
Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name:</th>
<th>IRIDEX CORPORATION</th>
</tr>
</thead>
</table>

**Event Date (B3):** 12-Aug-2009  
**Report Date (B4):** 10-Oct-2009  
**Report Date (F8):** 10-Oct-2009  
**Date Mfr Rec'd (G4):** 10-Oct-2009  
**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)  
**Device Operator:** PHYSICIAN  
**Report Source (G3):** PHYSICIAN  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Event Description (B5):**  
User 03-NOV-2009: PHYSICIAN USED FOR ABOUT 900 ENDOSPOTS WHEN THE PROBE STOPPED BEING EFFECTIVE DESPITE TURNING LASER ENERGY UP. A NEW PROBE WAS USED AND WORKED FINE. THE PROCEDURE CONTINUED WITHOUT COMPLICATION FOR THE PATIENT.

**Concomitant Medical Products:** NOT KNOWN

**Mfr Name:** IRIDEX CORPORATION  
**Address:** 1212 TERRA BELLA AVE.  
MOUNTAIN VIEW, CA 94043  
UNITED STATES

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 03-NOV-2009:
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

| Brand: *                                      |
| Device Type: LASER PROBE                     |
| Device Type: *                                |
| Catalog: 10562-1                              |
| Serial: (*confidential*)                      |
| Lot: 013083                                   |
| Other ID: *                                   |

Reprocessed & Reused: N/A

REPORTER INFORMATION:

| Name: (b) (6)                                |
| Address: (b) (b)                             |

Health Professional: No Information

EMAIL: (b) (6)

Phone: (b) (6)

International: 

Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:

Mfr Name: IRIDEX CORPORATION

Event Date (B3): 10-Sep-2009
Report Date (B4): 10-Oct-2009
Report Date (F8): 10-Oct-2009
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8): 500 - RISK MANAGER
Event Location (F12): HOSPITAL

Mfr Name: IRIDEX CORPORATION
Address: 1212 TERRA BELLA AVE
MOUNTAIN VIEW, CA 94043
UNITED STATES

Device Operator: PHYSICIAN

Adverse Event (B1): Problem (B1): Y
Report Date (F8): 500 - RISK MANAGER

Event Description (B5):
User 03-NOV-2009: LASER PROBE HAD VIRTUALLY NO AIMING BEAM. REPLACED WITH ANOTHER PROBE AND SURGERY CONTINUED WITHOUT INCIDENT.

Concomitant Medical Products:
NOT KNOWN

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
03-NOV-2009:

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** STANDARD STRAIGHT LASER PROBE 20 GAUGE
- **Device Type:** LASER PROBE
- **Device Type:** *
- **Catalog:** 10562-1
- **Serial:** (*confidential*)
- **Lot:** 013083
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b)(6)
- **Address:** (b)(6)

- **Health Professional:** No Information

- **EMAIL:** (b)(6)
- **Phone:** (b)(6)
- **International:**
- **Fax:**

**Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: MEDTRONIC INC., CARDIAC RHYTHM DISEASE MANAGEMENT</th>
<th>Date Received: 23-Oct-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 25-Sep-2009</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Problem (B1): N</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (CV)-IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (NON-CRT) (LWS)</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Device Operator: INVALID DATA</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): User 11-NOV-2009: THE PATIENT HAS A HISTORY OF V-TACH, A-FIB, END STAGE RENAL DISEASE, MULTIPLE CO-MORBID CONDITIONS OF NON-ISCHEMIC CARDIOMYOPATHY, AN EJECTION FRACTION OF 20%, AND WAS ON A HOME IV DOBUTAMINE INFUSION. THE PATIENT WAS ON VANCOMYCIN FOR A HICKMAN CATHETER INFECTION WITH POSITIVE BLOOD CULTURES FOR COAGULASE-NEGATIVE STAPHYLOCOCCUS. THE PATIENT WAS ADMITTED FOR AN ERODED ICD SITE (INFECTION) AND LASER LEAD EXTRACTION. THE PROCEDURE (PERFORMED IN THE OR) APPEARED TO GO SMOOTHLY UNTIL A SIGNIFICANT DROP IN BLOOD PRESSURE OCCURRED WHICH WAS DETERMINED TO BE CAUSED BY A LACERATION IN THE PATIENT'S RIGHT VENTRICLE. THE PATIENT WAS IMMEDIATELY PLACED ON BYPASS AND UNDERWENT SURGERY FOR CARDIAC REPAIR. THE PATIENT DID EXPIRE APPROXIMATELY TWO WEEKS LATER WHICH WAS THOUGHT TO BE DUE TO HIS DISEASE PROCESS AND MULTIPLE CO-MORBIDITIES. CAUSE OF DEATH IDENTIFIED AS SEPTIC SHOCK, CARDIOGENIC SHOCK AND END STAGE RENAL DISEASE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: NOT APPLICABLE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 182  Page: 364  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

11-NOV-2009:

DEVICE INFORMATION:

- **Brand:** SPRINT
- **Device Type:** LEAD, DEFIBRILLATION
- **Device Type:** 6945
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
Mfr Name: VASCULAR SOLUTIONS, INC.

User Facility Report No:

Mfr Name: VASCULAR SOLUTIONS, INC.

02-Nov-2010

Event Date (B3): 24-Aug-2009
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 04-Nov-2009
Event Outcome (B2):

Report Date (F8): 04-Nov-2009
Report Location (F12):

Date Mfr Rec'd (G4): Device Operator: PHYSICIAN

Device Operator: PHYSICIAN

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Single Use (H5):
Expiration Date:
Device Usage (H8):

Event Description (B5):
User 18-NOV-2009: PATIENT ADMITTED TO OUTPATIENT SURGERY CENTER FOR RIGHT ANTERIOR LATERAL GREATER SAPHENOUS VEIN ENDOVENOUS LASER ABLATION WITH MULTIPLE STAB PHLEBECTOMIES. VARI-LASE LASER WAS USED. A VARI-LASE STANDARD KIT, 4FR, 45 CM SHEATH WAS OPENED PER PHYSICIAN'S REQUEST.


RN CIRCULATOR IN THE ROOM CALLED THE VASCULAR LAB AT THE REQUEST OF DR. FOR NURSE TO BRING ANOTHER ULTRASOUND MACHINE TO THE ROOM. ULTRASOUND WAS PERFORMED AND NO PIECES OF PLASTIC WERE NOTED BY EITHER NURSE OR DR. THE PATIENT REMAINED STABLE DURING THE PROCEDURE. AFTER THE PROCEDURE THE PATIENT'S HUSBAND WAS BROUGHT TO THE CONFERENCE ROOM BY DR. AND RN WAS ALSO PRESENT FOR THE CONVERSATION WHILE DR. EXPLAINED THE INCIDENT TO THE HUSBAND. IT WAS ALSO EXPLAINED TO THE PATIENT. DR. TOLD THE PATIENT AND HUSBAND POTENTIAL COMPLICATIONS TO BE AWARE OF.

Concomitant Medical Products:
UNKNOWN

Mfr Name: VASCULAR SOLUTIONS, INC.

Recd: 183
Page: 366
Date Last Updated: 11/2/2010 9:17 AM
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Address: 6464 SYCAMORE COURT
          MAPLE GROVE, MN 55369
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-NOV-2009:

DEVICE INFORMATION:

  Brand: VARI-LASE
  Device Type: LASER FIBER
  Device Type: *
  Catalog: REF #7112
  Serial: (*confidential*)
  Lot: 546508
  Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

  Name: [REDACTED]
  Address: [REDACTED]
  EMAIL: [REDACTED]
  Phone: [REDACTED]
  International: [REDACTED]
  Fax: [REDACTED]

  Health Professional: No Information
  Occupation: 500 - RISK MANAGER

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 03-Nov-2009</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 04-Nov-2009</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 04-Nov-2009</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Operator: INVALID DATA</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): User 18-NOV-2009: SURGEONS REQUESTED 200 MICRON LASER FIBER. SLIMLINE 200 FIBER DELIVERY DEVICE WAS OPENED. SURGEON BEGAN USING THE FIBER BUT COMPLAINED THAT IT IS NOT WORKING. IT MADE A CLICKING SOUND WHICH IS DIFFERENT THAN THE USUAL SOUND WHEN PEDAL PRESSED. SURGEONS REQUESTED ANOTHER FIBER; NEW FIBER WORKED.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LUMENIS, INC.</td>
<td>Address: 3959 WEST 1820 SOUTH SALT LAKE CITY, UT 84104 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation: N</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 18-NOV-2009:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SLIMLINE
Device Type: LASER FIBER, HOLMIUM
Device Type: *
Catalog: UPN# M0068408400
Serial: (*confidential*)
Lot: 80770908
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

EMAIL: (b) (6)
Phone: (b) (6)
International:
Fax:

Health Professional: No Information

Occupation: -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 21-Sep-2009</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 07-Nov-2009</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 07-Nov-2009</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: INVALID DATA</td>
</tr>
<tr>
<td>Product Code: (CV)-STRIPPER, VEIN, EXTERNAL (DWQ)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NOT KNOWN

**Mfr Name:** INAVEIN, LLC

**Address:** 420 BEDFORD ST.
LEXINGTON, MA 02420
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
01-DEC-2009:

DEVICE INFORMATION:

Brand: TRIVEX
Device Type: LASER, ENDOVENOUS DEVICE
Device Type: INAVEIN TRIVEX SYSTEM
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: No Information

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>User Facility Report No:</th>
<th>Mfr Name: LUMENIS, INC.</th>
<th>Date Received: 25-Nov-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 18-Nov-2009</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 25-Nov-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 25-Nov-2009</td>
<td>Reporter Occupation (E3): -</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: NOT KNOWN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LUMENIS, INC.</td>
<td>Address: 3959 WEST 1820 SOUTH SALT LAKE CITY, UT 84104 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 02-DEC-2009:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** SLIM LINE EZ 550
- **Device Type:** LASER FIBER
- **Catalog:** M0068408941
- **Serial:** (*confidential*)
- **Lot:** 85850209
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** -
- **Health Professional:** No Information
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No: Mfr Name: LASER PERIPHERALS LLC.

Date Received: 14-Dec-2009

Event Date (B3): 04-Nov-2009
Report Date (B4): 14-Dec-2009
Report Date (F8): 14-Dec-2009
Date Mfr Rec'd (G4): Device Operator: PHYSICIAN

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Event Outcome (B2): Event Location (F12): HOSPITAL

Reporter Occupation (E3): -

Report Date (B4): 14-Dec-2009

Event Description (B5):

Concomitant Medical Products:
NOT APPLICABLE

Mfr Name: LASER PERIPHERALS LLC
Address: 1000 BOONE AVENUE NORTH
SUITE 300
GOLDEN VALLEY, MN 55427
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-DEC-2009:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: *
Device Type: LASER FIBER, HOLMIUM, SINGLE USE
Device Type: HB-200
Catalog: HB-200
Serial: (*confidential*)
Lot: LP-548
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: No Information

EMAIL: [b] (6)
Phone: [b] (6)
International: Fax:

Occupation: -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

User Facility Report No:  
Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE

Event Date (B3): 30-Jul-2009  
Event Report Type: MALFUNCTION  
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 27-Jan-2010  
Event Outcome (B2):  
Event Location (F12): HOSPITAL

Report Date (F8): 27-Jan-2010  
Reporter Occupation (E3): 002 - NURSE

Date Mfr Rec'd (G4):  
Device Operator: INVALID DATA

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9):  
Expiration Date:  
Device Usage (H8):

Event Description (B5):
User 03-FEB-2010: A HOLMIUM LASER LITHOTRIPSY PROBE WAS INSERTED AND PUT IN CONTACT WITH THE STONE. IT DID FRAGMENT THE STONE, HOWEVER THE PIECES MIGRATED AWAY FROM THE SCOPE. AFTER MULTIPLE ATTEMPTS, AT DIFFERENT ANGLES, THEY COULD NOT BE REACHED. SWITCHED OVER TO A FLEXIBLE SCOPE LEAVING A SECOND GUIDEWIRE IN PLACE. THE STONES COULD THEN BE VISUALIZED, ALTHOUGH THERE WAS A FAIRLY SIGNIFICANT DIFFICULT ANGLE WITH THE SCOPE. IT WAS THEN POSSIBLE TO GET THE LITHOTRIPSY PROBE IN CONTACT WITH THE STONE AND TREAT THE SIGNIFICANTLY LARGE PIECE WHICH WAS LEFT. AFTER MULTIPLE ATTEMPTS WITH THIS, THE LASER PROBE ACTUALLY BROKE AND THE FLEXIBLE CYSTOSCOPE JUST DISTAL TO IT. THE LASER BURNED THE LENS, SO AT THIS POINT THE CYSTOSCOPE WAS NO LONGER USEFUL. THE URETER LOOKED NORMAL WITH NO SIGN OF ANY INJURY OR PERFORATION. THE PATIENT WILL NEED TO RETURN FOR LITHOTRIPSY.

Concomitant Medical Products:

Mfr Name: AMERICAN MEDICAL SYSTEMS, INC.
Address: 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: N  
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
03-FEB-2010:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** INNOVAQUARTZ
- **Device Type:** LASER FIBER
- **Catalog:** CE0459
- **Serial:** (*confidential*)
- **Lot:** TRF0387A
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received


Event Date (B3): 16-Sep-1992  Event Report Type: INJURY
Report Date (F8): 25-Sep-1992  Reporter Occupation (E3): 999 - UNKNOWN
Date Mfr Rec'd (G4):  
Device Operator: OTHER

Product Code: (CV)-FIBEROPTIC (LWX)
Device Age (F9):  
Expiration Date:  
Device Usage (H8):

Adverse Event (B1): Y  Problem (B1): N
Event Location (F12): OTHER  Report Source (G3):

Event Description (B5):

INVALID DATA - REGARDING SINGLE USE LABELING OF DEVICE. PATIENT MEDICAL STATUS PRIOR TO EVENT: UNKNOWN. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS NOT EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: NO DATA. RESULTS OF EVALUATION: NO DATA. CONCLUSION: NO DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: UNKNOWN (CANNOT DETERMINE). CORRECTIVE ACTIONS: NONE OR UNKNOWN. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:

Mfr Name: TRIMEDYNE, INC.
Address: ,

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 22-OCT-1992:

DEVICE INFORMATION:

- **Brand:** BARD UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** UNKNOWN
- **Catalog:** 350000
- **Serial:** (*confidential*)
- **Lot:** 7231
- **Other ID:** 021992090258

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Unknown
- **Occupation:** 999 - UNKNOWN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Distributor Report No:</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date</th>
<th>Report Date (B4) 02-Oct-1992</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Event Outcome (B2):</td>
<td>Problem (B1): N</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3): 999 - UNKNOWN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>Device Operator: OTHER HEALTH CARE PROFE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Report Source (G3):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


INVALID DATA - REGARDING SINGLE USE LABELING OF DEVICE. PATIENT MEDICAL STATUS PRIOR TO EVENT: INVALID DATA. INVALID DATA - REGARDING MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

INVALID DATA - REGARDING WHETHER EVENT PRESENTS IMMINENT HAZARD. INVALID DATA - WHETHER DEVICE USED AS LABELED/INTENDED.

INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:

Mfr Name: TRIMEDYNE, INC.
Address: ,

Recd: 190 Page: 380 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Removal Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-NOV-1992:

DEVICE INFORMATION:

- **Brand:** BARD UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 350000
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:** 021992090326

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Unknown
- **Occupation:** 999 - UNKNOWN

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:** [Redacted]
**Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received:</th>
<th>17-Dec-1992</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Distributor Report No:</th>
<th>1018233-1992-00005</th>
</tr>
</thead>
</table>

**Event Date (B3):** 01-Dec-1992

**Report Date (B4):** 10-Dec-1992

**Report Date (F8):** 10-Dec-1992

**Date Mfr Rec'd (G4):**

**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)

**Device Operator:** OTHER HEALTH CARE PROFESSIONAL

**Event Description (B5):**


**Device Labeled for Single Use:**

**Patient Medical Status Prior to Event:** UNKNOWN.

**Invalid Data - Regarding Multiple Patient Involvement:**

**Invalid Data - On Device Service/Maintenance:** NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

**No Imminent Hazard to Public Health Claimed:** DEVICE USED AS LABELED/INTENDED.

**Device Was Not Evaluated After the Event:**

**Method of Evaluation:** NO DATA.

**Results of Evaluation:** NO DATA.

**Conclusion:** NO DATA.

**Certainty of Device As Cause of or Contributor to Event:** INVALID DATA.

**Corrective Actions:** NO DATA.

**Device Destroyed/Disposed of Status:**

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>,</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
26-JAN-1993:

DEVICE INFORMATION:

- **Brand:** BARD UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 350000
- **Serial:** (*confidential*)
- **Lot:** 7451
- **Other ID:** 021992120081

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Unknown
- **Occupation:** 999 - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Distributor Report No:** 1018233-1993-00001  
**Mfr Name:** TRIMEDYNE, INC.  
**Date Received:** 18-May-1993

<table>
<thead>
<tr>
<th>Event Date (B3): 06-Apr-1993</th>
<th>Event Report Type: INJURY</th>
<th>Adverse Event (B1): Y</th>
<th>Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: OTHER HEALTH CARE PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (GU)-ENDOSCOPE, FIBER OPTIC (GDB)  
**Device Operator:** OTHER HEALTH CARE PROFESSIONAL  
**Reporter Occupation:** 999 - UNKNOWN

**Device Usage (H8):**

**Event Description (B5):**


DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: UNKNOWN. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMENENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTainty OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

**Concomitant Medical Products:**

- **Mfr Name:** TRIMEDYNE, INC.  
- **Address:**

**Device Available for Evaluation:** *  
**Device Evaluated by Manufacturer (H3):** No Answer
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-AUG-1993:

DEVICE INFORMATION:

- **Brand:** BARD UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 350000
- **Serial:** (*confidential*)
- **Lot:** 7542
- **Other ID:** 021993040059

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Health Professional:** Unknown
- **Occupation:** 999 - UNKNOWN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Distributor Report No:</th>
<th>1018233-1993-00004</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>24-May-1993</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-May-1993</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>10-May-1993</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>10-May-1993</td>
<td>Reporter Occupation (E3):</td>
<td>999 - UNKNOWN</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>OTHER HEALTH CARE PROFE</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-ENDOSCOPE, FIBER OPTIC (GDB)</td>
<td>Manufacturer Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Importer 02-AUG-1993: IT WAS REPORTED THAT DURING A LASER PROCEDURE, THE FIBER TIP SEPERATED AT THE AREA WHERE THE TIP IS CRIMPED TO THE FIBER. THE EVENT OCCURED ON THE THIRD SIXTY-SECOND LASER APPLICATION AT 60 WATTS. THE TIP WAS RETREIVED USING GRASPING FORCEPS THROUGH THE PREVIOUSLY PLACED SCOPE AS DESCRIBED IN THE PRODUCT LABELING. THE PROCEDURE WAS COMPLETED WITH A SECOND FIBER AND NO FURTHER COMPLICATIONS WERE REPORTED.

DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: UNKNOWN. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: YES. CORRECTIVE ACTIONS: NONE OR UNKNOWN. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INCORPORATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>,</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-AUG-1993:

DEVICE INFORMATION:
Brand: BARD UROLASE RIGHT ANGLE LASER FIBER
Device Type: LASER FIBER
Catalog: 350000
Serial: (*confidential*)
Lot: 7433
Other ID: 021993050027

Reprocessed & Reused: N/A

REPORTER INFORMATION:
Name: [redacted]
Address: [redacted]
Health Professional: Unknown

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 999 - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Distributor Report No:</th>
<th>1018233-1993-00009</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Dec-1993</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Dec-1993</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Dec-1993</td>
<td>Reporter Occupation (E3):</td>
<td>999 - UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>OTHER HEALTH CARE PROFE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Importer 23-OCT-1995: IT WAS REPORTED THAT DURING A LASER PROCEDURE, THE FIBER TIP SEPERATED AT THE AREA WHERE THE TIP IS CRIMPED TO THE FIBER. THE EVENT OCCURRED ON THE THIRD SIXTY-SECOND LASER APPLICATION AT 60 WATTS. THE TIP WAS FLUSHED FROM THE PT'S BLADDER BY IRRIGATING THROUGH THE PREVIOUSLY PLACED CYSTOSCOPE. THE PROCEDURE WAS COMPLETED WITH A SECOND FIBER AAND NO PT INJURY OR FURTHER COMPLICATIONS WERE REPORTED.

DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: UNKNOWN. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: NONE OR UNKNOWN. RESULTS OF EVALUATION: NONE OR UNKNOWN. CONCLUSION: NONE OR UNKNOWN. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: YES. CORRECTIVE ACTIONS: NONE OR UNKNOWN.

Concomitant Medical Products:

Mfr Name: TRIMEDYNE, INC.
Address: 

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
23-OCT-1995:

DEVICE INFORMATION:

Brand:  BARD UROLASE RIGHT ANGLED LASER FIBER
Device Type:  LASER FIBER
Device Type:  
Catalog:  350000
Serial:  (*confidential*)
Lot:  UNKNOWN
Other ID:

Reprocessed & Reused:  N/A

REPORTER INFORMATION:

Name:  [redacted]
Address:  [redacted]

Health Professional:  Unknown

EMAIL:  [redacted]
Phone:  [redacted]
International:  [redacted]
Fax:  

Occupation:  999 - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Distributor Report No:</th>
<th>1018233-1996-00001</th>
<th>Mfr Name:</th>
<th>MICROQUARTZ MEDICAL, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Feb-1996</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Feb-1996</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>06-Feb-1996</td>
<td>Reporter Occupation (E3):</td>
<td>999 - UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>OTHER HEALTH CARE PROFE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVALID DATA - REGARDING SINGLE USE LABELING OF DEVICE. PATIENT MEDICAL STATUS PRIOR TO EVENT: INVALID DATA. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVALID DATA - REGARDING WHETHER EVENT PRESENTS IMMINENT HAZARD. INVALID DATA - WHETHER DEVICE USED AS LABELED/INTENDED.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

| Mfr Name: | MICROQUARTZ MEDICAL, INC. |
| Address: | , |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-APR-1996:

DEVICE INFORMATION:

- **Brand:** BARD HIGHLIGHT LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 351100
- **Serial:** (*confidential*)
- **Lot:** 03JFL001
- **Other ID:** 021996020093

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Unknown
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 999 - UNKNOWN
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>08-Mar-1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>25-Mar-1994</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>25-Mar-1994</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-Apr-1994</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>*</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td><em>AAT MID-PROCEDURE, THE LASER STOPPED WORKING TO SPECIFICATION. PT RETURNED FOUR DAYS LATER FOR COMPLETION OF PROCEDURE. NO PATIENT INJURY OCCURRED.</em></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDIZINTECHNIK GMBH</td>
</tr>
<tr>
<td>Address:</td>
<td>POSTFACH 1128 D82101 GEMERING, GERMANY</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>20-JUN-1994</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** FIBERTOME - 4060N
- **Device Type:** LASER
- **Device Type:** 4060N
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

Health Professional: Yes

Occupation: 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Distributor Report No:** 1037955-1994-00003  
**Mfr Name:** DORNIER MEDIZINTECHNIK GMBH

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>21-Mar-1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>08-Apr-1994</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>08-Apr-1994</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Event (B1):</th>
<th>Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Location (F12):</td>
<td>INVALID DATA</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
</tr>
<tr>
<td>Expiration Date:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importer 03-JUN-1994: LASER POWER ALLEGEDLY INCREASED FROM 4 WATTS TO 21 WATTS WITHOUT EXPLANATION. NO PATIENT INJURY OCCURRED.</td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

NONE

<table>
<thead>
<tr>
<th>Mfr Name: DORNIER MEDIZINTECHNIK GMBH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: POSTFACH 1128</td>
</tr>
<tr>
<td>D-8034 GEMERING 1</td>
</tr>
<tr>
<td>WEST, GERMANY</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation: R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 03-JUN-1994:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** MEDI LAS
- **Device Type:** LASER
- **Device Type:** 4060N
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **Occupation:** OTHER

- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1037955-2001-00003  Mfr Name: DORNIER MEDTECH AMERICA, INC.

Date Received: 11-Feb-2002

Event Date (B3): 27-Sep-2001  Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y
Report Date (B4): 02-Jan-2002  Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Report Date (F8): 08-Nov-2001  Reporter Occupation (E3): NA - NOT APPLICABLE
Date Mfr Rec'd (G4): 08-Nov-2001  Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2001
Expiration Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 15-FEB-2002: LASER FIBER BROKE DURING USE.

Concomitant Medical Products:
NA

Mfr Name: DORNIER MEDICAL SYSTEMS
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
15-FEB-2002: MDR WAS NOT FILED WHEN ORIGINALLY REPORTED. AUDIT OF COMPLAINT FILES DISCOVERED SITUATION AND THEREFORE MDR IS BEING FILED. DUE TO DATE OF INCIDENT NO ADDITIONAL INFORMATION IS AVAILABLE. DEVICE FAILED DURING USE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>DORNIER LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>HF0200 DSSM</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>A3401-04S</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>[b] (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>[b] (b)</td>
</tr>
</tbody>
</table>

Health Professional: No Information

EMAIL: [b] (b)

Phone: [b] (b)

International: 

Fax: 

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00001</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Oct-2001</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>24-Jan-2002</td>
<td>Event Outcome (B2):</td>
<td>DISABILITY OR PERMANENT DAMAGE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>15-Jan-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Received</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Adverse Event (B1): Y Problem (B1): Y
Event Location (F12): REPORTER
Report Source (G3): HEALTH PROFESSIONAL, DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Mar-2001
Expiration Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 07-FEB-2002: LASER FIBER BROKE NEAR TIP DURING PROCEDURE. TIP REMAINS IN PATIENT.

Concomitant Medical Products:
NA

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
07-FEB-2002:
DEVICE INFORMATION:

Brand: DORNIER LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200DSSM
Catalog: NA
Serial: (*confidential*)
Lot: A 1101-085
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Health Professional: No

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00002</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>30-Jan-2002</th>
</tr>
</thead>
</table>

**Event Date (B3):** 21-Dec-2001  
**Report Date (B4):** 29-Jan-2002  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 10-Jan-2002

**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY

**Adverse Event (B1):** Y  
**Problem (B1):** Y

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):** R

**Device Operator:** HEALTH PROFESSIONAL

**Concomitant Medical Products:**  
NA

**Mfr Name:** DORNIER MEDTECH AMERICA, INC  
**Address:** 1155 ROBERTS BLVD.  
KENNESAW, GA 30144  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  
**Remedial Action (H7):**  
**Correction/Removal No (H9):** NA

**Event Description (B5):**  

DEVICE INFORMATION:

- **Brand**: DORNIER LASER FIBER
- **Device Type**: LASER FIBER
- **Device Type**: HF0400DSSM
- **Catalog**: NA
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA
- **Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: [Redacted]
- **Address**: [Redacted]
- **Email**: [Redacted]
- **Phone**: [Redacted]
- **International**: [Redacted]
- **Fax**: [Redacted]
- **Health Professional**: No
- **Occupation**: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00003</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Mar-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Dec-2001</td>
<td>Event Report Type: INJURY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Feb-2002</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>15-Feb-2002</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>31-Jan-2002</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
<td>Address: 1155 ROBERTS BLVD. KENNESAW, GA 30144 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 20-MAR-2002:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200 DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

Date Received: 1037955-2002-00004

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00004</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Mfr Rec'd (G4):</th>
<th>31-Jan-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Dec-2001</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>15-Feb-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>31-Jan-2002</td>
<td>Device Age (F9): Manufacture Date (H4):</td>
<td>01-Sep-2001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 22-MAR-2002: PROXIMAL END OF FIBER BROKEN WHILE BEING USED WITH DUR-8. NO INJURY TO PATIENT. INSUFFICIENT INFORMATION AVAILABLE TO DETERMINE PROBABLE CAUSE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>1155 ROBERTS BLVD.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>KENNESAW, GA 30144</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>22-MAR-2002:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVELOPMENT INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>DORNIER LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>HF0200DSSM</td>
</tr>
<tr>
<td>Catalog</td>
<td>NA</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

| Name:          | [b] (6) |
| Address:       | [b] (6) |
| Health Professional: | No |

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>15-Jan-2002</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>12-Mar-2002</td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>01-May-2001</td>
<td>Single Use (H5):</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
<td>Remedio Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-MAR-2002:</td>
<td>FIBER TIP BROKE OFF IN PT. INSUFFICIENT INFO AVAILABLE TO DETERMINE PROBABLE CAUSE.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH, INC.</td>
<td>Address:</td>
<td>1155 ROBERTS BLVD.</td>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>KENNESAW, GA 30144</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>UNITED STATES</td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>20-MAR-2002:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0600 DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b)(6)
- **Address:** (b)(6)
- **Email:** (b)(6)
- **Phone:** (b)(6)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

**Event Description (B5):**
Mfr 22-MAR-2002: FIBER BROKE IN THE MIDDLE DURING A PROCEDURE. BREAK LOCATION WAS ABOUT 10CM FROM THE TIP OF THE FIBER. PATIENT WAS NOT INJURED. INSUFFICIENT INFORMATION AVAILABLE TO DETERMINE PROBABLE CAUSE.

**Concomitant Medical Products:**
NA

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
22-MAR-2002:

---

<table>
<thead>
<tr>
<th>Event Date (B3): 18-Jan-2002</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8): 13-Mar-2002</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 07-Mar-2002</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No: 1037955-2002-00006</td>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
</tr>
<tr>
<td>Event Description (B5): MFR 22-MAR-2002: FIBER BROKE IN THE MIDDLE DURING A PROCEDURE. BREAK LOCATION WAS ABOUT 10CM FROM THE TIP OF THE FIBER. PATIENT WAS NOT INJURED. INSUFFICIENT INFORMATION AVAILABLE TO DETERMINE PROBABLE CAUSE.</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Aug-2001</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): I</td>
</tr>
<tr>
<td>Date Last Updated: 11/2/2010 9:17 AM</td>
<td></td>
</tr>
</tbody>
</table>

---
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200 DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
Event Description (B5):
Mfr 17-APR-2002: FIBER BROKE NEAR DISTAL TIP DURING A PROCEDURE. BREAK LOCATION WAS ABOUT 30CM FROM THE TIP OF THE FIBER. PATIENT WAS NOT INJURED. INSUFFICIENT INFORMATION AVAILABLE TO DETERMINE PROBABLE CAUSE.

Concomitant Medical Products:
NA

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
17-APR-2002:
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200 DSSM
Catalog: NA
Serial: (*confidential*)
 Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: No

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00008</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>25-Apr-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Jan-2002</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>22-Apr-2002</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>01-Apr-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Aug-2001

**Expiration Date:**

**Device Usage (H8):** I

**Event Description (B5):**

Mfr 01-MAY-2002: FIBER BROKE EXTERNAL TO THE SCOPE AT THE POINT OF INSERTION INTO BIOPSY PORT. ALL THREE INCIDENTS, DOCTORS WERE BURNED.

**Concomitant Medical Products:**

NA

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

01-MAY-2002: USER FACILITY RETAINED DEFECTIVE FIBERS AND WOULD NOT RETURN THEM FOR INVESTIGATION. COULD NOT DETERMINE ROOT CAUSE BASED ON INSUFFICIENT INFORMATION AND WITHOUT THE DEFECTIVE FIBERS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200 DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00009</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>25-Apr-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>26-Feb-2002</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>23-Apr-2002</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Apr-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: DORNIER MEDTECH, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 1155 ROBERTS BLVD.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KENNESAW, GA 30144</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER LASER FIBER - SINGLE USE
- **Device Type:** LASER FIBER
- **Device Type:** HF0200 DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** OTHER

Recd: 207  Page: 415  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2002-00010</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Jul-2002</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>19-Jul-2002</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Jul-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

- **Adverse Event (B1):** Y
- **Problem (B1):** Y
- **Event Location (F12):**
- **Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Aug-2001

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** I

**Event Description (B5):**

Mfr 07-AUG-2002: URETEROSCOPY UNDER GENERAL ANAESTHIA FOR LEFT LOWER URETERIC STONE (CALCIUM OXALATE MONOHUDRATE 10 X 8MM). PROCEDURE AT 1,000MJ, 5 HZ. FIBER TIP BROKE WHILE FRAGMENTING STONE. NO URETERIC INJURY. BROKEN FIBER RETRIEVED AND STONE FRAGMENTATION AND RETRIEVAL COMPLETED UNEVENTFULLY.

**Concomitant Medical Products:** NA

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

07-AUG-2002: RETRIEVED FIBER FRAGMENT APPEARS TO INDICATE A BREAK IN THE GLASS FIBER WHERE THE OUTER INSULATION COATING WAS REMOVED TO PRODUCE THE EXPOSED DISTAL TIP. POSSIBLE THAT THE SCORED GLASS BROKE DURING THE PROCEDURE OR THE FIBER BROKE AT THE WEAKEST POINT WHEN BENT. THIS IS A REUSABLE FIBER AND CANNOT DETERMINE ROOT CAUSE SINCE FIBER WAS REUSED.

Recd: 208 Page: 416 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: DORNIER LASER FIBER
- **Device Type**: LASER FIBER
- **Device Type**: HF0400RSSM
- **Catalog**: NA
- **Serial**: (*confidential*)
- **Lot**: B3501-03R
- **Other ID**: NA

- **Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: SR CONSULTAN
- **Address**: [Redacted]
- **Email**: [Redacted]
- **Phone**: [Redacted]
- **International**: [Redacted]
- **Fax**: [Redacted]

- **Health Professional**: Yes

- **Occupation**: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2003-00001</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received:</th>
<th>09-Jan-2003</th>
</tr>
</thead>
</table>

**Event Date (B3):** 24-Jul-2002

**Report Date (B4):** 03-Jan-2003

**Report Date (F8):** 03-Jan-2003

**Date Mfr Rec’d (G4):** 02-Jan-2003

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):** REQUIRED INTERVENTION

**Reporter Occupation (E3):** OTHER

**Device Operator:** HEALTH PROFESSIONAL

**Adverse Event (B1):** Y

**Problem (B1):** Y

**Event Location (F12):**

**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Feb-2002

**Expiry Date: Single Use (H5):** Y

**Device Usage (H8):** U

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

17-JAN-2003: RETURNED FIBER DID NOT INDICATE ANY DEFECTS THAT WOULD CAUSE THE FIBER TO BREAK DURING USE. THE BEND RADIUS OF THE FIBER IS ACCEPTABLE TO MANUFACTURER'S STANDARDS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Device Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand:</strong></td>
<td>DORNIER LASER FIBER</td>
</tr>
<tr>
<td><strong>Device Type:</strong></td>
<td>LASER FIBER</td>
</tr>
<tr>
<td><strong>Catalog:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Serial:</strong></td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td><strong>Lot:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Other ID:</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Reprocessed &amp; Reused:</strong></td>
<td>N/A</td>
</tr>
</tbody>
</table>

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Reporter Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong></td>
<td>(b) (b)</td>
</tr>
<tr>
<td><strong>Address:</strong></td>
<td>(b) (b)</td>
</tr>
<tr>
<td><strong>Health Professional:</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Occupation:</strong></td>
<td>OTHER</td>
</tr>
<tr>
<td><strong>EMAIL:</strong></td>
<td>(b) (b)</td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(b) (b)</td>
</tr>
<tr>
<td><strong>International:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Fax:</strong></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2003-00002</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>02-Apr-2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 02-Apr-2003</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 02-Apr-2003</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 01-Apr-2003</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jul-2002</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 10-APR-2003: TWO SINGLE-USE HOLMIUM LASER FIBERS MADE POPPING NOISE AND BROKE NEAR LASER PRODUCING BLACK SMOKE DURING AN OPERATION. NO ONE WAS INJURED AND NO ADVERSE EVENT OCCURRED. FIBERS WERE OPERATING AT 8.0 - 12.0 WATTS FOR 35 MINUTES WHEN FIBERS FAILED.

Concomitant Medical Products:

NA

Mfr Name: DORNIER MEDTECH AMERICA, INC.

Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer
Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
10-APR-2003: MANUFACTURER CONTACTED REPORTER ON 04/03 DISCUSSING THE DETAILS OF THE EVENT AS NOTED IN HOSPITAL'S INCIDENT REPORT. TWO FIBERS WERE USED AT 8.0 - 12.0 WATTS FOR 35 MINUTES WHICH IS BEYOND THE OPERATING PARAMETERS ESTABLISHED IN THE FIBER INSTRUCTIONS FOR USE, QSF-029, REVISION B. USER OPERATED FIBERS OUTSIDE THE MAXIMUM ALLOWABLE POWER OF 8.0 WATTS CAUSING FAILURE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200DSSM
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Email: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes
Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2003-00005</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>21-Jan-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jun-2003</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>15-Jan-2004</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>09-Dec-2003</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Sep-2001
Expiration Date: Single Use (H5): N
Device Usage (H8): I

Event Description (B5):
Mfr 02-MAR-2004: DURING PROCEDURE THE FIBER BROKE AND SHOCKED THE SURGEON.

Concomitant Medical Products:
NA

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
02-MAR-2004: CAUSE OF BROKEN FIBER COULD NOT BE DECIDED DUE TO CONDITION OF RETURNED FIBER.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200RSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

- **Health Professional:** Yes
- **Occupation:** UNK - UNKNOWN

Date Last Updated: 11/2/2010 9:17 AM

Recd: 211 Page: 423
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 21-Jan-2004

MFR Report No: 1037955-2003-00006
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 12-Aug-2003
Report Date (B4): 15-Jan-2004
Report Date (F8): 15-Jan-2004
Date Mfr Rec'd (G4): 09-Dec-2003

Event Report Type: MALFUNCTION
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (B4): 15-Jan-2004
Date Mfr Rec'd (G4): 09-Dec-2003

Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y
Event Location (F12):

Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Nov-2002
Expiration Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 02-MAR-2004: FIBER BROKE NEAR SCOPE DURING PROCEDURE. BURNED DOCTOR ON ARM.

Concomitant Medical Products:
NA

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
02-MAR-2004: CAUSE OF BROKEN FIBER COULD NOT BE DETERMINED DUE TO CONDITION OF RETURNED FIBER.
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused:  N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2004-00001</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>20-Dec-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-Nov-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Dec-2004</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Dec-2004</td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td></td>
<td>Problem (B1):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 18-JAN-2005: DURING CYSTOSCOPY, RETROGRADE PYELOGRAM, URTEROSCOPY - 0.5MM CLEAR FIBER TIP NOTED TO BE MISSING WHILE LASERING THE NECK AT THE BLADDER. TIP WAS NOT RECOVERED. NO INJURIES.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>Mfr Name: DORNIER MEDTECH AMERICA</td>
<td>Address: *</td>
<td>KENNESAW, GA</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>18-JAN-2005: EVALUATION SUMMARY: NO FIBER RETURNED FOR EVALUATION. NO PRODUCT LOT NUMBER PROVIDED TO EVALUATE THE MANUFACTURING RECORDS. NO DETAILS AVAILABLE ABOUT THE PROCEDURE OR HOW THE TIP BROKE OFF. NO INJURY REPORTED BUT POTENTIAL FOR INJURY EXISTS SINCE 0.5MM OF DISTAL TIP REMAINED IN THE PATIENT. POSSIBLE CAUSES: EXCESSIVE ANGULAR FORCE APPLIED TO THE DISTAL TIP; USER MISHANDLING. NO CONCLUSION CAN BE STATED WITHOUT PRODUCT EVALUATION.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER LASAR FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM-02
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2005-00001</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>24-May-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-May-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>24-May-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>24-May-2005</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>KENNESAW, GA * UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 08-JUN-2005: TIP OF FIBER BROKE OFF DURING PROCEDURE. TIP WAS NOT RECOVERED. NO SERIOUS INJURIES REPORTED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>KENNESAW, GA * UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>08-JUN-2005: EVALUATION: RETURNED FIBER INDICATED AN ANGULAR BREAK AT DISTAL TIP TYPICALLY ASSOCIATED WITH AN ANGULAR FORCE APPLICATION. RETURNED FIBER WAS TESTED AGAINST PERFORMANCE SPECIFICATIONS AND MET REQUIREMENTS. PRODUCT MET OPERATIONAL REQUIREMENTS WHEN RELEASED TO THE CUSTOMER. THE DISTAL TIP SILICA GLASS IS INERT AND BIocompatibility TESTS ARE ACCEPTABLE. NO SERIOUS INJURY REPORTED BUT POTENTIAL FOR A SERIOUS INJURY EXISTS SINCE 5.0MM OF DISTAL TIP REMAINED IN THE PT. POSSIBLE CAUSES: EXCESSIVE ANGULAR FORCE APPLIED TO THE DISTAL TIP; USE MISHANDLING.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM-02
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** E1005-37S
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER

**PHONE:** [Redacted]

**EMAIL:** [Redacted]
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>29-Aug-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1037955-2007-00001</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Aug-2005</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-MAR-2007: THE BLUE BEFFER ON DORNIER HOLMIUM LASER FIBER CAME OFF IN PT. THIS HAS HAPPENED ABOUT THREE TIMES.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
</tbody>
</table>

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:**
- KENNESAW, GA
- UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

20-MAR-2007: NO FIBER WAS RETURNED FOR INVESTIGATION. CONTACTED THE CUSTOMER ON THREE SUBSEQUENT DATES TO REQUEST MORE INFORMATION AND NO RESPONSE WAS PROVIDED. STRIPPING THE BUFFER OF A REUSABLE FIBER IS THE RESPONSIBILITY OF THE USER. IT IS POSSIBLE THAT THE USER HAS A DULL STRIPPER BLADE, WRONG SIZE STRIPPER BLADE OR INCORRECT STRIPPING TECHNIQUE CAUSING DAMAGE TO THE BLUE BUFFER RESULTING IN THE BUFFER SEPARATING FROM THE FIBER CORE. THE BLUE BUFFER (ETFE MATERIAL) HAS BEEN BIOLOGICALLY TESTED AND DOES NOT POSE A PROBLEM IF A SMALL PORTION OF IT IS LEFT IN A PT. BIOLOGICAL DATA IS MAINTAINED IN THE TECHNICAL FILE FOR THE HOLMIUM FIBERS. THERE WAS NO INDICATION FROM THE CUSTOMER ON THE AMOUNT OF BUFFER BREAKING OFF FROM THE FIBER CORE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0270RSSM
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Email: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Occupation: 100 - OTHER HEALTH CARE PROFESSIONAL

Health Professional: No
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00002</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>20-Jan-2006</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>18-Feb-2007</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Feb-2006</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>01-Nov-2005</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Dec-2008</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 20-MAR-2007: THERE WERE 2 FIBERS INVOLVED IN THIS COMPLAINT. ONLY FIBER #1 IS MDR REPORTABLE. FIBER #1 BROKE NEAR THE DISTAL TIP INSIDE THE SCOPE AND FIBER #2 BROKE AT SMA CONNECTOR. FIBER #1: FIBER WAS BROKEN 4 CM FROM THE DISTAL TIP WITH A BURN MARK ON BOTH ENDS OF THE BREAK. THERE IS A BEND ON THE END OF THE BROKEN FIBER INDICATING THE FIBER WAS BENT WHEN FIRED.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>KENNESAW, GA * UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
20-MAR-2007: FIBER #1 HAD A BREAK 4CM FROM THE DISTAL TIP WHICH APPEARS TO BE AT THE FRONT OF THE SCOPE. IT IS POSSIBLE THAT THE USER PULLED THE FIBER THROUGH THE SCOPE DURING LASER FIRING CAUSING THE FIBER TO BREAK. THIS IS A USER HANDLING PROBLEM NOT A DESIGN OR MANUFACTURING DEFECT. FIBER #2 HAD THE FIBER SEPARATED/PULLED FROM THE SMA CONNECTOR. THIS APPEARS TO HAVE BEEN DONE BY THE USER SINCE THE FIBER HAD ACCEPTABLE POWER TRANSMISSION READINGS WHEN RELEASED FROM DORNIER.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** E4705-30S
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No Information
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** 
- **Fax:** 
- **Occupation:** UNK - UNKNOWN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No:</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Report Date (B4): 18-Feb-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 11-Apr-2006</td>
<td><strong>Event Report Type:</strong> MALFUNCTION</td>
<td><strong>Adverse Event (B1):</strong> Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 11-Apr-2006</td>
<td><strong>Event Outcome (B2):</strong> OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 11-Apr-2006</td>
<td><strong>Reporter Occupation (E3):</strong> UNK - UNKNOWN</td>
<td><strong>Event Location (F12):</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Device Operator:</strong> HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Report Source (G3):</strong> HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Sep-2005

**Expiration Date:** 30-Sep-2008

**Single Use (H5):** Y

**Device Usage (H8):** I

### Event Description (B5):

Mfr 20-MAR-2007: TIP OF FIBER BROKE OFF IN PATIENT AND USER RETRIEVED IT.

### Concomitant Medical Products:

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** KENNESAW, GA *

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0600DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** C3905-05S
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1037955-2007-00005
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 21-Apr-2006
Report Date (B4): 18-Feb-2007
Report Date (F8): 
Date Mfr Rec'd (G4): 18-May-2006
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Event Description (B5):
Mfr 20-MAR-2007: TIP OF FIBER BROKE OFF INSIDE PATIENT. FIBER RETRIEVED AND RETURNED FOR INVESTIGATION.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: *
KENNESAW, GA *
UNITED STATES

Device Available for Evaluation: Y

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

| **Brand:** | DORNIER HOLMIUM LASER FIBER |
| **Device Type:** | LASER FIBER |
| **Device Type:** | HF0200DSSM |
| **Catalog:** | NA |
| **Serial:** | (*)confidential*) |
| **Lot:** | E4705-06S |
| **Other ID:** | NA |

**Reprocessed & Reused:** N

### REPORTER INFORMATION:

| **Name:** | [redacted] |
| **Address:** | [redacted] |
| **Health Professional:** | No Information |

**EMAIL:** [redacted]

**Phone:** [redacted]

**International:** [redacted]

**Fax:** [redacted]

**Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1037955-2007-00006  Mfr Name: DORNIER MEDTECH AMERICA, INC.
MFR Report No: 1037955-2007-00006  Date Received: 19-Feb-2007

Event Date (B3): 08-Sep-2006  Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y
Report Date (B4): 18-Feb-2007  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8): 18-Sep-2006  Reporter Occupation (E3): 500 - RISK MANAGER
Date Mfr Rec’d (G4): 18-Sep-2006  Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  Event Location (F12):
Device Age (F9): Manufacture Date (H4): 01-Jun-2006
Expiration Date: 31-Jul-2009  Single Use (H5): N
Device Usage (H8): U

Event Description (B5):

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: *
KENNESAW, GA *
UNITED STATES

Device Available for Evaluation: N  Device not Returned to Manufacturer
Device Evaluated by Manufacturer (H3):
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
20-MAR-2007: SINCE THE FIBER WAS NOT RETURNED, A CAUSE CANNOT BE ASSIGNED TO THE FIBER BREAKAGE.

Date Last Updated: 11/2/2010 9:17 AM
Recd: 219  Page: 438
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>DORNIER HOLMIUM LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>HF0400RSSM</td>
</tr>
<tr>
<td>Catalog</td>
<td>NA</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>EB2506-06R</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name</th>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (6)</td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Professional</th>
<th>Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>500 - RISK MANAGER</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00007</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>26-Jul-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>18-Feb-2007</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>28-Jul-2006</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>28-Jul-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Aug-2008</td>
<td>Date Mfr Rec'd (G4):</td>
<td>28-Jul-2006</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Sep-2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Aug-2008</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr 20-MAR-2007: BLUE COATING ON END OF DISTAL TIP OF FIBER CAME OFF IN PATIENT. DOCTOR DID NOT RETRIEVE, STATED THAT THE PATIENT WILL PASS TIP. FIBER WAS INTACT.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>KENNESAW, GA * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>20-MAR-2007: THE RETURNED FIBER MEETS THE BEND RADIUS SPECIFICATION. A REVIEW OF THE FIBER ASSEMBLY AND POWER TEST RECORD SHOW THAT ALL FIBERS RELEASED AS PART OF THIS LOT MET DESIGN SPECIFICATIONS PRIOR TO RELEASE. THERE IS NO EVIDENCE THAT THE FIBER WAS DAMAGED PRIOR TO USE BY THE CUSTOMER.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200DSSM
Catalog: NA
Serial: (*confidential*)
Lot: E3705-22S
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

Sort By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received


Event Date (B3): 17-Aug-2006  Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y

Report Date (B4): 18-Feb-2007  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Report Date (F8): 14-Sep-2006  Reporter Occupation (E3): OTHER

Date Mfr Rec'd (G4): Event Location (F12): Reporter Occupation (E3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  Report Source (G3):

Device Operator: HEALTH PROFESSIONAL  Device Available for Evaluation: Y

Manufacture Date (H4): 01-Dec-2005  Device Evaluated by Manufacturer (H3): Yes

Expiry Date: 31-Dec-2008  Remedial Action (H7):

Device Age (F9):  SINGLE USE (H5): Y  Correction/Removal No (H9):

Device Usage (H8): I  Additional Mfr Narrative (H10 & H11):

Event Description (B5): Mfr 21-MAR-2007: FIBER BROKE INSIDE PATIENT DURING A PROCEDURE, THERE WAS ONE PIECE THAT COULD NOT BE REMOVED.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.

Address: *

KENNESAW, GA *

UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

21-MAR-2007: THE RETURNED FIBER MEETS THAT BEND RADIUS SPECIFICATION. A REVIEW OF THE FIBER ASSEMBLY AND POWER TEST RECORD SHOW THAT ALL FIBERS RELEASED AS PART OF THIS LOT MET DESIGN SPECIFICATIONS PRIOR TO RELEASE. THERE IS NO EVIDENCE THAT THE FIBER WAS DAMAGED PRIOR TO USE BY THE CUSTOMER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** E4905-16S
- **Other ID:** NA

Reprocessed & Reused: N

### REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Email:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No:</th>
<th>Mfr Name:</th>
<th>Product Code:</th>
<th>Device Available for Evaluation:</th>
<th>Device Evaluated by Manufacturer (H3):</th>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>1037955-2007-00009</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>N</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Event Details

**Event Date (B3):** 22-Mar-2006  
**Report Date (B4):** 26-Feb-2007  
**Report Date (F8):** 03-Apr-2006  
**Date Mfr Rec'd (G4):** 03-Apr-2006  
**Mfr Report No:** 07-AUG-2007  
**Report Date (F8):** 002 - NURSE  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Report Location (F12):** Reporter Occupation (E3): 002 - NURSE  
**Device Operator:** HEALTH PROFESSIONAL  
**Report Source (G3):** USER FACILITY  
**Concomitant Medical Products:**  

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.  
**Address:** KENNESAW, GA  
**Device Age (F9):** SINGLE USE (H5): Y  
**Manufacture Date (H4):**  
**Expiration Date:**  
**Device Usage (H8):** U  

**Event Description (B5):**  
Mfr 07-AUG-2007: UPON USING HOLMIUM LASER, THE LASER FIBER (1000 MICRON) GLASS TIP BROKE OFF FIBER - GLASS TIP RETRIEVED FROM BLADDER COMPARED TO ANOTHER 1000 MICRON FIBER - MEASURED AND FOUND TO BE INTACT AND LENGTH WAS THE SAME.

**Remedial Action (H7):**  
**Correction/Removal No (H9):** 07-AUG-2007: NO FIBER WAS RETURNED FOR INVESTIGATION. THIS IS THE FIRST "BROKEN" FIBER COMPLAINTS FOR THE 1000 MICRON FIBERS. CANNOT DETERMINE A ROOT CAUSE SINCE THE FIBER WAS NOT RETURNED FOR INVESTIGATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HLMIIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF100DSSM
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** 
- **EMAIL:** 
- **Phone:** *(b) (6)*
- **International:** 
- **Fax:** 
- **Occupation:** 002 - NURSE

- **Health Professional:** Yes
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1037955-2007-00010</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4): 05-Jun-2006</td>
<td>Event Date (B3): 16-May-2006</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 26-Feb-2007</td>
<td>Event Location (F12):</td>
<td>Report Source (G3): USER FACILITY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4): 01-Mar-2006</td>
<td>Expiration Date: 31-Mar-2009</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 07-AUG-2007: A PT ADMITTED DUE TO LEFT RENAL CALCULI SCHEDULED TO HAVE LEFT RETROGRADE PYELOGRAM LEFT FLEXIBLE UTERSCOPY LASER LITHOTRIPSY. PLACEMENT OF LEFT UTERAL STENT. DURING CASE, A LOUD POP WAS HEARD, FIBER OFF STERILE FIELD AND LASER WAS INACTIVATED AND FIBER REMOVED. FIBER HAD BROKEN. NOTE: CONFIRMED 06/14/2006 - THE BROKEN DISTAL FIBER TIP WAS RETRIEVED FROM THE PATIENT DURING THE PROCEDURE WITH NO INJURY TO THE PATIENT. THERE WAS NO SERIOUS INJURY OR POTENTIAL FOR SERIOUS INJURY REPORTED BY THE COMPLAINANT.

Concomitant Medical Products:
- Mfr Name: DORNIER MEDTECH AMERICA, INC.
  Address: *KENNESAW, GA *
  UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9): 

Additional Mfr Narrative (H10 & H11):
07-AUG-2007: FIBER WAS NOT RETURNED TO DORNIER. THERE IS A POSSIBILITY THAT THE USER HANDLING CAUSED THE FIBER BREAK SINCE IT HAPPENED TWO MORE TIMES WITH A DIFFERENT PART/LOT NUMBER THE NEXT DAY 05/2006. THERE IS NO EVIDENCE THAT THERE WAS A DESIGN OR MANUFACTURING DEFECT CAUSING THE COMPALINT EVENTS. IT IS POSSIBLE THAT THE ROOT CAUSE IS "USER HANDLING ERROR" BASED ON THE INFORMATION PROVIDED.
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** B1106-03S
- **Other ID:** *

Reprocessed & Reused: N

REPORER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:** [Redacted]
**Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 1037955-2007-00011
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 17-May-2006
Report Date (B4): 07-Mar-2007
Report Date (F8): 17-May-2006
Date Mfr Rec'd (G4): 17-May-2006

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8): 07-Mar-2007
Event Location (F12): Reporter Occupation (E3): 500 - RISK MANAGER
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Oct-2005
Expiration Date: 31-Oct-2008
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 07-AUG-2007: A PT ADMITTED FOR LEFT URETERAL STONE PROCEDURE CYSTOSCOPY URETERASCOPY AND ATTEMPTED LASER LITHOTRIPSY OF KIDNEY STONE. DURING PROCEDURE, THE LASER BECAME INEFFECTIVE AND IT WAS NOTED LASER FIBERS NOT WORKING. FIBERS REMOVED AND FOUND TO BE BROKEN. PROCEDURE ATTEMPTED 2 TIMES AFTER THAT WITH SOME RESULTS - FIBER BROKE. SOME DISCUSSION AS TO FIBERS BEING REFURBISHED. ONLY 20% OF STONE WAS FRAGMENTED USING LASER.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: *KENNESAW, GA *UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3):
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
07-AUG-2007: FIBER WAS NOT RETURNED TO MANUFACTURER. USER HANDLING COULD HAVE BEEN A CAUSE TO THE FIBER BREAKAGE.

Recd: 224
Page: 448
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** E4205-03S
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER

**EMAIL:** [REDACTED]

**Phone:** [REDACTED]

**International:** [REDACTED]

**Fax:** [REDACTED]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00012</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received:</th>
<th>07-Mar-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Jun-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Jul-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Nov-2004
Expiration Date: 01-Nov-2007
Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 07-AUG-2007: THE LASER FIBER BROKE IMMEDIATELY UPON FIRING OF THE LASER. FIBER WAS IN PATIENT AT TIME OF FIRING. NOTE: FIBER BREAK WAS IN SCOPE AND NOT PATIENT BASED ON THE LOCATION.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: "KENNESAW, GA * UNITED STATES"

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>DORNIER HOLMIUM LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>HF0400RSSM</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>B4704-02R</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused:  N

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>002 - NURSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Health Professional:</td>
<td>Yes</td>
</tr>
<tr>
<td>EMAIL:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td></td>
</tr>
<tr>
<td>International:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Occupation:</td>
<td>002 - NURSE</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1037955-2007-00013</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 09-Feb-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4): 01-Sep-2006</td>
<td>Expired Date: 30-Sep-2009</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8): I</td>
<td>Event Description (B5): Mfr 05-JUN-2007: FIBER BREAK NEAR SMA CONNECTOR RESULTED IN NURSE RECEIVING SUPERFICIAL BURN ON ARM. NURSE DID NOT REQUIRE MEDICAL TREATMENT.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 05-JUN-2007: MFG BATCH RECORDS WERE REVIEWED WITH NO NON-CONFORMANCES NOTED. USER HANDLING MAY BE THE CAUSE SINCE FIBER PASSED RELEASE TESTING PRIOR TO SHIPMENT.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0400DSSM
Catalog: NA
Serial: (*confidential*)
Lot: B3506-36S
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

EMAIL: 
Phone: [b] (b)
International: 
Fax: 

Health Professional: No

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 1037955-2007-00014
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 09-Feb-2007
Report Date (B4): 16-Mar-2007
Report Date (F8): 
Date Mfr Rec’d (G4): 12-Mar-2007

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): DISTRIBUTOR
Date Mfr Rec’d (G4): OTHER

Mfr 05-JUN-2007: FIBER BROKE WHEN IT WAS FLEXED; FIBER BENT AT TIP AND BURNED THE SCOPE.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: *
*, UNKNOWN

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
05-JUN-2007: MFG BATCH RECORDS WERE REVIEWED WITH NO NON-CONFORMANCES NOTED. USER HANDLING MAY BE THE CAUSE SINCE FIBER PASSED RELEASE TESTING PRIOR TO SHIPMENT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0400DSSM
Catalog: NA
Serial: (*confidential*)
Lot: B3206-77S
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: No

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Jan-2005</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>03-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>25-Jan-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4): 02-Sep-2004</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Sep-2007</td>
<td>Device Usage (H8): I</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 06-AUG-2007: TWO HOLMIUM LASER FIBERS BROKE DURING PROCEDURE AT DISTAL TIP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
<td>Address: 1155 ROBERTS BLVD. KENNESAW, GA 30144 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** E3604-31S
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER

**Date Last Updated:** 11/2/2010 9:17 AM

*CDRH MAUDE EVENT REPORT (FOI)*

SORTED BY

02-Nov-2010

(b) (6)

(b) (6)

(b) (6)

(b) (6)
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
13-Jul-2007

MFR Report No: 1037955-2007-00016
Mfr Name: DORNIER MEDTECH AMERICA, INC.
Date Mfr Rec'd (G4): 09-Feb-2005

Event Date (B3): 19-Jan-2005
Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (B4): 03-Jul-2007
Report Date (F8):
Date Mfr Rec'd (G4): 09-Feb-2005

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): DISTRIBUTOR

Report Date (F8):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Jun-2004
Expiration Date: 30-Jun-2007

Device Operator: HEALTH PROFESSIONAL
Device Usage (H8): I

Event Description (B5):
Mfr 06-AUG-2007: DURING PROCEDURE, ACCOUNT HEARD A POP SOUND. THE LASER FIBER HAD BROKEN APART ON OUTSIDE WHERE THE FIBER ENTERS THE URETEROSCOPE. NO PATIENT INJURY.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative No (H10 & H11):
06-AUG-2007: APPEARS TO BE A USER HANDLING ERROR THAT CONTRIBUTED TO THE BROKEN FIBER SINCE THE BREAK OCCURRED AT THE INPUT OF THE SCOPE. THE RETURNED FIBER INDICATES THE FIBER WAS BENT WHEN FIRED CAUSING THE BREAKAGE. NO CORRECTIVE ACTION IS POSSIBLE BASED ON THE RESULTS OF THIS INVESTIGATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER  
Device Type: LASER FIBER  
Device Type: HF0200DSSM  
Catalog:  
Serial: (*confidential*)  
Lot: A2204-03S  
Other ID:  
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]  
Address: [redacted]  
EMAIL: [redacted]  
Phone: [redacted]  
International:  
Fax:  
Health Professional: No  
Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1037955-2007-00017</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 09-Feb-2005</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 04-Jul-2007</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 10-Feb-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3): DISTRIBUTOR</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacturing Date (H4): 15-Oct-2004</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Event Description (B5): Mfr 06-AUG-2007: CUSTOMER SAW A RED FLASH 1/2 WAY DOWN THE SHAFT AND ALSO SMELLED SOMETHING BURNING. NO PATIENT INJURY WAS REPORTED.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>Device Usage (H8): I</td>
</tr>
<tr>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 1155 ROBERTS BLVD.</td>
<td>Device Available for Evaluation: Y</td>
</tr>
<tr>
<td>KENNESAW, GA 30144</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>Remedial Action (H7):</td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Correction/Removal No (H9):</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td>Additional Mfr Narrative (H10 &amp; H11): 06-AUG-2007:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOILMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF1000DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** D4504-04S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Health Professional: No

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MFR Report No:** 1037955-2007-00018

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Event Date (B3):** 12-Jan-2005

**Report Date (B4):** 04-Jul-2007

**Event Outcomes (B2):**

**Reporter Occupation (E3):** OTHER

**Device Operator:** HEALTH PROFESSIONAL

**Event Description (B5):**


**Concomitant Medical Products:**

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

06-AUG-2007: REUSABLE FIBER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200RSSM
Catalog: NA
Serial: ("confidential")
Lot: A0402-03R
Other ID: NA
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
Email: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)
Health Professional: No
Occupation: OTHER
Event Description (B5):
Mfr 06-AUG-2007: CUSTOMER EXPLAINED THAT THE LASER FIBER ONLY LIGHTS UP IN ONE SPOT. ACCORDING TO WHAT WAS EXPLAINED TO THEM, IT SHOULD LIGHT ALL AROUND.

Concomitant Medical Products:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0600RSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** C0604-04R
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 09-Mar-2005 | Event Report Type: | MALFUNCTION |
| Report Date (B4): | 04-Jul-2007 | Event Outcome (B2): | |
| Report Date (F8): | | Reporter Occupation (E3): | OTHER |
| Date Mfr Rec'd (G4): | 10-Mar-2005 | Device Operator: | HEALTH PROFESSIONAL |
| MFR Report No: | 1037955-2007-00020 | Mfr Name: | DORNIER MEDTECH AMERICA, INC. |
| Event Description (B5): | Mfr 06-AUG-2007: LASER FIBER POPPED AND CAUSED A SMALL SMOKY FIRE WHEN ATTACHED TO A LUMINOUS LASER. OPERATING ROOM CHARGE NURSE INDICATED THAT THEY WERE NOT EXCEEDING THE RECOMMENDED POWER. |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): | | Manufacture Date (H4): | 30-Nov-2003 |
| Expiration Date: | 30-Nov-2006 | Single Use (H5): | Y |
| Device Usage (H8): | I |
| Event Location (F12): | | Report Source (G3): | DISTRIBUTOR |
| Date Mfr Rec'd (G4): | 10-Mar-2005 | Mfr Name: | DORNIER MEDTECH AMERICA, INC. |
| Address: | 1155 ROBERTS BLVD. |
| KENNESAW, GA 30144 | UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200DSSM
Catalog:
Serial: (*confidential*)
Lot: A4503-30S
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

International: [REDACTED]
Fax: [REDACTED]

Health Professional: Yes
Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1037955-2007-00021  Mfr Name: DORNIER MEDTECH AMERICA, INC.  Date Received: 13-Jul-2007

Event Date (B3): 04-Jan-2005  Event Report Type: MALFUNCTION
Report Date (B4): 05-Jul-2007  Adverse Event (B1): Problem (B1): Y
Report Date (F8): 07-Jan-2005  Event Outcome (B2):
Date Mfr Rec'd (G4): 07-Jan-2005  Event Location (F12):

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 30-Apr-2007  Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 09-JAN-2008: LASER STONE EXTRACTION - 200 MICRON LASER FIBER BROKE AT POINT OF ENTRY INTO CYSTOSCOPE, RETAINED FIBER REMOVED FROM THE CYSTOSCOPE. ANOTHER 200 MICRON FIBER WAS USED (LOT A1504-16S) THE SAME BREAKAGE OCCURRED. RN STATED THAT THE ACMI COMPANY HAS HAD PROBLEMS REPORTED AND IS STOPPING PRODUCTION OF 200 FIBER. NO RECALL ON THE 200 FIBERS WAS SENT BY THE COMPANY. NO INFO PROVIDED ON THE EVENT SITE OR CONTACT SO FOLLOW-UP CANNOT BE DETERMINED BY DORNIER.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
09-JAN-2008:

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** A1504-16S
- **Other ID:** *
- Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** *
- **Address:** *
- **Email:**
- **Phone:** (UNK)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>12-Apr-2005</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>05-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>27-Apr-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>19-Feb-2004</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Mar-2007</td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 06-AUG-2007: THE 200 MICRON FIBER BROKE WHEN TAKING OUT FROM THE PACKAGING.

**Concomitant Medical Products:**

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200RSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** A1004-06R
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** OTHER

**Health Professional:** Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00023</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>12-Apr-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>05-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>14-Apr-2005</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>14-Apr-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 06-AUG-2007: A 200 MICRON FIBER SPARKED COMING WHERE FIBER ATTACHES TO THE LASER AND RESULTED IN A NEAR FIRE INCIDENT (SMOKE).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td>Address:</td>
<td>1155 ROBERTS BLVD.</td>
<td>KENNESAW, GA 30144</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>06-AUG-2007:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** A1403-07S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 19-Apr-2005</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 05-Jul-2007</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Report Location (F12): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 20-Apr-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No: 1037955-2007-00024</td>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
</tr>
<tr>
<td>Mfr Report No: 1037955-2007-00024</td>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
</tr>
<tr>
<td>Event Date (B3): 19-Apr-2005</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 05-Jul-2007</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Report Location (F12): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 20-Apr-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No: 1037955-2007-00024</td>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
</tr>
</tbody>
</table>

Adverse Event (B1): Problem (B1): Y

Event Description (B5):

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD.
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand:   DORNIER HOLMIUM LASER FIBER
   Device Type:  LASER FIBER
   Device Type:  HF0400DSSM
   Catalog:
      Serial:  (*confidential*)
      Lot:    B1005-01S
   Other ID:
   Reprocessed & Reused:  N

REPORTER INFORMATION:

   Name:  [b] (b)
   Address:  [b] (b)
   EMAIL:  [b] (b)
   Phone:  [b] (b)
   International:
      Fax:
   Occupation:  OTHER

Health
Professional:  No
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1037955-2007-00025</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 21-Apr-2005</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 06-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 02-May-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): DISTRIBUTOR</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 03-Jun-2004
Expiration Date: 30-Jun-2007
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BLVD,
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM
- **Catalog:** (*confidential*)
- **Serial:** C2204-02R/C2204-03R
- **Lot:** C2204-02R/C2204-03R
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 13-Jul-2007

MFR Report No: 1037955-2007-00026
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 11-May-2005
Report Date (B4): 06-Jul-2007
Report Date (F8): 27-May-2005
Date Mfr Rec'd (G4): 27-May-2005

Event Report Type: MALFUNCTION
Event Outcome (B2):
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Reporter Occupation (E3):
Report Source (G3): DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Evaluated by Manufacturer (H3): Yes
Device Available for Evaluation: Y

Event Description (B5):

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200DSSM
Catalog:
   Serial: (*confidential*)
   Lot: UNKNOWN
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

Health Professional: No

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00027</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>31-May-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>01-Jun-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>25-Mar-2005</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Mar-2008</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 06-AUG-2007: THE LASER FIBER WAS RECEIVED BENT.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** B1205-03S

Reprocessed & Reused: N

REPORTER INFORMATION:

**Name:**

**Address:**

**Health Professional:** No

**Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Details

- **Mfr Name:** DORNIER MEDTECH AMERICA, INC.
- **Mfr Report No:** 1037955-2007-00029
- **Event Date (B3):** 04-Oct-2005
- **Report Date (B4):** 08-Jul-2007
- **Report Date (F8):** 21-Sep-2005
- **Date Mfr Rec'd (G4):** 13-Jul-2007
- **Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
- **Device Available for Evaluation:** Y
- **Device Evaluated by Manufacturer (H3):** Yes
- **Remedial Action (H7):**
- **Correction/Removal No (H9):**
- **Additional Mfr Narrative (H10 & H11):**

### Event Description

**Mfr 06-AUG-2007:** FIBER BROKE.

### Concomitant Medical Products

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.
**Address:** KENNESAW, GA 30144 UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** UNKNOWN
- **Other ID:**
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No
- **Email:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00030</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>08-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Sep-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 06-AUG-2007: FIBER BROKE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>KENNESAW, GA 30144</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>06-AUG-2007:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** (*confidential*)
- **Serial:** UNKNOWN
- **Lot:** UNKNOWN
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>04-Oct-2005</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>08-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Sep-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 06-AUG-2007: FIBER BROKE "HARD TO SCREW INTO LASER".

**Concomitant Medical Products:**

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.
**Address:** KENNESAW, GA 30144
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 06-AUG-2007
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** UNKNOWN
- **Other ID:**

Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1037955-2007-00032
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 21-Sep-2005
Report Date (B4): 10-Jul-2007
Report Date (F8): 11-Oct-2005
Date Mfr Rec'd (G4): 13-Jul-2007

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Available for Evaluation: Y
Date Mfr Rec'd (G4): 13-Jul-2007

Expiration Date: 31-Jul-2008
Device Usage (H8): I

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): DISTRIBUTOR

Mfr 06-AUG-2007: CUSTOMER RECEIVED FIBER WITH CONNECTOR BROKEN AT TIP. LASER DOES NOT RECOGNIZE THE FIBER.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): 06-AUG-2007: USER RETURNED FIBER THAT DID NOT MATCH THE COMPLAINT INFORMATION. THE USER REPORTED A PROBLEM WITH A 400 MICRON DISPOSABLE FIBER, BUT RETURNED A 270 MICRON DISPOSABLE FIBER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEDEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>DORNIER HOLMIUM LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>HF0400DSSM</td>
</tr>
<tr>
<td>Catalog</td>
<td></td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>B3005-06S</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Fax: [redacted]

Email: [redacted]
Phone: [redacted]
International: [redacted]

Health Professional: No
Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00034</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 11-Nov-2005  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y

**Report Date (B4):** 11-Jul-2007  
**Event Outcome (B2):**  
**Event Location (F12):**

**Report Date (F8):** 11-Jul-2007  
**Reporter Occupation (E3):** OTHER  
**Report Source (G3):** DISTRIBUTOR

**Date Mfr Rec’d (G4):** 19-Dec-2005  
**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**  
**Manufacture Date (H4):** 15-Oct-2004

**Expiration Date:** 31-Oct-2007  
**Single Use (H5):** N  
**Device Usage (H8):** R

**Event Description (B5):**
Mfr 06-AUG-2007: FIBER RETURNED 12/19/2005. EMAIL ON 12/20/2005 STATED "POSSIBLY THE CONNECTOR FELL OFF OR BECAME DISCONNECTED."

**Concomitant Medical Products:**

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.  
**Address:** KENNESAW, GA 30144 UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand: DORNIER HOLMIUM LASER FIBER
   Device Type: LASER FIBER
   Device Type: HF0600RSSM
   Catalog:
     Serial: (*confidential*)
     Lot: C4004-02R
   Other ID:

   Reprocessed & Reused: N

REPORTER INFORMATION:

   Name:
   Address: [b] (b)
   EMAIL: [b] (b)
   Phone: [b] (b)
   International: [b] (b)
   Fax: [b] (b)

   Health Professional: No
   Occupation: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
13-Jul-2007

MFR Report No: 1037955-2007-00035 Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 01-Nov-2005 Event Report Type: MALFUNCTION
Report Date (B4): 11-Jul-2007 Event Outcome (B2):

Report Date (F8): 19-Dec-2005 Reporter Occupation (E3): HEALTH PROFESSIONAL
Date Mfr Rec'd (G4): 19-Dec-2005 Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 20-Oct-2005
Expiration Date: 31-Oct-2008

Event Description (B5):
Mfr 06-AUG-2007: FIBER BROKE AND BURNED DOCTOR. CUSTOMER WILL BE RETURNING ALL FIBERS THEY HAVE IN STOCK (8 FIBERS).

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** (confidential)
- **Serial:** (*confidential*)
- **Lot:** E4205-06S
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No
- **Occupation:** OTHER

**EMAIL:**

**Phone:** (b) (b)

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 1037955-2007-00037  Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 16-Nov-2005  Event Report Type: MALFUNCTION
Report Date (B4): 11-Jul-2007  Event Outcome (B2):
Report Date (F8): 19-Dec-2005  Reporter Occupation (E3): OTHER
Date Mfr Rec’d (G4): 19-Dec-2005  Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y

Event Description (B5): Mfr 06-AUG-2007: BROKEN FIBER. NO PATIENT INJURY REPORTED.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** E3004-21S
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *(b) (6)*
- **Address:** *(b) (6)*
- **Health Professional:** No
- **Occupation:** OTHER
- **EMAIL:**
- **Phone:**
- **International:** *(b) (6)*
- **Fax:** *(b) (6)*
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00038</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>29-Dec-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>13-Jan-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>07-Apr-2005</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Apr-2008</td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 06-AUG-2007: THE FIBERS BROKE IN THE SURGEONS HAND WHEN HE TRIED TO FIRE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Device Information:**
- **Device Name:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
- **Manufacturer:** DORNIER MEDTECH AMERICA, INC.
- **Address:** KENNESAW, GA 30144
- **United States**

**Remedial Action (H7):**
- **Correction/Removal No (H9):**

**Additional Mfr Narrative:**
- **06-AUG-2007:**

**Date Last Updated:** 11/2/2010 9:17 AM

**Recd:** 248 **Page:** 496
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400RSSM
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** B1405-02R
- **Other ID:**

  - Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (6)
- **International:** (b) (b)
- **Fax:**

- **Health Professional:** No

  - **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00039</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Jan-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>03-Feb-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>02-Sep-2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Sep-2008</td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 06-AUG-2007: BREAKAGE NEAR SMA FITTING, CRACK THEN LASER FIBER BURNED BEFORE PROCEDURE. NO PATIENT INVOLVEMENT.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007: 
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0400DSSM
Catalog:
Serial: (*confidential*)
Lot: B3505-24S
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (b)
Address: (b) (b)

Email: (b) (b)
Phone: (b) (b)
International:
Fax:

Health Professional: No
Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1037955-2007-00040  Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 01-Feb-2006  Event Report Type: MALFUNCTION
Report Date (B4): 11-Jul-2007  Adverse Event (B1): Problem (B1): Y
Report Date (F8): 01-Feb-2006  Event Outcome (B2):
Date Mfr Rec’d (G4): 02-Mar-2006  Reporter Occupation (E3): OTHER

Event Description (B5):
Mfr 06-AUG-2007: FIBERS CONNECTED TO LASER CORRECTLY, LASER WOULD NOT WORK. LIGHT COMING FROM END, BROKEN FIBER.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** E4205-10S
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

**Name:** [REDACTED]
**Address:** [REDACTED]
**Email:** [REDACTED]
**Phone:** (UNK)
**Fax:**

**Health Professional:** No
**Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00044</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-May-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 06-AUG-2007: FIBER BROKE AT DISTAL TIP INSIDE PATIENT AND WAS RETRIEVED BY DOCTOR. THERE WAS NO INJURY TO PATIENT.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td>Address:</td>
<td>KENNESAW, GA 30144 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>06-AUG-2007:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200RSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**

- **Health Professional:** No

- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00045</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-May-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Use (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 06-AUG-2007: FIBER BROKE AT DISTAL TIP INSIDE PATIENT AND WAS RETRIEVED BY DOCTOR. THERE WAS NO INJURY TO PATIENT.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Health Professional: No

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00046</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received: 13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-May-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>18-Jul-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 06-AUG-2007: FIBER BROKE AT DISTAL TIP INSIDE PATIENT AND WAS RETRIEVED BY DOCTOR. THERE WAS NO INJURY TO PATIENT.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-AUG-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER (HF0200DSSM)
- **Catalog:** (confidential)
- **Serial:** (confidential)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1037955-2007-00047</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received: 13-Jul-2007</td>
<td></td>
</tr>
</tbody>
</table>

**Event Date (B3):** 01-Jul-2006  
**Report Date (B4):** 12-Jul-2007  
**Report Date (F8):** 25-Jul-2006  
**Date Mfr Rec'd (G4):** 25-Jul-2006  

**Event Report Type:** MALFUNCTION  
**Event Report Type:** MALFUNCTION  
**Event Report Type:** MALFUNCTION  

**Adverse Event (B1):** Problem (B1): Y  
**Event Outcome (B2):**  
**Reporter Occupation (E3):** OTHER  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Location (F12):**  
**Report Source (G3):** DISTRIBUTOR  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:** 30-May-2009  
**Manufacture Date (H4):** 03-May-2006  
**Single Use (H5):** Y  
**Device Usage (H8):** I  

**Event Description (B5):**  
Mfr 06-AUG-2007: FIBER BROKE AND BURNED DOCTOR.  
Concomitant Medical Products:  

<table>
<thead>
<tr>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: KENNESAW, GA 30144</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  
Remedial Action (H7):  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
06-AUG-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** B1806-18S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1037955-2007-00048
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Date Received: 13-Jul-2007

Event Date (B3): 23-Aug-2006
Report Date (B4): 13-Jul-2007
Event Report Type: MALFUNCTION
Event Date (B3): 23-Aug-2006
Report Date (B4): 13-Jul-2007
Event Outcome (B2): NA - NOT APPLICABLE
Report Date (F8): 01-Sep-2006
Date Mfr Rec'd (G4): 01-Sep-2006
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Report Date (F8): NA - NOT APPLICABLE
Event Location (F12): DISTRIBUTOR

Report Source (G3): DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Sep-2006
Expiration Date: 31-Dec-2008
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 27-JUL-2007: FIBER SEPARATED FROM THE SMA.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: DORNIER HOLMIUM LASER FIBER
- **Device Type**: LASER FIBER
- **Device Type**: HF0200DSSM
- **Catalog**: (*confidential*)
- **Serial**: (*confidential*)
- **Lot**: E4905-17S

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: [redacted]
- **Address**: [redacted]
- **Fax**: [redacted]
- **Phone**: [redacted]
- **International**: [redacted]
- **EMAIL**: [redacted]

Health Professional: No

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 25-Aug-2006</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 29-Aug-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
</tbody>
</table>

**Date Received**: 13-Jul-2007

**MFR Report No:** 1037955-2007-00049

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Event Description (B5):**

Mfr 27-JUL-2007: LASER FIBER LEAKED DURING PROCEDURE CAUSING A BURN ON THE DOCTORS ARM.

**Concomitant Medical Products:**

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** KENNESAW, GA 30144

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

Correction/Removal No (H9):

**Additional Mfr Narrative (H10 & H11):**

27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400DSSM
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** B2106-01S
- **Other ID:**

- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Email:** [redacted]
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1037955-2007-00050</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received 13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 29-Jun-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 01-Jul-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): DISTRIBUTOR</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-May-2006</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 30-May-2009</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): I</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 27-JUL-2007: TIP DISINTEGRATED AFTER LIMITED USE.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** F1706-24S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:** (b) (6)
- **Email:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**

Health Professional: No

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00051</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>29-Jun-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>01-Jul-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): DISTRIBUTOR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4): 25-Apr-2006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-May-2009</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Mfr 27-JUL-2007: TIP DISINTEGRATED AFTER LIMITED USE.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** F1706-12S
- **Other ID:**

| Reprocessed & Reused | N |

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** No
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00052</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Apr-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Jul-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr 27-JUL-2007:</td>
<td>DEFECTIVE TIP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td>Recd:</td>
<td>259</td>
</tr>
</tbody>
</table>

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): DISTRIBUTOR

| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): |  |
| Expiration Date: | 30-Sep-2008 |
| Manufacture Date (H4): | 15-Sep-2005 |
| Single Use (H5): | Y |
| Device Usage (H8): | I |

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** E3805-26S
- **Other ID:**
  - **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): DISTRIBUTOR</td>
<td></td>
</tr>
</tbody>
</table>

**MFR Report No:** 1037955-2007-00053

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** KENNESAW, GA 30144

UNITED STATES

**Event Description (B5):**

Mfr 27-JUL-2007: PRODUCT WAS RETURNED AFTER 4 USES WITH A BURNED TIP.

**Concomitant Medical Products:**

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400RSSM
- **Catalog:** (*confidential*)
- **Serial:** (*)
- **Lot:** UNKNOWN
- **Other ID:**

- **Reprocessed & Reused:** N

### REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1037955-2007-00054</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received: 13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 17-Aug-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 14-Sep-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): DISTRIBUTOR</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 04-May-2006</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 30-May-2009</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr 27-JUL-2007: BURN ON FIBER NEAR TIP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0400RSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** B1806-01R
- **Other ID:**

Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:** [b](6)
- **Address:** [b](6)
- **Health Professional:** No

**EMAIL:**

**Phone:**

**International:** [b](6)

**Fax:**

**Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**


**Concomitant Medical Products:**

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** ,

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11): 27-JUL-2007:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** UNKNOWN
- **Other ID:**

Reprocessed & Reused: N

### REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE

- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00056</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>30-Aug-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Aug-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4):</td>
<td>24-May-2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-May-2008</td>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 27-JUL-2007: FIBERS WERE BROKEN IN PACKAGES RECEIVED BY CUSTOMER.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td>Address:</td>
<td>KENNESAW, GA 30144</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>27-JUL-2007:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 263 Page: 526 Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER MEDTECH AMERICA, INC.
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** E2105-05S
- **Other ID:**

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MAUDE EVENT REPORT (FOI)**

### Event Description (B5):

Mfr 27-JUL-2007: FIBER WAS BROKEN IN THE PACKAGE.

### Concomitant Medical Products:

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.  
**Address:** KENNESAW, GA 30144

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Corretion/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**  
27-JUL-2007:

### Date Mfr Rec'd (G4): 30-Aug-2005

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00057</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Event Date (B3):</th>
<th>30-Aug-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>14-Mar-2005</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Mar-2008</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010  9:17 AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 264  
Page: 528
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** B1005-56S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE

Health Professional: No

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1037955-2007-00060

Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 04-Sep-2007

Adverse Event (B1):
Problem (B1): Y

Event Report Type: MALFUNCTION

Event Outcome (B2):

Reporter Occupation (E3): NA - NOT APPLICABLE

Device Operator: HEALTH PROFESSIONAL

Report Source (G3): DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): 30-May-2006

Single Use (H5): Y

Expiration Date: 30-May-2009

Device Usage (H8): I

Event Description (B5):
Mfr 02-OCT-2007: LASER FIBER TIP BROKEN AND CRACKED DURING A PROCEDURE. THREE FIBERS MISFIRED ACCORDING TO THE SURGEON, DURING THIS TIME THE FLEXIBLE URETEROSCOPE WAS DAMAGED. NO HARM TO PATIENT.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: HF0200DSSM
Catalog: (*confidential*)
Serial: Lot: F2006-23S
Other ID: 

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: No

EMAIL: [Redacted]
Phone: [Redacted]
International: 
Fax: 

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00061</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>20-Sep-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Sep-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>20-Sep-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12): Report Source (G3): DISTRIBUTOR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>04-Sep-2007</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacturing Date (H4): 30-Apr-2007</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Apr-2010</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 02-OCT-2007: TIP BROKE OFF INSIDE PATIENT, ALL PARTS RECOVERED. NO PATIENT HARM.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
02-OCT-2007: IF THE LASER WAS TESTED PRIOR TO INSERTION INTO THE PATIENT AND SHOWED AN INTACT CIRCLE WHEN THE PILOT LIGHT FOR THE LASER WAS TESTED, THEN THE DISTAL TIP MUST HAVE BEEN DAMAGED DURING THE PROCEDURE, WHICH WOULD INDICATE A USER CONTRIBUTED DAMAGE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DUR400DBX
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** B1507S
- **Other ID:**

- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** No

- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>04-Sep-2007</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>20-Sep-2007</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Sep-2007</td>
<td>Reporter Occupation (E3):</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>20-Sep-2007</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>DISTRIBUTOR</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>15-Dec-2005</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>15-Dec-2008</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 02-OCT-2007: FIBER BROKE DURING A PROCEDURE, UNKNOWN IF PART WAS RECOVERED. PATIENT IS CURRENTLY FINE, NO HARM, NO INJURY. FIBER HAS BEEN TESTED AND IS BIOLOGICALLY INSERT.

Concomitant Medical Products:

- Mfr Name: DORNIER MEDTECH AMERICA, INC.
- Address: KENNESAW, GA UNITED STATES
- Device Available for Evaluation: Y
- Device Evaluated by Manufacturer (H3): Yes
- Remedial Action (H7):
- Correction/Removal No (H9):
- Additional Mfr Narrative (H10 & H11):
  02-OCT-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** E4905-33S
- **Other ID:**

  Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

  Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2007-00063</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Sep-2007</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>20-Sep-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Sep-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>20-Sep-2007</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>04-Sep-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>KENNESAW, GA UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>15-Sep-2006</td>
<td>Manufacture Date (H4):</td>
<td>15-Sep-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Sep-2009</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 18-OCT-2007: FIBER BROKE IN PATIENT APPROXIMATELY 18 INCHES FROM DISTAL TIP. NO HARM TO THE PATIENT, PARTS RECOVERED.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>KENNESAW, GA UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>18-OCT-2007:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER  
- **Device Type:** LASER FIBER  
- **Device Type:** HF0200DSSM  
- **Catalog:** \(\text{(*) confidential*}\)  
- **Serial:** F3306-17S  
- **Lot:** F3306-17S  
- **Other ID:** 

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**  
- **Address:**  
- **Health Professional:** No  
- **Email:**  
- **Phone:**  
- **International:**  
- **Fax:**  
- **Occupation:** NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1037955-2007-00065</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received: 20-Dec-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 25-May-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 31-Mar-2007</td>
<td>Manufacture Date (H4): 31-Mar-2007</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 31-Mar-2010</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): I</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 12-MAR-2008: NO LIGHT IS COMING OUT OF THE END OF THE FIBER, TESTED WITH NO PATIENT INVOLVEMENT.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: KENNESAW, GA 30144</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

12-MAR-2008:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DUR400D
- **Catalog:** DUR400D
- **Serial:** (*confidential*)
- **Lot:** B1207S
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [b](6) [b] (b)
- **Address:** [b](6) [b] (b)
- **Health Professional:** No
- **EMAIL:** [b](6) [b] (b)
- **Phone:** [b](6) [b] (b)
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>17-Jan-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:** 31-Dec-2009

**Manufacture Date (H4):** 15-Dec-2006

**Single Use (H5):** Y

**Device Usage (H8):** I

**Event Description (B5):**

Mfr 04-APR-2008: LASER FIBER BROKE AND THEN SPARKED.

**Concomitant Medical Products:**

**Mfr Name:** DORNIER MEDTECH AMERICA, INC.

**Address:** KENNESAW, GA 30144

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>DORNIER HOLMIUM LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type:</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type:</td>
<td>HF0400DSSM</td>
</tr>
<tr>
<td>Catalog:</td>
<td></td>
</tr>
<tr>
<td>Serial:</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot:</td>
<td>B5006-07S</td>
</tr>
<tr>
<td>Other ID:</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

### REPORTER INFORMATION:

| Name:                  | [REDACTED]                  |
| Address:               | [REDACTED]                  |

Health Professional: No

| EMAIL:               | [REDACTED]                  |
| Phone:               | [REDACTED]                  |

International: [REDACTED]

Fax: [REDACTED]

Occupation: NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2008-00005</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>27-Jun-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>20-May-2008</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>27-Jun-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>29-May-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4): 01-Apr-2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Apr-2010</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 29-AUG-2008: THE CUSTOMER COMPLAINED OF A SMALL CRACK WHEN TAKEN OUT OF THE PACKAGE. NO PATIENT CONTACT.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 29-AUG-2008: THE CUSTOMER COMPLAINED OF A SMALL CRACK WHEN TAKEN OUT OF THE PACKAGE. NO PATIENT CONTACT.

**Adverse Event (B1):**

Problem (B1): Y

**Event Location (F12):**

Distributor

**Date Last Updated:** 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: DUR400DBX
Catalog: (*confidential*)
Serial: B1507S
Lot: B1507S
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Email: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Health Professional: No

Occupation: NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2008-00006</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
<th>Date Received</th>
<th>19-Aug-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Jul-2008</td>
<td>Event Event Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Aug-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Jul-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jan-2008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>28-Feb-2011</td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 29-OCT-2008: A FIBER BROKE INSIDE THE PT AND THE TIP WAS NOT RECOVERED. IT MAY STILL BE IN THE PATIENT. BREAK OCCURRED (B) (6) 2008 AT (B) (5) HOSPITAL.

**Concomitant Medical Products:**

- **Mfr Name:** DORNIER MEDTECH AMERICA, INC.
- **Address:** KENNESAW, GA 30144
  UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

29-OCT-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DUR270DBX
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** F0408S
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2008-00008</th>
<th>Mfr Name: DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>24-Oct-2008</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>25-Nov-2008</td>
<td>Event Outcome (B2): NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>27-Oct-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>28-Feb-2011</td>
<td>manufacture Date (H4): 01-Feb-2008</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
<td>Device Usage (H8): I</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 01-MAY-2009: SILVER END SMOKED WHEN PUT INTO THE MACHINE.

**Concomitant Medical Products:**

**Mfr Name: DORNIER MEDTECH AMERICA, INC.**
**Address: KENNESAW, GA 30144 UNITED STATES**

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

01-MAY-2009: DEVICE WAS TESTED AND DID NOT HAVE A PILOT BEAM. THIS WOULD INDICATE THAT THE DEVICE WAS DAMAGED POST POWER TEST. DAMAGE TO DEVICE COULD HAVE HAPPENED AT ANY POINT AFTER POWER TEST. THE SILVER END (SMA CONNECTOR) SMOKING ISSUE IS MOST LIKELY RELATED TO AN INTERNAL BREAK OF THE FIBER INSIDE THE SMA CONNECTOR WHICH WOULD CAUSE THE SMA CONNECTOR TO HEAT UP AND POSSIBLY SMOKE.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DUR270D
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** F0708S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**

Health Professional: No

Occupation: NA - NOT APPLICABLE

Recd: 273  Page: 547  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 26-Nov-2008

MFR Report No: 1037955-2008-00009

Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 24-Oct-2008
Report Date (B4): 25-Nov-2008
Report Date (F8): 27-Oct-2008
Date Mfr Rec’d (G4): 27-Oct-2008

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date: 31-Oct-2010

Event Description (B5):
Mfr 01-MAY-2009: FIBER BROKE DURING CASE, NO PATIENT HARM.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
01-MAY-2009: DEVICE WAS TESTED, HAD PILOT BEAM, AND PASSED THE BEND RADIUS TEST. DEVICE FAILURE APPEARS TO BE CAUSED BY USER HANDLING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DUR270R
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** F4507R
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-May-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>03-Jul-2009</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Sep-2008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Sep-2011</td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-OCT-2009: SURGEON WAS DOING A LASER PROCEDURE FOR A BLADDER TUMOR, TIP OF THE FIBER BLEW OFF AND SHATTERED. THEY HAD TO IRRIGATE THE AREA AND CHANGED LASER FIBERS. NO ADDITIONAL SURGERY WAS REQUIRED. AFTER THE FIBER BREAK, THE SURGEON IRRIGATED THE AREA TO FLUSH ANY FIBER FRAGMENTS FROM THE PATIENT, THEN USED A DIFFERENT FIBER FROM THE SAME FIBER LOT TO COMPLETE THE PROCEDURE WITH NO ISSUES NOTED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDTECH AMERICA, INC.</td>
<td>Address:</td>
<td>KENNESAW, GA 30144 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>20-OCT-2009: THE CAUSE OF THE FIBER BREAK IS NOT ABLE TO BE DETERMINED. FIBER BREAKS OF THIS NATURE ARE OFTEN RELATED TO USER HANDLING, BUT CANNOT BE CONFIRMED IN THIS CASE. FIBER WAS TESTED MECHANICALLY AND PASSED MECHANICAL TESTING. THERE DOES NOT APPEAR TO BE ANY MATERIAL DEFECTS RELATED TO THIS FIBER. NO FURTHER ACTION IS NECESSARY AT THIS TIME. FIBER BREAKS OF THIS TYPE DO NOT GENERALLY CAUSE ANY PATIENT ISSUES AS THE MATERIAL IS BIOLOGICALLY INERT AND FRAGMENTS FROM THE BREAK WERE FLUSHED FROM THE BODY DURING THE PROCEDURE. A FIBER FROM THE SAME LOT WAS USED TO COMPLETE THE PROCEDURE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: DUR1000D
Catalog: (*confidential*)
Serial: (*confidential*)
Lot: D3608S
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: No

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**


**Concomitant Medical Products:**

**Remedial Action (H7):**

**Additional Mfr Narrative (H10 & H11):**

26-OCT-2009: THE CAUSE OF THE FIBER BREAK IS NOT ABLE TO BE DETERMINED. FIBER BREAKS OF THIS NATURE ARE OFTEN RELATED TO USE HANDLING, BUT CANNOT BE CONFIRMED IN THIS CASE. FIBER WAS TESTED MECHANICALLY AND PASSED MECHANICAL TESTING. THERE DOES NOT APPEAR TO BE ANY MATERIAL DEFECTS RELATED TO THIS FIBER. NO FURTHER ACTION IS NECESSARY AT THIS TIME. FIBER BREAKS OF THIS TYPE DO NOT GENERALLY CAUSE ANY PATIENT ISSUES AS THE MATERIAL IS BIOLOGICALLY INERT AND FRAGMENTS FROM THE BREAK WERE FLUSHED FROM THE BODY DURING THE PROCEDURE. A DIFFERENT FIBER LOT WAS USED TO COMPLETE THE PROCEDURE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** DUR1000D
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** D2908S
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**

Health Professional: No

- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Occupation: NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1037955-2009-00004</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH AMERICA, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Jun-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>10-Jul-2009</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Jun-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jul-2007</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-Jul-2010</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: DORNIER MEDTECH AMERICA, INC.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: KENNESAW, GA 30144</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26-OCT-2009: THE CAUSE OF THE FIBER BREAK IS NOT ABLE TO BE DETERMINED. FIBER BREAKS OF THIS NATURE ARE OFTEN RELATED TO USER HANDLING, BUT CANNOT BE CONFIRMED IN THIS CASE. FIBER WAS TESTED MECHANICALLY AND PASSED MECHANICAL TESTING. THERE DOES NOT APPEAR TO BE ANY MATERIAL DEFECTS RELATED TO THIS FIBER. NO FURTHER ACTION IS NECESSARY AT THIS TIME.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DORNIER HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: DUR1000D
Catalog: (*)confidential*)
Serial: (*)confidential*)
Lot: D2707S
Other ID: Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)
Health Professional: No
EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)
Occupation: NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1218402-1996-00015</th>
<th>Mfr Name: CANDELA LASER CORP.</th>
</tr>
</thead>
</table>

| Event Date (B3): 01-Aug-1996 | Event Report Type: MALFUNCTION | Adverse Event (B1): |
| Report Date (F8): 05-Aug-1996 | Reporter Occupation (E3): 002 - NURSE | Event Location (F12): HOSPITAL |
| Date Mfr Rec'd (G4): | Device Operator: HEALTH PROFESSIONAL | Report Source (G3): USER FACILITY |

| Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK) |
| Device Age (F9): 0 YR 120 DAYS (4 MO) |
| Expiration Date: |
| Device Usage (H8): U |

**Event Description (B5):**
Mfr 04-SEP-1996: LASER FIBER NOTED TO HAVE "FRAYED" SMALL PIECES OF GOLD COATING DURING USE FOR LITHOTRIPSY OF BLADDER CALCULUS. ALL PIECES REMOVED WITH GRASPING FORCEPS.

**Concomitant Medical Products:**
CANDELA MDL 2000 LASER TRIPTER

**Mfr Name:** CANDELA LASER CORP
**Address:** 530 BOSTON POST RD WAYLAND, MA 01778 UNITED STATES

**Device Available for Evaluation:** R
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

**Date Last Updated:** 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** CANDELA
- **Device Type:** LASER FIBER
- **Device Type:** 8075-26-1300
- **Catalog:** 8075-26-1300
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 24-Jun-1996</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): Omitted</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 12-Aug-1996</td>
<td>Reporter Occupation (E3): -</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Operator:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec’d (G4): 12-Aug-1996</td>
</tr>
<tr>
<td>Device Age (F9):</td>
</tr>
<tr>
<td>Expiration Date:</td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

**Concomitant Medical Products:**

**Mfr Name:** CANDELA CORP.

**Address:**

**Device Available for Evaluation:**

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative No (H10 & H11):**

: THE THREE BROKEN SEGMENTS FROM THE DISTAL 16 3/8" OF THE FIBER WERE EVALUATED. IN GENERAL, BREAKS EXHIBITED CHARACTERISTICS SIMILAR TO BREAKING DUE TO BEING BENT TOO TIGHT. SOME ASPECTS WERE UNDETERMINABLE DUE TO CONTINUED USEAGE FACTORS. THE REMAINING 19FT 2IN OF FIBER WAS ASSESSED WITH NO DEFECTS NOTED. BREAKAGE OBSERVED BY THE CUSTOMER IS BELIEVED TO BE RELATED TO THE FIBER BEING STRESSED BEYOND SPEC EITHER AT THE TIME OF THE INCIDENT OR SOME TIME PRIOR, THEREBY WEAKENING THE FIBER.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand:
Device Type:
Device Type:
Catalog:
  Serial: (*confidential*)
  Lot:
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: EMAIL:
Address: Phone:
Health Professional: International:
  No Answer Fax:
  -

Health Professional: Occupation:

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>18-Nov-1996</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): Omitted</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3):</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Nov-1996</td>
<td>Device Operator:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1218402-1996-00038</th>
<th>Mfr Name:</th>
<th>CANDELA CORP.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jul-1996</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
<th>Unk</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>Address: ,</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Device Evaluated by Manufacturer (H3):</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Correction/Removal No (H9):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Additional Mfr Narrative (H10 &amp; H11):</th>
</tr>
</thead>
</table>

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand:
- Device Type:
- Catalog:
  - Serial: (*confidential*)
- Lot:
- Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name:
- Address:

  EMAIL:
  Phone:
  International:
  Fax:

  Health
  Professional: No Answer

  Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1218402-1997-00018</th>
<th>Mfr Name:</th>
<th>CANDELA CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>11-Apr-1997</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>23-Apr-1997</td>
<td>Reporter Occupation (E3):</td>
<td>-</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>23-Apr-1997</td>
<td>Device Operator:</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LINK)

**Device Age (F9):**

**Expiration Date:**

**Manufacture Date (H4):** 01-Jul-1996

**Single Use (H5):** N

**Device Usage (H8):** U

**Event Description (B5):**

Unk :

**Concomitant Medical Products:**

**Mfr Name:**

**Address:** ,

**Device Available for Evaluation:**

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

OPTICAL FIBER IS FRAGILE AND MAY BREAK DUE TO A NUMBER OF FACTORS ASSOCIATED WITH HANDLING. REFERENCE IS MADE TO THIS RISK IN LABELING AND THE OPERATOR INSTRUCTIONS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand:
- Device Type:
- Device Type:
- Catalog:
- Serial: (*confidential*)
- Lot:
- Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name:
- Address:
- EMAIL:
- Phone:
- International:
- Fax:
- Health Professional: No Answer
- Occupation: -
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>02-Jun-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>01-Jul-1998</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Jun-1998</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Report No:</th>
<th>1218402-1998-00014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>CANDELA CORP.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Jun-1998</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>401 - BIOMEDICAL ENGINEER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Jul-1998</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Jun-1998</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Report No:</th>
<th>1218402-1998-00014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>CANDELA CORP.</td>
</tr>
</tbody>
</table>

| Mfr Name:               | CANDELA CORP.       |
| Address:                | 530 BOSTON POST RD. WAYLAND, MA 01778 UNITED STATES |

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
</tbody>
</table>

| Device Age (F9):               | | |
| Expiration Date:               | | |

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
</tbody>
</table>

| Event Description (B5):        | Mfr 07-JUL-1998: WHILE THE LASER WAS IN WARM-UP MODE A COMPONENT FAILED RESULTING IN SMOKE IN THE PROCEDURE ROOM. |

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>CANDELA CORP.</td>
</tr>
<tr>
<td>Address:</td>
<td>530 BOSTON POST RD. WAYLAND, MA 01778 UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
</tbody>
</table>

| Remedial Action (H7):            | |
| Correction/Removal No (H9):      | |
| Additional Mfr Narrative (H10 & H11): | 07-JUL-1998: |

<table>
<thead>
<tr>
<th>Date Last Updated:</th>
<th>11/2/2010 9:17 AM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recd:</td>
<td>282</td>
</tr>
<tr>
<td>Page:</td>
<td>564</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** MDL-1 LASER
- **Device Type:** LASERTRIPTER
- **Catalog:** 9903-ML-0010
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 401 - BIOMEDICAL ENGINEER
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
During a laser lithotripsy procedure, a Candela laser optical fiber broke. A replacement fiber also broke. Both fibers broke external to the patient at the entry port into an ACMI ureteroscope. Breakage at this point is typically related to abnormal handling stress on the fiber. The operators manual refers to related precautions to be taken to minimize the risk of breakage.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand:
Device Type:
Device Type:
Catalog:
   Serial: (*confidential*)
   Lot:
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: 
Address: 
EMAIL: 
Phone: 
International: 
Fax: 

Health Professional: No Answer

Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1221543-2005-00001</th>
<th>Mfr Name:</th>
<th>LASER PERIPHERALS LLC.</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>23-Aug-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>13-Sep-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Apr-2005</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 21-OCT-2005: TWO LASER FIBERS WERE POSITIONED (ONE IN THE GSV, THE OTHER IN THE GSV-ACCESSORY) WHEREBY THE FIRST LASER FIRED CONTINUOUSLY AND POSSIBLY CROSSED SUFFICIENTLY CLOSE TO THE OTHER FIBER SUCH THAT THE POLYMER WAS MELTED THROUGH AND THE QUARTZ FIBER BROKE OR BECAME BRITTLE AND SUBSEQUENTLY BROKE. THE ONLY WAY TO CONFIRM THIS IS TO EXCISE THE 3.8 CM LASER FIBER TIP FROM THE PATIENT AND ANALYZE THE FIBER TIP TO DETERMINE WHETHER MELTING OR BREAKAGE HAD OCCURRED. THE DOCTOR MADE AN INFORMED MEDICAL DECISION TO LEAVE THE LASER FIBER TIP IN VIVO WITHIN THE PATIENT SINCE IT IS INERT AND BIOCOMPATIBLE; EXCISION AT THE SFJ REGION COULD RESULT IN SIGNIFICANT BLEEDING, FISTULA FORMATION, INFECTION, AND MORE POTENTIAL MORBIDITY.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>LASER PERIPHERALS LLC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>* GOLDEN VALLEY, MN * UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
21-OCT-2005: IT APPEARS THAT THE USER MAY HAVE POTENTIALLY POSITIONED TWO LASER FIBERS SUFFICIENTLY CLOSE TO EACH OTHER AS TO CAUSE POLYMER MELTING OF THE OTHER FIBER AND THE QUARTZ FIBER BROKE AND REMAINED DISLODGED WITHIN THE PATIENT. RETURN ANALYSIS WAS NOT POSSIBLE SINCE THE DOCTOR MADE AN INFORMED DECISION TO LEAVE THE LASER TIP IN VIVO SINCE THE MATERIAL IS INERT AND BIOCOMPATIBLE. NO FURTHER PROBLEMS WITH THE PATIENT HAVE BEEN REFERRED TO LASER PERIPHERALS. A MANUFACTURING REVIEW OF THIS DEVICE SHOWS NO MANUFACTURING PROBLEMS THAT WOULD HAVE CONTRIBUTED TO THIS OCCURRENCE. THIS TYPE OF EVENT HAS NOT ROUTINELY OCCURRED.

DEVICE INFORMATION:

Brand: LASER PERIPHERALS DIODE LASER FIBER  
Device Type: LASER FIBER  
Device Type: DBLF-60  
Catalog: *  
Serial: (*confidential*)  
Lot: UNK  
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name:  
Address:  
Health Professional: Yes  
Email:  
Phone:  
International:  
Fax:  
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>1222625-2001-00002</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>BIOLITEC, INC.</td>
</tr>
</tbody>
</table>

| Event Date (B3): | 25-Jun-2001 |
| Report Date (B4): | 17-Jul-2001 |
| Report Date (F8): | |
| Date Mfr Rec'd (G4): | 17-Jul-2001 |
| Event Report Type: | OTHER |
| Event Outcome (B2): | OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) |
| Reporter Occupation (E3): | 500 - RISK MANAGER |
| Device Operator: | HEALTH PROFESSIONAL |
| Event Location (F12): | |
| Report Source (G3): | USER FACILITY |
| Adverse Event (B1): | Problem (B1): N |
| Report Date (F8): | 17-Jul-2001 |
| Event Outcome (B2): | OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) |
| Reporter Occupation (E3): | 500 - RISK MANAGER |
| Device Operator: | HEALTH PROFESSIONAL |
| Event Location (F12): | |
| Report Source (G3): | USER FACILITY |

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Oct-2000
Expiration Date: 14-Oct-2002

Single Use (H5): N
Device Usage (H8): U

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
24-JUL-2001: THE FIBER WAS WORKING AND THE PHYSICIAN NOTICED THAT 1-2MM BROKE OFF DURING THE PROCEDURE. THE COMPANY BELIEVES THAT THIS EVENT WAS PROCEDURELLY RELATED AND NOT CAUSED BY ANY DEVICE DESIGN OR OPERATION MALFUNCTION. THE COMPANY THOUGHT IT PRUDENT TO FILE THIS REPORT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** BIOLITEC MEGABEAM
- **Device Type:** LASER FIBER - FIBER OPTIC LASER DELIVERY SYSTEM
- **Device Type:** RHBFSF 365-400-3
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** A0-0170
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

**EMAIL:**

**Phone:** (*)

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1222625-2006-00002</th>
<th>Mfr Name:</th>
<th>BIOLITEC, INC.</th>
</tr>
</thead>
</table>

- **Event Date (B3):** 04-May-2006
- **Report Date (B4):** 09-May-2006
- **Report Date (F8):**
- **Date Mfr Rec'd (G4):** 08-May-2006
- **Event Report Type:** OTHER
- **Event Outcome (B2):** REQUIRED INTERVENTION
- **Reporter Occupation (E3):** OTHER
- **Device Operator:** HEALTH PROFESSIONAL
- **Report Date (F8):**
- **Event Location (F12):**
- **Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY

- **Date Last Updated:** 11/2/2010  9:17 AM
- **Recd:** 286
- **Page:** 572

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**
**Expiration Date:**
**Device Usage (H8):** U

**Event Description (B5):**

**Concomitant Medical Products:**

**Mfr Name:** BIOLITEC, INC.
**Address:** 515 SHAKER RD.
EAST LONGMEADOW, MA 01028
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):** PATIENT MONITORING
**Correction/Removal No (H9):** 15-MAY-2006: THE HOSPITAL HAS RETAINED THE FIBER OPTIC DELIVERY SYSTEM. THEY MAY RETURN THE LASER FOR EVALUATION. IT APPEARS THE LASER FUNCTIONED NORMALLY. IT IS NOT CLEAR WHETHER THE FIBER WAS USED CORRECTLY OR WHETHER THE ENDOTRACHEAL TUBE WAS ONE CAPABLE OF BEING USED WITH THE LASER. OPERATOR ERROR IS ALSO POSSIBLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: CERALES/ MEDABEAM
Device Type: LASER AND FIBER OPTIC LASER DELIVERY SYSTEM
Device Type: LASER-D25, FIBER-BFHF 403
Catalog: *
Serial: (*confidential*)
Lot: FIBER A05-0131, 0139, 0051
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1223483-1997-00001</th>
<th>Mfr Name:</th>
<th>PALOMAR MEDICAL PRODUCTS, INC.</th>
</tr>
</thead>
</table>

| Event Date (B3):        | 25-Apr-1997         | Event Report Type: | OTHER                     |
| Report Date (B4):       | 22-May-1997         | Event Outcome (B2):| OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) |
| Report Date (F8):       |                      | Reporter Occupation (E3): | 001 - PHYSICIAN |
| Date Mfr Rec'd (G4):    | 29-Apr-1997         | Device Operator:     | HEALTH PROFESSIONAL       |

| Product Code:           | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9):        | Manufacture Date (H4): 01-Jan-1996 |
| Expiration Date:        | Single Use (H5): N     |
|                        | Device Usage (H8): *    |

**Event Description (B5):**

Mfr 11-SEP-1997: ON 4/29/97, A PHYSICIAN CONTACTED THE COMPANY'S SERVICES SUPPORT GROUP STATING THAT HE WANTED SOMEONE TO COME CHECK HIS EPILASER, BECAUSE A PT OF HIS HAD BEEN BURNED DURING AN EPILASER TREATMENT (FOUR DAYS PRIOR). THE DR ALSO REPORTED THAT THE MACHINE WAS DISPLAYING A "FAULT ERROR" MESSAGE. A SERVICE TECHNICIAN WAS SENT TO THE DR'S OFFICE THAT SAME DAY.

**Concomitant Medical Products:**

NA

**Mfr Name:** SPECTRUM MEDICAL TECHNOLOGIES

**Address:** 45 HARTWELL AVE.
LEXINGTON, MA 02173
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** REPAIR

**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

11-SEP-1997: AN ESSENTIAL COMPONENT OF EPILASER IS COOLING HANDPIECE, WHICH PREVENTS DAMAGE TO DERMAL LAYER. THIS HANDPIECE IS COOLED BY WATER (APPROX. TWO PINTS). WHEN SERVICE TECHNICIAN ARRIVED, HE DISCOVERED THAT TUBING THROUGH WHICH WATER RAN WAS DISCONNECTED FROM MACHINE, RESULTANTLY, ALL WATER HAD LEAKED OUT AND THERE WAS NO WATER TO COOL COOLING HANDPIECE. DR. NEVER REPORTED A LEAK IN MACHINE. WHEN OPERATED WITHOUT WATER TO COOL HANDPIECE, EPILASER MAKES A LOUD WHINING NOISE THAT SHOULD ALERT OPERATOR THAT THERE IS A PROBLEM. TECHNICIAN RECONNECTED TUBING, AND FILLED CHILLER WITH WATER, AND RECALIBRATED LASER. TECHNICIAN WAS NEITHER ABLE TO OBSERVE NOR CAUSE MACHINE TO DISPLAY "ERROR CODE" MESSAGE THAT DR. HAD REPORTEDLY SEEN. DR. RECEIVED TWO TRAINING VIDEOTAPES FROM PALMOAR PRIOR TO INCIDENT IN QUESTION. SHORTLY AFTER RECEIVING HIS LASER, AND PRIOR TO INCIDENT IN QUESTION, HE AND MEMBERS OF HIS STAFF WERE SHOWN ONE OF THESE VIDEOTAPES BY ONE OF PALOMAR'S SALES REPS. BOTH VIDEOTAPES CLEARLY STATE THAT FIRST STOP TO AN EPILASER TREATMENT IS TO ASSESS THE PT'S SKIN COLOR, AND THAT DARK OR SUNTANNED SKIN IS AT RISK OF DERMAL DAMAGE, AND THAT IT IS SOMETIMES NECESSARY THEREFORE IN SUCH CASES TO PRE-TREAT (FOUR TO SIX WEEKS PRIOR TO TREATMENT) TO REDUCE EPIDERMAL PIGMENTATION. ONE OF TAPES ADVISES THAT PEOPLE WHO ARE TANNED OR PIGMENTED SHOULD STAY OUT OF SUN PRIOR TO TREATMENT. TAPES ALSO CLEARLY STATE THAT, IN ORDER TO DETERMINE APPROPRIATE FLUENCE LEVEL, IT IS NECESSARY TO APPLY A FEW TEST DOES IN INCREASING FLUENCE LEVELS TO TEST SKIN REACTION, AND THAT ONE SHOULD WAIT FIVE MINUTES AFTER EACH TEST SPOT TO ASSESS SKIN REACTION. TAPES ADVISE PERSON ADMINISTERING TREATMENT TO LOOK FOR ANY EVIDENCE OF EPIDERMAL DAMAGE (E.G., EARLY FORMATION OF BLISTER OR EDEMA, SIGNS THAT EPIDERMIS HAS STARTED TO SEPARATE) WHICH IS AN INDICATION THAT FLUENCE LEVEL IS TOO HIGH. TAPE ADVISES THAT ONE SHOULD CHOOSE HIGHEST FLUENCE THAT DOES NOT SHOW NIKOLSKY SIGN (A CONDITION WHERE APPARENTLY NORMAL EPIDERMIS MAY BE SEPARATED AT BASE LAYER AND RUBBED OFF WHEN PRESSED WITH A SLIDING MOTION. DESPITE THESE INSTRUCTIONS, DR. IN QUESTION PROCEEDED TO TREAT PT AFTER DETERMINING THAT 1) SHE HAD A DEEP TAN AND 2) SHOWED NIKOLSKY SIGN AT EVERY FLUENCE LEVEL. DESPITE HIS OBSERVATION THAT PT BLISTERED AT EVERY FLUENCE LEVEL, DR. THEN TURNED OVER TREATMENT TO BE PERFORMED BLISTERED AT EVERY FLUENCE LEVEL, DR. THEN TURNED OVER TREATMENT TO BE PERFORMED BY ONE OF HIS ASSISTANTS (WHOM IT APPEARS HAD NOT BEEN TRAINED ON USE OF EPILASER). AN INVESTIGATION OF THIS INCIDENT WAS CONDUCTED BY THE CO'S QUALITY SYSTEMS MANAGER. PHYSICIAN STATED TO CO'S INVESTIGATOR THAT HIS MEDICAL ASSISTANT HAD NO IDEA THAT HANDPIECE NEEDED TO BE COOL. PHYSICIAN ALSO REPORTED TO INVESTIGATOR THAT PT WAS HEALING NICELY AND STILL WISHED TO HAVE FURTHER HAIR REMOVAL TREATMENT. PT HAD ADVISED CO AND DR. THROUGH AN ATTORNEY THAT HER SKIN IS HYPOPIGMENTED IN AREAS WHERE SHE WAS TREATED WITH EPILASER. IN EXPERIENCE OF THE [*]

**DEVICE INFORMATION:**

- **Brand:** EPILASER
- **Device Type:** LASER
- **Device Type:** EPILASER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1319211-2005-00017</th>
<th>Mfr Name:</th>
<th>ANGIODYNAMICS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>15-Jul-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>01-Sep-2005</td>
<td>Event Outcome (B2):</td>
<td>HOSPITALIZATION</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 07-SEP-2005: THREE PATIENTS DEVELOPED INFECTIONS AFTER THE PROCEDURES. THE INFECTIONS WERE TREATED WITH KEFLEX. ONE PATIENT REQUIRED HOSPITALIZATION.

**Concomitant Medical Products:**

Mfr Name: ANGIODYNAMICS, INC.
Address: *
    QUEENSbury, NY *
    United States

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

07-SEP-2005: H.10: THE CATALOG NUMBER AND LOT NUMBER WERE NOT REPORTED. A SHIP HISTORY WAS CONDUCTED ON PRODUCTS THAT THE COMPLAINANT HAD PURCHASED IN THE LAST 6 MONTHS. THE SHIP HISTORY SHOWED THAT CATALOG NUMBER 11402001, LOT NUMBER CP578637 AND CATALOG NUMBER 11402002, LOT NUMBER 578824 WERE SHIPPED TO THE COMPLAINANT. THE LOT HISTORY RECORD WAS REVIEWED FOR ANY ABNORMALITIES WHICH, MAY HAVE CONTRIBUTED TO THE CAUSE OF THE COMPLAINT. NOTHING KNOWN TO HAVE CONTRIBUTED TO THE COMPLAINT WAS OBSERVED. THE COMPLAINT SAMPLES ARE NOT AVAILABLE FOR EVALUATION. STOCK SAMPLES OF BOTH POSSIBLE LOTS ARE NOT AVAILABLE FOR EVALUATION. IT HAS BEEN REPORTED THAT THE PHYSICIAN HAS STERILE SAMPLES AND WILL BE RETURNING THEM FOR EVALUATION. TO DATE, THESE SAMPLES HAVE NOT BEEN RECEIVED. THE COMPLAINT INVESTIGATION IS INCONCLUSIVE. THE SAMPLES WERE NOT RETURNED FOR EVALUATION. THE CAUSE OF THE COMPLAINT IS UNKNOWN. A REVIEW OF THE MANUFACTURING RECORDS INDICATED THAT ALL THE DEVICE SPECIFICATION AND QUALITY REQUIREMENTS WERE SATISFIED ON THE POSSIBLE LOT NUMBERS. IT IS KNOWN THAT LOT CP578637 WAS STERILIZED ON STERILE LOAD NUMBER 20050525-5592 AND LOT #578824 WAS STERILIZED ON STERILE LOAD NUMBER 20050607-5823. THE PAPERWORK FROM BOTH STERILE LOADS WAS REVIEWED AND A SAMPLE FROM EACH OF THE POSSIBLE LOTS WAS ALSO SENT OUT FOR PYROGEN TESTING AND PASSED. ANGIODYNAMICS HAS NOT RECEIVED ANY OTHER COMPLAINTS FOR THIS TYPE OF DEFECT. IT HAS BEEN REPORTED THAT STERILE SAMPLES ARE AVAILABLE FOR EVALUATION, BUT HAVE NOT YET BEEN RECEIVED. UPON THE ARRIVAL OF THE STERILE SAMPLES THE COMPLAINT INVESTIGATION WILL BE REOPENED TO INCLUDE THE INVESTIGATION OF THE STERILE SAMPLES. THIS APPEARS TO BE AN ISOLATED INCIDENT. THIS TYPE OF COMPLAINT WILL CONTINUE TO BE MONITORED FOR TRENDS. NO FURTHER ACTION AT THIS TIME. FREQUENCY HAS INCREASED, BUT THE SEVERITY OF THIS EVENT IS NOT GREATER THAN USUAL.

DEVICE INFORMATION:

Brand: VENACURE
Device Type: LASER VEIN TREATMENT

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)
Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)

Occupation: 001 - PHYSICIAN

Recd: 288 Page: 578 Date Last Updated: 11/2/2010 9:17 AM
Event Description (B5):
Mfr 15-MAY-2008: AN .018 GUIDEWIRE ADVANCED THROUGH NEEDLE INTO VEIN BELOW THE POPLITEAL AREA APPROX 3CM. THE MICRO PUNCTURE SHEATH DILATOR ADVANCED OVER THE WIRE WITH NO RESISTANCE. AT THIS TIME, THE PT STATED "I DO NOT FEEL WELL," HER EYES ROLLED BACK, HER HANDS WENT TO HER FACE, SHE DEMONSTRATED WHAT LOOKED LIKE SEIZURE ACTIVITY, HER ARMS CAME DOWN AND APPEARED TO BE IN A COLONIC POSTURING WITH ARMS EXTERNALLY ROTATED AND STIFF, SHE HAD FROTHING AT THE MOUTH, HER HEAD WAS TURNED TO PREVENT POSSIBLE ASPIRATION, WHEN SHE BECAME AWARE OF US, SHE ONLY REMEMBERED SAYING "I DO NOT FEEL WELL." THIS LASTED APPROX 1.5 MINS. AFTER TALKING TO HER IN THE WAITING ROOM, SHE REVEALED SHE HAD A FAINTING EPISODE TO A FEW MONTHS PRIOR AND TAKEN BY THE AMBULANCE TO THE ER. NO REPORTED COMPLAINT FROM PHYSICIAN OR PT ABOUT OUR PRODUCT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

15-MAY-2008: LOT HISTORY RECORD REVIEW: THE CATALOG NUMBER AND LOT NUMBER WERE NOT REPORTED. A SHIP HISTORY WAS CONDUCTED ON THE REPORTED COMPLAINANT, HOWEVER, THE COMPLAINANT WAS NOT FOUND IN OUR SYSTEM. A SHIP HISTORY WAS THEN CONDUCTED ON THE SALES REP. THIS SHIP HISTORY SHOWED THE SALES REP HAD RECEIVED 5 NEVERTOUCH SAMPLES, CATALOG NUMBER 11402001-LOT NUMBERS 950690. THE LOT HISTORY RECORDS WERE REVIEWED FOR THE ABOVE POSSIBLE LOT NUMBER, ANY ABNORMALITIES WHICH, MAY HAVE CONTRIBUTED TO THE CAUSE OF THE COMPLAINT. NOTHING KNOWN TO HAVE CONTRIBUTED TO THE COMPLAINT WAS OBSERVED. REVIEW OF RETURNED SAMPLE: THE COMPLAINT SAMPLE IS NOT AVAILABLE FOR EVALUATION. CONCLUSION: THE COMPLAINT INVESTIGATION IS INCONCLUSIVE. THE REPORTED COMPLAINT STATES AN ADVERSE EVENT THAT APPEARS TO BE CAUSED BY A PT CONDITION AND NOT A PRODUCT FAILURE. THE PT HAD EXPERIENCED SIMILAR SYMPTOMS ABOUT A MONTH BEFORE THE PROCEDURE. THE FOLLOW UP INFORMATION HAS NOT BEEN SUBMITTED TO ANGIODYNAMICS AS OF YET. IT IS NOT BELIEVED THE PRODUCT FAILED IN ANY WAY AS THE REPORTED COMPLAINT DOES NOT STATE ANY PRODUCT DEFECT AND THE COMPLAINT SAMPLE WAS NOT RETURNED FOR EVALUATION. THE INSTRUCTIONS FOR USE STATE: THE POTENTIAL COMPLICATIONS INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING: VESSEL PERFORATION, THROMBOSIS, PULMONARY EMBOLISM, PHLEBITIS, HEMATOMA, INFECTION, SKIN PIGMENTATION ALTERATION, NEOVASCULARIZATION, PARESTHESIA DUE TO THERMAL DAMAGE OF ADJACENT SENSORY NERVES, ANESTHETIC TUMESCIENCE, NON TARGET IRRADIATION, VASOSPASM, HEMORRHAGE, NECROSIS, SKIN BURNS AND PAIN. THIS TYPE OF COMPLAINT WILL CONTINUE TO BE MONITORED FOR TRENDS. NO FURTHER ACTION AT THIS TIME. FREQUENCY HAS INCREASED BUT THE SEVERITY OF THIS EVENT IS NOT GREATER THAN USUAL.

**DEVICE INFORMATION:**

- **Brand:** NEVERTOUCH VENACURE PROCEDURE KIT
- **Device Type:** LASER VEIN TREATMENT
- **Catalog:** NOT REPORTED
- **Serial:** (*confidential*)
- **Lot:** NOT REPORTED

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN

Recd: 289  Page: 580  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1319211-2008-00011</th>
<th>Mfr Name: ANGIODYNAMICS, INC.</th>
<th>Date Received</th>
<th>28-Mar-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-Feb-2008</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4): 01-Jan-2008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Jan-2009</td>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 29-MAY-2008: GOLD TIP FELL OFF POST PROCEDURE.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ANGIODYNAMICS, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: QUEENSbury, NY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** NEVERTOUCH VENACURE PROCEDURE KIT
- **Device Type:** LASER VEIN TREATMENT
- **Catalog:** 11402002
- **Serial:** (*confidential*)
- **Lot:** 948872
- **Other ID:**

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| MFR Report No: | 1319211-2008-00049 | Mfr Name: ANGIODYNAMICS, INC. | Date Received | 21-Nov-2008 |
| Event Date (B3): | 10-Oct-2008 | Event Report Type: MALFUNCTION |  |
| Report Date (B4): | 03-Nov-2008 | Event Outcome (B2): REQUIRED INTERVENTION |  |
| Date Mfr Rec'd (G4): | 14-Oct-2008 | Reporter Occupation (E3): 002 - NURSE |  |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) | Event Location (F12): |  |
| Device Age (F9): | Manufacture Date (H4): 01-Mar-2008 | Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE |  |
| Expiration Date: | Single Use (H5): Y | Device Operator: HEALTH PROFESSIONAL |  |
| Device Usage (H8): | U |  |

Event Description (B5):


Concomitant Medical Products:

| Mfr Name: ANGIODYNAMICS, INC. |
| Address: QUEENSBURY, NY UNITED STATES |

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): 
Correction/Removal No (H9): 

Recd: 291 Page: 583 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** NEVER TOUCH VENACURE
- **Device Type:** LASER VEIN TREATMENT
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:**
  - **Other ID:**

- **Reprocessed & Reused:** N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)
Phone: (b) (6)
Fax: (b) (6)
EMAIL: (b) (6)
Health Professional: Yes
Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Description (B5):

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

MFR Report No: 1319211-2008-00061
Mfr Name: ANGIODYNAMICS, INC.

Event Date (B3): 01-Dec-2008
Report Date (B4): 22-Dec-2008
Report Date (F8): 
Date Mfr Rec'd (G4): 01-Dec-2008

Event Report Type: MALFUNCTION
Event Outcome (B2): 
Report Date (F8): 

Adverse Event (B1): Problem (B1): Y
Event Location (F12): 
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Jun-2008
Expiration Date: 01-Jun-2009
Single Use (H5): Y
Device Usage (H8): U

Date Last Updated: 11/2/2010  9:17 AM
Recd: 292  Page: 586
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: VENACURE NEVERTOUCH
Device Type: LASER VEIN TREATMENT
Catalog: 959991
Serial: (*confidential*)
Lot: 51402006
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED] MGR
Address: [REDACTED]
Email: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]
Health Professional: Yes
Occupation: 112 - PHYSICIAN ASSISTANT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

**MFR Report No:** 1319211-2009-00008  
**Mfr Name:** ANGIODYNAMICS, INC.  
**Date Received:** 1319211-2009-00008  
**Mfr Report No:** 1319211-2009-00008  
**Report Date (B4):** 25-Feb-2008  
**Event Date (B3):** 04-Feb-2009  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):**  
**Report Source (G3):** COMPANY REPRESENTATIVE  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Date (B5):**
Mfr 24-JUL-2009: PT FOUND TIP OF FIBER IN LEG. THE INCISION SITE HAD NOT HEALED AND AFTER ULTRA SOUND, IT WAS REALIZED THAT THE FIBER HAD BROKEN OFF IN THE LEG.

**Concomitant Medical Products:**

**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:**  
**Device Usage (H8):** U  
**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  
**Additional Mfr Narrative (H10 & H11):**
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand: VENACURE PROCEDURE KIT
   Device Type: LASER VEIN TREATMENT
   Catalog: 11402002
   Serial: (*confidential*)
   Lot: UNKNOWN
   Other ID:

   Reprocessed & Reused: N/A

REPORTER INFORMATION:

   Name: [redacted]
   Address: [redacted]
   EMAIL: [redacted]
   Phone: [redacted]
   International: [redacted]
   Fax:

Health Professional: No

Occupation: NA - NOT APPLICABLE
CDRH MAUDE EVENT REPORT (FOI)

02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1319211-2009-00042</th>
<th>Mfr Name: ANGIODYNAMICS, INC.</th>
<th>13-Oct-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 14-Sep-2009</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 07-Oct-2009</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 15-Sep-2009</td>
<td>Mfr Report No:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adverse Event (B1): Y</td>
<td>Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jun-2009</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expiration Date: 01-Jun-2010</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ANGIODYNAMICS, INC.</td>
<td>Address: QUEENSbury, NY UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: VENACURE NEVERTOUCH
Device Type: LASER VEIN TREATMENT
Catalog: 11402002
Serial: (*confidential*)
Lot: 985801
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:
Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International:
Fax:

Occupation: 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-1996-00005</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date Received: 06-Sep-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Date (B3):</strong> 08-Aug-1996</td>
<td><strong>Event Report Type:</strong> MALFUNCTION</td>
<td><strong>Adverse Event (B1):</strong> Problem (B1): Y</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong> 08-Aug-1996</td>
<td><strong>Event Outcome (B2):</strong> OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td><strong>Event Location (F12):</strong> INVALID DATA</td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td><strong>Reporter Occupation (E3):</strong> OTHER</td>
<td><strong>Event Source (G3):</strong> HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td><strong>Date Mfr Rec'd (G4):</strong> 08-Aug-1996</td>
<td><strong>Device Operator:</strong> HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td><strong>Product Code:</strong> (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td><strong>Device Age (F9):</strong> Manufacture Date (H4): 01-Jan-1996</td>
<td></td>
</tr>
<tr>
<td><strong>Expiration Date:</strong></td>
<td><strong>Single Use (H5):</strong> Y</td>
<td></td>
</tr>
<tr>
<td><strong>Device Usage (H8):</strong> I</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Event Description (B5):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr 10-OCT-1996: LASER ENERGY BURNT THROUGH FIBER NEAR BOOT/PROXIMAL CONNECTOR. REPORTER STATED THAT PHYSICIAN HAD COMPLETED FIRST LEVEL AND MOST OF NEXT LEVEL ON AN ENDOSCOPIC LUMBAR DISCECTOMY PROCEDURE, WHEN SCRUB TECHNICIAN HEARD A &quot;POP&quot; AND LOOKED AT FIBER TO LASER CONNECTION AT WHICH TIME HE NOTED TWO RAYS OF &quot;LIGHT&quot; EXITING FIBER NEAR BOOT ONE AT APPROX 10:30 AND ONE AT APPROX 4:00 (IF YOU WERE LOOKING AT A CLOCK). LASER WAS IMMEDIATELY SHUT DOWN AND DISCONTINUED USE OF THE FIBER. REPORTER STATED THAT THE INCIDENT OCCURRED AND THAT NO ONE HAD BENT THE TIME THAT NO ONE WAS NEAR THE LASER AT THE TIME THAT THE INCIDENT OCCURRED AND THAT NO ONE HAD BENT FIBER AND OR LEANED UP AGAINST IT. NO INJURIES WERE REPORTED. NOTE: VISUAL INSPECTION (BY REPORTER) SHOWS A VISIBLE HOLE IN THE BOOT (STRAIN RELIEF) OF DEVICE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Concomitant Medical Products:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mfr Name:</strong> TRIMEDYNE, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Address:</strong> 2801 BARRANCA ROAD IRVINE, CA 92606 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Device Available for Evaluation:</strong> Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Device Evaluated by Manufacturer (H3):</strong> Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Remedial Action (H7):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Correction/Removal No (H9):</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
10-OCT-1996: NOTE ALL OF THE INFO ON THIS FORM HAS BEEN COMPLETED BY CO MFR. THE APPLICABLE CODES FOR SECTION F10 ARE AS FOLLOWS. PT CODE: 2199. DEVICE CODE: 1219. CODE 1738 LABELED. EXPLANTATION FOR CODE 68 FOR SECTION H6 CONCLUSIONS: DEVICE FAILURE RELATED TO HANDLING.

**DEVICE INFORMATION:**
- **Brand:** SIDEFIRE 29 CM LASER NEEDLE
- **Device Type:** LASER FIBER
- **Device Type:** 20361
- **Catalog:** 20361
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Phone:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** OTHER
- **EMAIL:** [REDACTED]

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 09-Oct-1996 |
| Report Date (B4): | 09-Oct-1996 |
| Report Date (F8): | 09-Oct-1996 |
| Date Mfr Rec’d (G4): | 09-Oct-1996 |

**Event Description (B5):**


**Concomitant Medical Products:**

OMNIPULSE-MAX 80-WATT HOLMIUM LASER SYS 1210-VHP P

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
IRVINE, CA 92606
UNITED STATES

Concomitant Medical Products:

- OMNIPULSE-MAX 80-WATT HOLMIUM LASER SYS 1210-VHP P
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-NOV-1996:

DEVICE INFORMATION:

- **Brand:** OMNITIP SJ-90 SIDEFIRE SWITCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20496-HP, 20496-HP
- **Catalog:** 20496-HP, 20496-HP
- **Serial:** (*confidential*)
- **Lot:** 11765, 11765
- **Other ID:** C9610005

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]

Health Professional: No

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr 04-DEC-1996: FORTY (40) YEAR OLD PT WITH INTERNAL DERANGEMENT WAS HAVING AN ARTHROSCOPY DONE WHEN THE HAND PIECE OF THE LASER AT THE CONNECTION MELTED. IT WAS REPLACED BY THE 60 DEGREE PROBE AND CASE CONTINUED. PHYSICIAN PREFERRED THE SIDE FIRE PROBE. IT IS NOT KNOWN AT THIS TIME WHAT ADVERSE OUTCOME PT MAY HAVE. THE PHYSICIAN STATES IT WILL BE APPROXIMATELY SIX (6) MONTHS BEFORE THIS IS KNOWN.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>LASER SYSTEM 40-WATT, SERIAL NUMBER 228</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: 2801 BARRANCA RD</td>
</tr>
<tr>
<td>IRVINE, CA 92606</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation: Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
</tr>
<tr>
<td>Device not Returned to Manufacturer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
04-DEC-1996: FOLLOW-UP CONVERSATION WITH CONTACT PERSON CONFIRMED THAT REPORTED DEVICE MELTED AT THE TIP TO HANDPIECE CONNECTION (WHERE TIP THREADS ONTO HANDPIECE). CO COULD ONLY VERIFY THE MODEL AND LOT NUMBER FOR THE HANDPIECE: 20470, LOT NUMBER 8115 WITH CONTACT PERSON. THE LOT NUMBER AND MODEL NUMBER ON THE TIP WAS UNREADABLE. CONTACT PERSON WAS NOT FAMILIAR WITH PRODUCT AND COULD NOT VERIFY ALL OF THE PRODUCTS USED DURING THIS EVENT. CO WAS ALSO INFORMED THAT REPORTED PRODUCT WAS NOT GOING TO BE RETURNED FOR EVALUATION. NOTE: LOT NUMBER (REPORTED BY USER FACILITY AS SERIAL NUMBER) 8406 CORRESPONDS WITH MODEL 20403 TAPERTIP 60 DEGREE AND TIP NUMBER 228 CORRESPONDS WITH LASER MODEL NUMBER 1210 LISTED IN SECTION D10 AS A CONCOMITANT PRODUCT. ATTEMPTS AT IDENTIFICATION OF PRODUCTS ARE STILL ONGOING. BASED ON THE INFO PROVIDED IN SECTION B5, CO BELIEVES THAT THE TIP USED IN THIS EVENT IS PROBABLY A TIP SIDEFIRE; ATTEMPTS AT CONFIRMING MODEL NUMBER IS ONGOING. SECTION F10: MFR'S INTERPRETATION OF CODES BASED ON INFO PROVIDED. PT CODE 2202 NA.

DEVICE INFORMATION:
- **Brand:** OMNI MULTIUSE HANDPIECE
- **Device Type:** LASER FIBER
- **Device Type:** 20470
- **Catalog:** 20470
- **Serial:** (*confidential*)
- **Lot:** 8115228
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** MGR
- **Address:**
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

Recd: 297  Page: 597  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 17-Jan-1997

MFR Report No: 1419951-1997-00001
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 05-Nov-1996
Report Date (B4): 20-Dec-1996
Report Date (F8): 20-Dec-1996
Date Mfr Rec'd (G4): 20-Dec-1996

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Adverse Event (B1): Problem (B1): Y

Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 0 YR 120 DAYS (4 MO)
Manufacture Date (H4): 01-Aug-1996
Expiration Date: 20-Aug-2000
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:
OMNIPULSE MAX HOLMIUM LASER MODE 1210-VHP

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA ROAD
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JAN-1997:
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 365 MICRON HOLMIUM FIBER WITH FLAT TIP
Device Type: LASER FIBER
Device Type: 20007
Catalog: 20007
Serial: (*confidential*)
Lot: 12236
Other ID: NA
Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Email: [Redacted]
Phone: (*)
International: [Redacted]
Fax: [Redacted]
Health Professional: Yes
Occupation: OTHER

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-1997-00002</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received:</th>
<th>31-Jan-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>03-Jan-1997</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>03-Jan-1997</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>03-Jan-1997</td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>03-Jan-1997</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR - 95 DAYS (9 MO)</td>
<td>Manufacture Date (H4):</td>
<td>01-Mar-1996</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Mar-2000</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.
**Address:**
2801 BARRANCA RD
IRVINE, CA 92606
UNITED STATES

**Device Available for Evaluation:** R
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** TAPERTIP RESPONSIBLE HANDPIECE-20 DEGREE
- **Device Type:** LASER FIBER
- **Device Type:** 20405-M, 20405-M
- **Catalog:** 20405-M, 20405-M
- **Serial:** (*confidential*)
- **Lot:** 11676, 11676
- **Other ID:** NA

REPROCESSED & REUSED: N/A

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [b] (6)
- **Email:** [b] (6)
- **Phone:** [b] (6)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

Recd: 299  Page: 601  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>29-Oct-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>10-Feb-1997</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>10-Feb-1997</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>10-Feb-1997</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1419951-1997-00006</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>2801 BARRANCA RD</td>
</tr>
<tr>
<td>IRVINE, CA 92606</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, DISTRIBUTOR</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 20001
- **Catalog:** 350000
- **Serial:** (*confidential*)
- **Lot:** 03ADT001
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

EMAIL: [Redacted]  Phone: [Redacted]  International: [Redacted]  Fax: [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-1997-00007  Mfr Name: TRIMEDYNE, INC.

Date Received: 11-Mar-1997

Event Date (B3): 03-Oct-1996
Report Date (B4): 10-Feb-1997
Report Date (F8): 10-Feb-1997
Date Mfr Rec'd (G4): 10-Feb-1997

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Device Age (F9): 4 YR -182 DAYS (3.5 YR)
Manufacture Date (H4): 01-Jun-1993
Expiration Date: 01-Jun-1997

Device Evaluated by Manufacturer (H3): Yes

Event Description (B5):

Concomitant Medical Products:
UNK

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 20001
- **Catalog:** 350200
- **Serial:** (*confidential*)
- **Lot:** 03EDT017G
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Jan-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>10-Feb-1997</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>10-Feb-1997</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>10-Feb-1997</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR -35 DAYS (11 MO)</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Mar-1996</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Mfr 20-MAR-1997: IT WAS REPORTED THAT FIBER BROKE NEAR PROXIMAL END.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>UNK</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>2801 BARRANCA RD IRVINE, CA 92606 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
</tr>
</tbody>
</table>

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

20-MAR-1997:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>OMNI REPLACEMENT FIBER ASSEMBLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>20472-HP</td>
</tr>
<tr>
<td>Catalog</td>
<td>20472-HP</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>11760</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

| Reprocessed & Reused | N/A |

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMAIL:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>(*)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Professional</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupation</td>
<td>OTHER</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-1997-00009  Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 06-Nov-1996  Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y

Report Date (B4): 14-Feb-1997  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Report Date (F8): 14-Feb-1997  Reporter Occupation (E3): OTHER

Date Mfr Rec'd (G4): 14-Feb-1997  Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-LASER FOR GASTRO- UROLOGY USE (LNK)

Device Age (F9): 3 YR -182 DAYS (2.5 YR)  Manufacture Date (H4): 01-May-1994

Expiration Date: 01-May-1998  Single Use (H5): Y

Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:
YAG LASER, MODEL AND LOT NUMBER UNKNOWN

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 20001
- **Catalog:** 350200
- **Serial:** (*confidential*)
- **Lot:** 03EEG509
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 12-Mar-1997
Event Report Type: MALFUNCTION

Mfr Name: TRIMEDYNE, INC.

Adverse Event (B1): Problem (B1): Y

Date Mfr Rec'd (G4): 20-Mar-1997

Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Event Date (B3): 12-Mar-1997

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
IRVINE, CA 92606
UNITED STATES

Report Date (B4): 20-Mar-1997

Device Operator: -

Report Date (F8): 20-Mar-1997

Reporter Occupation (E3): HEALTH PROFESSIONAL, USER FACILITY

Date Received 1419951-1997-00023

Mfr Report No: 1419951-1997-00023
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 12-Mar-1997

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Report Date (B4): 20-Mar-1997

Event Outcome (B2): -

Report Date (F8): 20-Mar-1997

Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Date Mfr Rec'd (G4): 20-Mar-1997

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: *

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

Event Description (B5):

Concomitant Medical Products:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNITIP (TM) 20 DEGREE SWITCHABLE TIP
- **Device Type:**
- **Catalog:** 20475-HP
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** No Answer
- **Occupation:** -
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-1997-00024</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Date (B3):</strong> 09-Apr-1997</td>
<td><strong>Event Report Type:</strong> MALFUNCTION</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong> 14-Apr-1997</td>
<td><strong>Adverse Event (B1):</strong> Problem (B1): Y</td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong> 14-Apr-1997</td>
<td><strong>Event Outcome (B2):</strong> OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td><strong>Date Mfr Rec'd (G4):</strong> 01-May-1997</td>
<td><strong>Event Location (F12):</strong> UNKNOWN</td>
</tr>
<tr>
<td><strong>Event Description (B5):</strong> Mfr 22-MAY-1997: NO AIMING BEAM AND NO POWER WAS NOTED. REPORTER STATED THAT APPROXIMATELY 3,000 JOULES INTO A KNEE ARTHROSCOPY PROCEDURE, THE PHYSICIAN NOTED THAT THERE WAS NO POWER AND NO AIMING BEAM EXITING FROM THE DISTAL END OF THE DEVICE. THE PROCEDURE WAS COMPLETED USING ANOTHER DEVICE (SHAVER). NO INJURIES REPORTED. NOTE: VISUAL INSPECTION OF TIP BY REPORTER NOTED A BURN HOLE LOCATED WHERE THE 30-DEGREE CURVE BEGINS.</td>
<td></td>
</tr>
<tr>
<td><strong>Concomitant Medical Products:</strong> OMNIPULSE-MAX HOLMIUM LASER (MODEL 1210-VHP)</td>
<td></td>
</tr>
<tr>
<td><strong>Device Available for Evaluation:</strong> Y</td>
<td></td>
</tr>
<tr>
<td><strong>Device Evaluated by Manufacturer (H3):</strong> No</td>
<td></td>
</tr>
<tr>
<td><strong>Remedial Action (H7):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Correction/Removal No (H9):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Additional Mfr Narrative (H10 &amp; H11):</strong> 22-MAY-1997: NOTE: ALL OF THE INFORMATION ON THIS FORM WAS COMPLETED BY THE MANUFACTURER.</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNITIP(TM)30-DEGREE SWITCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20476-HP
- **Catalog:** 20476-HP
- **Serial:** (*confidential*)
- **Lot:** 12660
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (*)
- **International:** [Redacted]
- **Fax:** [Redacted]

Health Professional: No

Occupation: OTHER

Date Last Updated: 11/2/2010 9:17 AM
Page: 613
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-1997-00026</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Date Received</td>
<td>13-Jun-1997</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>15-May-1997</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-May-1997</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>15-May-1997</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>15-May-1997</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, RENTAL COMPANY</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR 182 DAYS (1.5 YR)</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Nov-1995</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products: TRIMEDYNE OMNI SWITCHTIP SYSTEM(HANIDPECIE WITH FIB

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
           IRVINE, CA 92606
           UNITED STATES

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
20-JUN-1997: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR. SECTION H3- EVALUATION OF FOOTSWITCH IS ON-GOING. SECTION H6-CODES ARE ONLY FOR THE LASER EMERGENCY STOP BUTTON FOOTSWITCH EVALUATION IS-GOING. EXPLANATION FOR CODE 100 (CONCLUSION)- USER PERFORMED THEIR OWN MAINTENANCE AND INSTALLED THE EMERGENCY STOP BUTTON INCORRECTLY WHICH CAUSED IT TO MALFUNCTION.

DEVICE INFORMATION:

Brand: OMNIPULSE-MAX (TM) HOLMIUM LASER
Device Type: LASER
Device Type: 1210-VHP
Catalog: 1210-VHP
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Email: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Health Professional: Yes
Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 26-Jun-1997

MFR Report No: 1419951-1997-00027
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 23-May-1997
Report Date (B4): 27-May-1997
Report Date (F8): 27-May-1997
Date Mfr Rec'd (G4): 27-May-1997

Event Report Type: MALFUNCTION
Report Date (F8): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 1 YR 0 DAYS (1 YR)
Expiration Date: 01-Sep-1997

Manufacture Date (H4): 01-Sep-1996
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 02-JUL-1997: IT WAS REPORTED THAT "THE TIP OF THE FIBER FELL OFF INTO PT WHILE TREATING A STONE." CONTACT PERSON REPORTED THAT IMMEDIATELY AFTER PHYSICIAN PLACED FIBER AT TREATMENT SITE AND ACTIVATED LASER (BY DEPRESSION FOOTSWITCH), THE FIBER APPEARED NOT TO BE WORKING. THIS WAS DETERMINED BY THE LACK OF TISSUE INTERACTION AT THE TREATMENT SITE. PHYSICIAN REQUESTED FOR LASER SETTING TO BE RAISED TO APPROXIMATELY 15 WATTS AND HE STILL NOTED NO TISSUE INTERACTION. FIBER WAS REMOVED FROM TREATMENT SITE AND PHYSICIAN NOTED THAT THE TIP WAS MISSING. PHYSICIAN RETRIEVED FIBER TIP FROM PT USING FORCEPS. THE PROCEDURE WAS THEN COMPLETED BY ANOTHER METHOD (TO OTHER METHOD WAS STENT PLACEMENT). NO INJURIES WERE REPORTED.

Concomitant Medical Products:
OMNIPULSE(TM) HOLMIUM LASER MODEL 1210.

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-JUL-1997:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 365 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20007
- **Catalog:** 20007
- **Serial:** (*confidential*)
- **Lot:** 12445
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

- **Health Professional:** Yes

- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Date Received
11-Jul-1997

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-1997-00028</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 09-May-1997

**Report Date (B4):** 13-Jun-1997

**Report Date (F8):** 13-Jun-1997

**Date Mfr Rec'd (G4):** 13-Jun-1997

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):**

**Reporter Occupation (E3):** 002 - NURSE

**Device Operator:** HEALTH PROFESSIONAL

**Adverse Event (B1):**

**Problem (B1):** Y

**Event Location (F12):** HOSPITAL

**Report Source (G3):** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** 1 YR -65 DAYS (10 MO)

**Expiration Date:** 01-Sep-2000

**Single Use (H5):** Y

**Device Usage (H8):** I

**Event Description (B5):**


**Concomitant Medical Products:**

OMNIPULSE-MAX HOLMIUM LASER

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 2801 BARRANCA RD.

IRVINE, CA 92606

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H4):**

Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

16-JUL-1997:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** 365 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20007
- **Catalog:** 20007
- **Serial:** (*confidential*)
- **Lot:** 12445
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received 25-Jul-1997

MFR Report No: 1419951-1997-00030  Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 25-Jun-1997  Event Report Type: MALFUNCTION
Report Date (F8): 25-Jun-1997  Reporter Occupation (E3): OTHER

Adverse Event (B1):  Problem (B1): Y

Date Mfr Rec'd (G4): 25-Jul-1997

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Code:  
Expiration Date:  
Device Age (F9):  
Manufacture Date (H4): 01-Jul-1997
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: Y  Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
30-JUL-1997: NOTE: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR. SECTION H6-CODES ARE ONLY FOR THE LASER; FOOTSWITCH EVAL IS ANTICIPATED UPON ITS RECEIPT.

**DEVICE INFORMATION:**

- **Brand:** OMNIPULSE-MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **Phone:** [Redacted]
- **International:**
- **Fax:** [Redacted]

**Email:** [Redacted]

**Health Professional:** Yes

**Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**


Concomitant Medical Products:

20470-HP (LOT NUMBER, UNKNOWN).

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

05-SEP-1997:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OMNI TIP(TM) SJ-90 MM STRAIGHTFIRE SWITCHABLE TIP
Device Type: LASER FIBER
Device Type: 20495-HP
Catalog: 20495-HP
Serial: (*confidential*)
Lot: 12794
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Email: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes
Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>17-Jul-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>04-Aug-1997</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Aug-1997</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1419951-1997-00032</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):** 01-May-1994

**Expiration Date:** 01-May-1998

**Single Use (H5):** Y

**Device Usage (H8):** I

**Event Description (B5):**

Mfr 11-SEP-1997: IT WAS REPORTED ON DISTRIBUTOR'S INCIDENT REPORT THAT "WHILST USING THE FIBER DURING "ELAP" PROCEDURE, SURGEON STATED "THE TIPS CAME OFF." HE COLLECTED MISSING TIP." NO INJURIES WERE REPORTED.

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 2801 BARRANCA RD.

IRVINE, CA 92606

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

11-SEP-1997:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVELOPMENT INFORMATION:

Brand: UROLASE(TM) SL RIGHT ANGLE LASER FIBER
Device Type: LASER FIBER
Catalog: 3500SL
Serial: (*confidential*)
Lot: 03EEG504

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Unknown

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-1997-00033</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
</table>

| Event Date (B3): | 29-Sep-1997 |
| Report Date (B4): | 12-Nov-1997 |
| Report Date (F8): | |
| Date Mfr Rec'd (G4): | 12-Nov-1997 |

| Event Report Type: | MALFUNCTION |
| Event Outcome (B2): | |
| Reporter Occupation (E3): | OTHER |
| Device Operator: | HEALTH PROFESSIONAL |

| Adverse Event (B1): | Problem (B1): Y |

| Device Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): | 01-Aug-1995 |
| Expiration Date: | 01-Aug-1999 |
| Single Use (H5): | Y |
| Device Usage (H8): | I |

Event Description (B5):

Concomitant Medical Products:
OMNIPULSE-MAX HOLMIUM LASER MODEL 1210-VHP.

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA ROAD
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** DISPOSABLE TAPERTIP SIDEFIRE
- **Device Type:** LASER FIBER
- **Device Type:** 20409
- **Catalog:** 20409
- **Serial:** (*confidential*)
- **Lot:** 11059
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Occupation:** OTHER

Recd: 312  Page: 627  Date Last Updated: 11/2/2010 9:17 AM
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>24-Nov-1997</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>25-Nov-1997</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>25-Nov-1997</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Product Code: | (GU)-LASER FOR GASTRO-UROLOGY USE (LNK) |
| Device Age (F9): | 01-Sep-1993 |
| Expiration Date: | 01-Sep-1997 |

**Event Description (B5):**

Mfr 02-JAN-1998: AS REPORTED ON DISTRUBUTOR REPORT: "TIP OF FIBER SEPARATED DURING USE. TIP WAS RETRIEVED WITHOUT INCIDENT BY PLACING GRASPING FORCEPS THROUGH THE PREVIOUSLY PLACED SCOPE." NO INJURY WAS REPORTED.

**Concomitant Medical Products:**

| Mfr Name: | TRIMEDYNE, INC. |
| Address: | 2801 BARRANCA ROAD |
| IRVINE, CA 92606 |
| UNITED STATES |

**Device Available for Evaluation:**

| N |

**Device Evaluated by Manufacturer (H3):**

| Yes |

**Remedial Action (H7):**

| Correction/Removal No (H9): | NA |

**Additional Mfr Narrative (H10 & H11):**

| 02-JAN-1998: |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 20001
- **Catalog:** 350200
- **Serial:** (*confidential*)
- **Lot:** 0HDT024
- **Other ID:** NA

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**

**Health Professional:** No

**Occupation:** OTHER
**Event Description (B5):**

Mfr 02-APR-1998: IT WAS REPORTED THAT TIP BROKE WHILE IN PT'S KNEE. REPORTER STATED THAT APPROXIMATELY 10 MINUTES INTO A KNEE ARTHROSCOPY PROCEDURE, PHYSICIAN NOTED ON THE VIDEO MONITOR THAT THE TIP (DEVICE # 1) HAD BROKEN AND WAS IN THE PT'S KNEE. A SHAVER WAS USED TO RETRIEVE THE GLASS PIECES. A BRAND NEW TAPERTIP (DEVICE # 2) WAS CONNECTED, PROCEDURE CONTINUED. APPROXIMATELY 15 MINUTES OF LASING WITH SECOND DEVICE, AGAIN THE PHYSICIAN NOTED THAT THERE WAS NO ENERGY EMITTING AT TREATMENT SITE. UPON INSPECTING DISTAL TIP OF DEVICE IT WAS NOTED TO BE BROKEN. THE PROCEDURE WAS THEN COMPLETED USING A SHAVER (THIS WAS ALSO USED TO RETRIEVE THE FRAGMENTS FROM PT'S KNEE). NO INJURIES WERE REPORTED. NOTE: DEVICE # 1 HAD BEEN PREVIOUSLY USED AND STEAM STERILIZED ONCE PRIOR TO THIS PROCEDURE. DEVICE # 2 WAS BRAND NEW (OUT OF PACKAGE).

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 2801 BARRANCA RD.

IRVINE, CA 92606

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
02-APR-1998: NOTE: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR. SECTION H6: POSSIBLE CAUSES OF FIBER FRACTURE ARE LASING AGAINST HARD TISSUES, LASING IN CONTACT MODE, MECHANICAL DAMAGE AND/OR END OF LIFE. NOTE: THE EVENT DESCRIPTION INCLUDES 2 PRODUCTS USED IN THIS PROCEDURE, THEREFORE PRODUCT # 1 RESULTS ARE INCLUDED IN THIS REPORT, PRODUCT # 2 RESULTS ARE DESCRIBED IN MDR # 1419951-1998-00002. VISUAL INSPECTION OF REPORTED DEVICE SHOWED FIBER IS FRACTURED AT THE DISTAL TIP. METAL SHAFT DEMONSTRATES CONSIDERABLE THERMAL DAMAGE. TRIMEDYNE BELIEVES THE POSSIBLE CAUSES ARE LASING AGAINST HARD TISSUES, LASING IN CONTACT MODE INSTEAD OF NEAR CONTACT, MECHANICAL DAMAGE AND/OR END OF LIFE. THERE IS NO CORRECTIVE ACTION BECAUSE CARE OF DEVICE IS ADDRESSED IN INSTRUCTIONS FOR USE.

DEVICE INFORMATION:
- **Brand:** TAPERTIP RESPOSABLE HANDPIECE - 30 DEGREE
- **Device Type:** LASER FIBER
- **Device Type:** 20402-M
- **Catalog:** 20402-M
- **Serial:** (*confidential*)
- **Lot:** 13768
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** OTHER
- **Health Professional:** Yes

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 24-Feb-1998
Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

MFR Report No: 1419951-1998-00002
Event Date (B3): 18-Feb-1998
Report Date (B4): 24-Feb-1998
Report Date (F8): 24-Feb-1998
Date Mfr Rec'd (G4): 24-Feb-1998

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL
Report Source (G3): 3RD PARTY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Oct-1997
Expiration Date: 01-Oct-2001
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 02-APR-1998: IT WAS REPORTED THAT TIP BROKE WHILE IN PT'S KNEE. REPORTER STATED THAT APPROXIMATELY 10 MINUTES INTO A KNEE ARTHROSCOPY PROCEDURE, PHYSICIAN NOTED ON THE VIDEO MONITOR THAT THE TIP (DEVICE #1) HAD BROKEN AND WAS IN THE PT'S KNEE. A SHAVER WAS USED TO RETRIEVE THE GLASS PIECES. A BRAND NEW TAPETIP (DEVICE #2) WAS CONNECTED, PROCEDURE CONTINUED. APPROXIMATELY 15 MINUTES OF LASING WITH SECOND DEVICE, AGAIN THE PHYSICIAN NOTED THAT THERE WAS NO ENERGY EMITTING AT TREATMENT SITE. UPON INSPECTING DISTAL TIP OF DEVICE IT WAS NOTED TO BE BROKEN. THE PROCEDURE WAS THEN COMPLETED USING A SHAVER (THIS WAS ALSO USED TO RETRIEVE THE FRAGMENTS FROM PT'S KNEE). NO INJURIES WERE REPORTED. NOTE: DEVICE #1 HAS BEEN PREVIOUSLY USED AND STEAM STERILIZED ONCE PRIOR TO THIS PROCEDURE. DEVICE #2 WAS BRAND NEW (OUT OF THE PACKAGE).

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Recd: 315
Page: 632

Date Last Updated: 11/2/2010 9:17 AM
02-APR-1998: NOTE: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR. SECTION H6: POSSIBLE CAUSES OF FIBER FRACTURE ARE LASING AGAINST HARD TISSUES, LASING IN CONTACT MODE, MECHANICAL DAMAGE AND/OR END OF LIFE. NOTE: THE EVENT DESCRIPTIONS INCLUDES 2 PRODUCTS USED IN THIS PROCEDURE, THEREFORE PRODUCT # 2 RESULTS ARE INCLUDED IN THIS REPORT, PRODUCT # 1 RESULTS ARE DESCRIBED IN MDR # 1419951-1998-00001. VISUAL INSPECTION OF REPORTED DEVICE SHOWED FIBER FRACTURED AT THE DISTAL TIP. METAL SHAFT DEMONSTRATES CONSIDERABLE THERMAL DAMAGE. TRIMEDYNE BELIEVES THE POSSIBLE CAUSES ARE LASING AGAINST HARD TISSUES, LASING IN CONTACT MODE INSTEAD OF NEAR CONTACT, MECHANICAL DAMAGE AND/OR END OF LIFE. THERE IS NO CORRECTIVE ACTION BECAUSE CARE OF DEVICE IS ADDRESSED IN INSTRUCTIONS FOR USE.

DEVICE INFORMATION:

Brand: TAPERTIP RESPOSABLE HANDPIECE - 30 DEGREE
Device Type: LASER FIBER
Devicet Type: 20402-M
Catalog: 20402-M
Serial: (*confidential*)
Lot: 13768
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (redacted)
Address: (redacted)

Health Professional: Yes

EMAIL: (redacted)
Phone: (redacted)
International: (redacted)
Fax: (redacted)

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>26-Mar-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>1419951-1998-00003</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
</tbody>
</table>

| Event Date (B3): | 19-Feb-1998 |
| Report Date (B4): | 24-Feb-1998 |
| Report Date (F8): | 24-Feb-1998 |
| Date Mfr Rec'd (G4): | 24-Feb-1998 |
| Event Report Type: | MALFUNCTION |
| Event Outcome (B2): | |
| Reporter Occupation (E3): | HEALTH PROFESSIONAL |
| Device Operator: | HEALTH PROFESSIONAL |
| Adverse Event (B1): | Problem (B1): Y |
| Event Location (F12): | 3RD PARTY |
| Report Source (G3): | HEALTH PROFESSIONAL |
| MFR Report No: | 3RD PARTY |
| Report Date (F8): | 24-Feb-1998 |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): | 01-Oct-1997 |
| Expiration Date: | 01-Oct-2001 |
| Manufacture Date (H4): | 01-Oct-1997 |
| Single Use (H5): | N |
| Device Usage (H8): | R |

**Event Description (B5):**

Mfr 02-APR-1998: IT WAS REPORTED THAT TIP BROKE IN PT'S KNEE. REPORTER STATED THAT APPROXIMATELY 10 MINUTES INTO A KNEE ARTHROSCOPY PROCEDURE WHILE LASING THE MENISCAL TISSUE, PHYSICIAN NOTED THAT THE TIP BROKE (FIBER) INTO PT'S KNEE. THE PHYSICIAN USED A SHAVER TO REMOVE THE FRAGMENTS AND TO COMPLETE PROCEDURE. NO INJURIES WERE REPORTED.

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:**

2801 BARRANCA RD.

IRVINE, CA 92606

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

02-APR-1998: NOTE: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR. SECTION H6: RESULT CODE: 400- FIBER FRACTURE CONCLUSION CODE: -POSSIBLE CAUSES OF FIBER FRACTURE ARE LASING AGAINST HARD TISSUES, LASING IN CONTACT MODE AND/OR MECHANICAL DAMAGE. VISUAL INSPECTION OF REPORTED DEVICE NOTED FIBER IS FRACTURED AT THE DISTAL TIP. METAL SHAFT DEMONSTRATES CONSIDERABLE THERMAL DAMAGE. TRIMEDYNE BELIEVES THE POSSIBLE CAUSES ARE LASING AGAINST HARD TISSUES, LASING IN CONTACT MODE INSTEAD OF NEAR CONTACT, AND OR MECHANICAL DAMAGE. THERE IS NO CORRECTIVE ACTION BECAUSE CARE OF DEVICE IS ADDRESS INSTRUCTIONS FOR USE.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TAPERTIP RESPOSABLE HANDPIECE- 30 DEGREE
- **Device Type:** LASER FIBER
- **Device Type:** 20402-M
- **Catalog:** 20402-M
- **Serial:** (*confidential*)
- **Lot:** 13768
- **Other ID:** NA

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

| Event Date (B3): | 01-Feb-1998 | Event Report Type: | MALFUNCTION | |
| Report Date (B4): | 25-Feb-1998 | Event Outcome (B2): | | |
| Report Date (F8): | | Reporter Occupation (E3): | OTHER | |
| Date Mfr Rec'd (G4): | 25-Feb-1998 | Device Operator: | HEALTH PROFESSIONAL | |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) | |
| Device Age (F9): | 01-Jan-1996 | Manufacture Date (H4): | | |
| Expiration Date: | 01-Jan-2000 | Single Use (H5): | Y | |
| Device Usage (H8): | | |

Event Description (B5):


Concomitant Medical Products:

NA

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):

03-APR-1998: NOTE: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>TAPERTIP SJ-90 MM STRAIGHTFIRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type 2</td>
<td>20435</td>
</tr>
<tr>
<td>Catalog</td>
<td>20435</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>11578</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>[b] [b]</th>
</tr>
</thead>
<tbody>
<tr>
<td>[b] [b]</td>
<td>[b] [b]</td>
</tr>
<tr>
<td>Address:</td>
<td>[b] [b]</td>
</tr>
<tr>
<td>Health Professional:</td>
<td>No</td>
</tr>
<tr>
<td>EMAIL:</td>
<td>[b] [b]</td>
</tr>
<tr>
<td>Phone:</td>
<td>[b] [b]</td>
</tr>
<tr>
<td>International:</td>
<td>[b] [b]</td>
</tr>
<tr>
<td>Fax:</td>
<td>[b] [b]</td>
</tr>
</tbody>
</table>

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>03-Apr-1998</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>06-Apr-1998</td>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td>3RD PARTY SERVICE PROVIDER</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>06-Apr-1998</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>06-Apr-1998</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1419951-1998-00005</td>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 13-MAY-1998: IT WAS REPORTED THAT, FIBER FRACTURED AND BLISTERED PHYSICIAN'S HAND.* REPORTER STATED THAT APPROXIMATELY 700 JOULES INTO A URETORSCOPY PROCEDURE, THE FIBER FRACTURED WHERE IT ENTERS THE SCOPE; BLISTERING THE PHYSICIAN'S HAND. PHYSICIAN IMMEDIATELY STOPPED LASING TO REPLACE IT WITH ANOTHER BRAND NEW FIBER (SAME MODEL, LOT NUMBER UNKNOWN). PROCEDURE WAS COMPLETED WITH SECOND FIBER WITHOUT ANY FURTHER INCIDENT. NO INJURIES TO PT WERE REPORTED. REPORTER DESCRIBED THE BLISTER TO BE APPROXIMATELY THE SIZE OF AN ERASER ON A PENCIL, WITH THE CENTER BEING PINK.

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:**

2801 BARRANCA RD

IRVINE, CA 92606

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

13-MAY-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20005
- **Catalog:** 20005
- **Serial:** (*confidential*)
- **Lot:** 14023
- **Other ID:** NA

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER
- **Phone:** [Redacted]
- **Fax:** [Redacted]
- **EMAIL:** [Redacted]

Reprocessed & Reused: N/A

Date Last Updated: 11/2/2010 9:17 AM
Event Date (B3): 01-May-1998
Report Date (B4): 14-May-1998
Report Date (F8):
Date Mfr Rec’d (G4):

MFR Report No: 1419951-1998-00007
Mfr Name: TRIMEDYNE, INC.

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Location (F12):

Report Date (B4): 14-May-1998
Event Report Type: MALFUNCTION
Event Location (F12):

Adverse Event (B1):
Problem (B1): Y

Event Location (F12):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Code:

Device Age (F9): Manufacture Date (H4): 01-Aug-1997
Expiration Date: 01-Aug-2001
Single Use (H5): N
Device Usage (H8): I

Event Description (B5):
Mfr 18-JUN-1998: IT WAS REPORTED THAT, "TIP BROKE OFF AND FELL INTO PT'S KNEE." RPTR STATED THAT IMMEDIATELY UPON DEPRESSING FOOTSWITCH (ACTIVATING LASER ENERGY AT TREATMENT SITE), PHYSICIAN NOTED ON THE VIDEO MONITOR THAT A PIECE OF FIBER (APPROX 1/4 OF INCH) FELL INTO PT'S KNEE. THE PHYSICIAN ATTEMPTED TO REMOVE FIBER, HOWEVER PHYSICIAN WAS NOT SURE WHETHER EVERYTHING WAS RETRIEVED. A BRAND NEW FIBER TIP WAS USED TO COMPLETE THE PROCEDURE WITHOUT FURTHER INCIDENT. NO INJURIES WERE REPORTED. NOTE: REPORTED DEVICE WAS BRAND NEW (FIRST TIME USE) IN THIS PROCEDURE.

Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
18-JUN-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** RESPOSABLE OMNITIP 30-DEGREE SWITCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20476M-HP
- **Catalog:** 20476M-HP
- **Serial:** (*confidential*)
- **Lot:** 13591
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER

**EMAIL:** [redacted]
**Phone:** [redacted]
**International:** [redacted]
**Fax:** [redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1419951-1998-00008</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Event Date (B3): 09-Jun-1998</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Report Date (F8): 10-Jun-1998</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date Mfr Rec'd (G4): 10-Jun-1998</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9): 01-Dec-1997</td>
<td>Manufacture Date (H4): 01-Dec-1997</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expiration Date: 01-Dec-2001</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 16-JUL-1998: IT WAS REPORTED THAT "WHILE RUBBER STRAIN RELIEF AND FIBEROPTIC DISCONNECTED FROM PROXIMAL CONNECTOR."

REPORTER STATED THAT APPROXIMATELY ONE MINUTE INTO A UROLOGICAL PROCEDURE, REPORTER NOTED THAT THERE WAS NO LASER ENERGY EMITTING AT TREATMENT SITE. THE PROCEDURE WAS PAUSED TO REPLACE THE FIBER. UPON DISCONNECTING FIBER FROM LASER THE WHITE STRAIN RELIEF AND FIBEROPTIC COMPLETELY SEPARATED FROM METAL CONNECTOR. PROCEDURE WAS COMPLETED USING A SECOND FIBER (SAME MODEL) WITHOUT FURTHER INCIDENT. NO INJURIES TO PT OR PERSONNEL WERE REPORTED.

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 2801 BARRANCA RD

IRVINE, CA 92606

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

16-JUL-1998:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: 200 MICRON HOLMIUM BARE FIBER WITH FLAT TIP
- Device Type: LASER FIBER
- Device Type: 20005
- Catalog: 20005
- Serial: (*confidential*)
- Lot: 14023
- Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- EMAIL: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
- Occupation: OTHER

Health Professional: Unknown
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 31-Aug-1998

MFR Report No: 1419951-1998-00010
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 05-Aug-1998
Report Date (B4): 06-Aug-1998
Report Date (F8): 06-Aug-1998
Date Mfr Rec'd (G4): 06-Aug-1998

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8):
Device Operator: HEALTH PROFESSIONAL

Device Age (F9): 01-Dec-1997
Expiration Date: 01-Dec-2001
Single Use (H5): N
Device Usage (H8): R

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):

Event Description (B5):
Mfr 03-SEP-1998: IT WAS REPORTED THAT FIBER BROKE (COMPLETELY SEPARATED NEAR LASER CONNECTOR. CONTACT PERSON HEARD A POPPING SOUND UPON PHYSICIAN STEPPING ON FOOTSWITCH DURING A SHOULDER ARTHROSCOPY PROCEDURE. CONTACT PERSON PROCEEDED TO INSPECT FIBER AND FIBER FELL APART INTO TWO PIECES (SEPARATING AT THE LASER CONNECTOR). A SECOND FIBER ASSEMBLY WAS CONNECTED AND PROCEDURE WAS COMPLETED WITHOUT FURTHER INCIDENT. NO INJURIES TO STAFF OR PT REPORTED. REPORTED DEVICE HAD BEEN PREVIOUSLY USED AND RESTERILIZED AT LEAST ONCE PRIOR TO PROCEDURE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
03-SEP-1998: ALL OF THE INFO ON THIS FORM WAS COMPLETED BY THE MFR. SECTION A (PT INFO): ATTEMPTS AT ACQUIRING PT INFO IS ON-GOING.
H6: FIBER OPTIC BREAK. DEVICE DAMAGED DURING HANDLING. EVAL SUMMARY: NOTE: THE FOLLOWING INFO IS CONSIDERED TO BE CONFIDENTIAL. VISUAL INSPECTION OF RETURNED PRODUCT NOTED THE PROXIMAL CONNECTOR IS BROKEN OFF (COMPLETELY SEPARATED) AT BOOT STRAIN RELIEF, FIBER IS BURNT AT BREAK. EPOXY IS BURNED WHERE FIBER BREAK OCCURRED INDICATING THAT LASING CONTINUED AFTER OUTPUT AT THE OPERATING SITE HAD SIGNIFICANTLY DIMINISHED. TRIMEDYNE BELIEVES THE POSSIBLE CAUSE COULD BE THAT DEVICE WAS DAMAGED DURING HANDLING. CARE OF DEVICE IS ADDRESSED IN PACKAGE INSERT.

DEVICE INFORMATION:

- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 14060
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:** (b) (b)
- **Fax:**
- **Occupation:** 002 - NURSE
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>09-Feb-1999</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Date Mfr Rec'd (G4):</th>
<th>22-Feb-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>22-Feb-1999</td>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td>3RD PARTY SERVICE PROVIDER</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Feb-1999</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Nov-1998</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Nov-2002</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer
**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
31-MAR-1999: NOTE: THE MANUFACTURER COMPLETED ALL OF THE INFORMATION ON THIS FORM. ATTEMPTS AT ACQUIRING PRODUCT FOR EVALUATION ARE ON-GOING.
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

Brand: RESPONSABLE OMNITIP 30-DEGREE SWITCHABLE TIP
Device Type: LASER FIBER
Device Type: 20476M-HP
Catalog: 20476M-HP
Serial: (*confidential*)
Lot: 14853
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health Professional: Unknown

EMAIL: [b] (b)
Phone: [b] (b)
International: Fax:

Occupation: OTHER
CDRH MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Products Code:</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>09-Jun-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>1419951-1999-00002</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Date (B3):** 08-Apr-1999  
**Report Date (B4):** 11-May-1999  
**Report Date (F8):** 11-May-1999  
**Date Mfr Rec'd (G4):** 11-May-1999  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Report Type:** MALFUNCTION  
**Event Date (B3):** 08-Apr-1999  
**Event Outcome (B2):**  
**Report Date (F8):** 11-May-1999  
**Report Source (G3):** HEALTH PROFESSIONAL  
**Event Location (F12):** OUTPATIENT TREATMENT FACILITY  
**Adverse Event (B1):** Problem (B1): Y  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Report Date (F8):** 11-May-1999  
**Report Source (G3):** HEALTH PROFESSIONAL  

**Event Description (B5):**  
Mfr 18-JUN-1999: IT WAS REPORTED THAT FIBER BROKE AT PROXIMAL END OF FIBER ASSEMBLY (NEAR LASER CONNECTION). CONTACT PERSON REPORTED THAT DURING AN ARTHROSCOPY PROCEDURE, AFTER PHYSICIAN HAD LASED FOR APPROX TWO CYCLES (UNKNOWN NUMBER OF JOULES), PHYSICIAN AND LASER STAFF NOTICED THAT THE FIBER HAD BROKEN NEAR THE PROXIMAL CONNECTOR. THE PROCEDURE WAS IMMEDIATELY PAUSED TO REPLACE THE REPORTED DEVICE. PROCEDURE WAS COMPLETED WITHOUT FURTHER INCIDENT. NO INJURIES WERE REPORTED.

**Concomitant Medical Products:**  
NA

**Mfr Name:** TRIMEDYNE, INC.  
**Address:** 2801 BARRANCA RD.  
IRVINE, CA 92606  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  
**Remedial Action (H7):**  
**Correction/Removal No (H9):** NA  
**Additional Mfr Narrative (H10 & H11):** 18-JUN-1999:
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

DEVICE INFORMATION:

Brand:  HO: YAG STRAIGHTFIRE LASER NEEDLE
Device Type:  LASER FIBER
Device Type:  20302
Catalog:  20302
Serial:  (*confidential*)
Lot:  R8278
Other ID:  NA

Reprocessed & Reused:  N/A

REPORTER INFORMATION:

Name:  [b] (6)
Address:  [b] (6)

Health Professional:  No

EMAIL:  [b] (6)
Phone:  [b] (6)
International:  
Fax:  

Occupation:  OTHER

Recd:  323 Page:  649 Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 1419951-1999-00003 Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 25-Sep-1998
Report Date (B4): 11-Dec-1998
Report Date (F8): 12-Oct-1998
Date Mfr Rec'd (G4): 11-Dec-1998
Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3):
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3): 3RD PARTY SERVICE PROVIDER

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 0 YR 180 DAYS (6 MO)
Expiration Date: 01-Mar-2002
Manufacture Date (H4): 01-Mar-1998
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 21-JUN-1999: IT WAS REPORTED THAT NO AIMING BEAM AND A PUFF OF SMOKE WAS SEEN AT FIBER ASSEMBLY TO HANDPIECE CONNECTION. THE REPORTER STATED THAT IMMEDIATELY UPON PHYSICIAN STEPPING ON LASER FOOTSWITCH, THERE WAS NO PRESENCE OF AN AIMING BEAM AND AT THE SAME TIME A PUFF OF SMOKE WAS SEEN AT THE HANDPIECE TO FIBER ASSEMBLY CONNECTION. THE LASER PROCEDURE WAS PAUSED AND THE SWITCHTIP SYSTEM WAS REPLACED. PROCEDURE WAS COMPLETED WITHOUT FURTHER INCIDENT. NO INJURIES INVOLVED.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 14321
- **Other ID:** NA

Additional Mfr Narrative (H10 & H11):

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>28-Jun-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>1419951-1999-00004</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>16-Mar-1998</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>05-May-1998</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>2801 BARRANCA RD. IRVINE, CA 92606 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 06-JUL-1999: IT WAS REPORTED THAT NO POWER EXITING FROM TIPS DURING PROCEDURE. RPTR STATED THAT APPROX 30 MINUTES INTO A SHOULDER ARTHROSCOPY PROCEDURE, PHYSICIAN NOTED THAT THERE WAS NO TISSUE INTERACTION AT TREATMENT SITE. DEVICES WAS REMOVED FROM TREATMENT SITE AND REPLACED WITH ANOTHER OF THE SAME MODEL AND LOT NUMBER. AFTER LASING WITH 2ND DEVICE FOR APPROX 10 MINUTES, PHYSICIAN ONCE AGAIN NOTED NO TISSUE INTERACTION AT TREATMENT SITE. A THIRD TAPETIP WAS USED TO COMPLETE THE PROCEDURE. NO INJURIES WERE REPORTED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** TAPERTIP RESPONSABLE HANDPIECE - 30 DEGREE
- **Device Type:** LASER FIBER
- **Device Type:** 20402-M
- **Catalog:** 20402-M
- **Serial:** (*confidential*)
- **Lot:** 13867
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-1999-00005  Mfr Name: TRIMEDYNE, INC.  Date Received: 28-Jun-1999

Event Date (B3): 13-Feb-1998  Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y
Report Date (B4): 26-May-1998  Event Outcome (B2):  
Report Date (F8):  
Date Mfr Rec'd (G4): 26-May-1998  Reporter Occupation (E3): OTHER  Event Location (F12):  
Device Operator: HEALTH PROFESSIONAL  Report Source (G3): THIRD PARTY SERVICE PROVIDER

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
Device Age (F9): Manufacture Date (H4): 01-Dec-1996  Single Use (H5): Y  
Expiration Date: 01-Dec-2000  Device Usage (H8): I

Event Description (B5):
Mfr 06-JUL-1999: IT WAS REPORTED THAT AFTER SEVERAL SECONDS OF LASING, BOTH FIBERS HAD NO POWER OUTPUT. RPTR STATED THAT DURING A LITHOTRIPSY PROCEDURE PHYSICIAN NOTED THAT AFTER LASING FOR ABOUT 5 SECONDS USING LESS THAN 10 WATTS THERE WAS NO ENERGY EXITING THE DISTAL END. THE MACHINE (LASER) PLACED ON STANDBY, A SECOND FIBER WAS CONNECTED. PHYSICIAN DEPRESSED FOOTSWITCH AND AFTER A COUPLE OF SECONDS NOTED THAT THERE WAS NO EFFECT AT THE TREATMENT SITE. THE LASER PROCEDURE WAS STOPPED. NO INJURIES WERE REPORTED.

Concomitant Medical Products: NA

Mfr Name: TRIMEDYNE, INC.  Address: 2801 BARRANCA RD.  
IRVINE, CA 92606  UNITED STATES  
Device Available for Evaluation: R  
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:
- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20005
- **Catalog:** 20005
- **Serial:** (*confidential*)
- **Lot:** 12622
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER
### MAUDE EVENT REPORT (FOI)

#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2000-00001</th>
<th>Date Received</th>
<th>08-Feb-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-Jan-2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>13-Jan-2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>13-Jan-2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>13-Jan-2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>13-Jan-2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>THIRD PARTY SERVICE PROVIDER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>2801 BARRANCA RD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92606</td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR -35 DAYS (11 MO)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Mar-2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Feb-1999</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Event Description (B5):


#### Concomitant Medical Products:

NA

#### Device Available for Evaluation:

Y

#### Device Evaluated by Manufacturer (H3):

Yes

#### Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TAPERTIP SJ-90MM STRAIGHTFIRE
- **Device Type:** LASER FIBER
- **Device Type:** 20435
- **Catalog:** 20435
- **Serial:** (*confidential*)
- **Lot:** 14979
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Unknown
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>24-Jan-2000</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>24-Jan-2000</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>24-Jan-2000</td>
<td>Reporter Occupation (E3):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 24-FEB-2000: IT WAS REPORTED: FIBER BREAK APPROX 3 FEET BACK FROM HANDPIECE. REPORTER STATED: SOMETIME INTO A KNEE ARTHROSCOPY PROCEDURE A LOUD POPPING WAS HEARD AND REPORTER SAW A SPARK. REPORTER DISCONTINUED USE OF THE FIBER. APPROX 3 FEET BACK FROM HANDPIECE FIBER RUPTURED OUT THE SIDE. REPORTER HOOKED UP A NEW DEVICE AND FINISHED THE PROCEDURE WITHOUT FURTHER INCIDENT. NO INJURIES WERE REPORTED.

**Concomitant Medical Products:**
NA

**Mfr Name:** TRIMEDYNE, INC.
**Address:** 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
24-FEB-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. ATTEMPTS AT ACQUIRING PRODUCT FOR EVALUATION ARE ON-GOING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TAPERTIP RESPONSABLE HANDPIECE-30 DEGREE
- **Device Type:** LASER FIBER
- **Device Type:** 20402-M
- **Catalog:** 20402-M
- **Serial:** (*)confidential*)
- **Lot:** 15799
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2000-00003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Feb-2000</td>
</tr>
</tbody>
</table>

- **Event Date (B3):** 22-Feb-2000
- **Report Date (B4):** 24-Feb-2000
- **Date Mfr Rec'd (G4):** 24-Feb-2000

- **Event Report Type:** MALFUNCTION
- **Event Outcome (B2):**
- **Report Date (B4):** 22-Feb-2000
- **Event Location (F12):** HOSPITAL

- **Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
- **Device Age (F9):** 0 YR 150 DAYS (5 MO)
- **Manufacture Date (H4):** 01-Sep-1999
- **Expiration Date:** Single Use (H5): N
- **Device Usage (H8):** R

- **Event Description (B5):**
  Mfr 29-MAR-2000: IT WAS REPORTED THAT 24 HERTZ AND 24 WATTS, DOUBLE PULSE, THE LASER OUTPUT ENERGY IS 82 WATTS WHERE IT SHOULD ONLY BE 24 WATTS. THE PROBLEM WAS DISCOVERED DURING ROUTINE PRE-OPERATION LASER OUTPUT TESTS TO VERIFY FIBER OUTPUT ENERGY PRIOR TO SURGERY. THIS WAS PERFORMED BY A HOSP TECHNICIAN. NO INJURIES WERE REPORTED.

- **Concomitant Medical Products:**
  NA

- **Mfr Name:** TRIMEDYNE, INC.
- **Address:**
  2801 BARRANCA RD.
  IRVINE, CA 92606
  UNITED STATES

- **Device Available for Evaluation:** R
- **Device Evaluated by Manufacturer (H3):** Yes
- **Remedial Action (H7):**
- **Correction/Removal No (H9):**
- **Additional Mfr Narrative (H10 & H11):**
  29-MAR-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. EVAL SUMMARY: THE REPORTED LASER WAS RETURNED TO THE MFG FACILITY ON 3/3/2000 FOR EVAL. TESTING SHOWED THAT THE INTERNAL ENERGY DETECTOR HAD STOPPED WORKING. THE MFR OF THE ENERGY DETECTOR DETERMINED FROM ITS OWN EVAL THAT THERE WAS A MFG PROCESS NONCONFORMANCE. THIS NONCONFORMANCE HAS BEEN DETERMINED TO BE AN ISOLATED EVENT THAT RESULTED IN THE MALFUNCTIONING ENERGY DETECTOR. TRIMEDYNE WILL CONTINUE TO MONITOR REPORTED EVENTS TO DETECT ANY TRENDS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNIPULSE-MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** No
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 1419951-2000-00004
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 29-Mar-2000
Report Date (B4): 17-Apr-2000
Report Date (F8): 29-Mar-2000
Date Mfr Rec'd (G4): 17-Apr-2000

Event Report Type: MALFUNCTION
Event Location (F12): HOSPITAL

Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): OTHER
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 3 YR -182 DAYS (2.5 YR)
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
22-MAY-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. EVAL SUMMARY: THE REPORTED DETECTOR WAS RETURNED TO TRIMEDYNE FOR EVAL. TESTING FOUND THE (LOCAL LOOP) DETECTOR FAILED TO ADEQUATELY DETECT LASER OUTPUT ENERGY. THE DETECTOR WAS SENT BACK TO THE MFR FOR FURTHER INVESTIGATION AND REPAIR. NO CORRECTIVE ACTION IS PLANNED AT THIS TIME. TRIMEDYNE WILL CONTINUE TO MONITOR REPORTED EVENTS TO DETECT ANY TRENDS.

Event Description (B5):
Mfr 22-MAY-2000: IT WAS REPORTED THAT: LOW OUTPUT ERROR MESSAGE DISPLAYED ON SCREEN. FURTHER INVESTIGATION BY FIELD SVC FOUND THE PROGRAM VOLTAGE ON BOTH A AND B POWER SUPPLIES, WAS RAMPING UP TO MAXIMUM VOLTAGE BECAUSE THE INTERNAL METER (LOCAL LOOP) DETECTOR WAS NOT REGISTERING ANY ENERGY. NO INJURIES WERE REPORTED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OMNIPULSE MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (*)
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Description (B5): Mfr 01-JUN-2000: IT WAS REPORTED THAT FIBER TIP BROKE OFF IN PT'S URETER. REPORTER STATED: AT THE BEGINNING OF A URETEROSCOPY STONE MANIPULATION PROCEDURE, FIBER TIP BROKE OFF IN PT'S URETER UPON INSERTION IN SCOPE. PHYSICIAN FLUSHED THE PT'S URETER AND BLADDER AND FELT DR HAD WASHED OUT THE TIP. PROCEDURE WAS COMPLETED WITH ANOTHER DEVICE WITHOUT FURTHER INCIDENT. NO INJURIES WERE REPORTED.</td>
<td>Concomitant Medical Products: NA</td>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 365 MICRON RESPONSABLE HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20017-M
- **Catalog:** 20017-M
- **Serial:** (*confidential*)
- **Lot:** 15887
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-2000-00006  Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 01-Nov-1999  Event Report Type: MALFUNCTION
Report Date (B4): Omitted  Event Outcome (B2):
Report Date (F8): 10-Nov-1999  Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER

Date Mfr Rec'd (G4): 03-May-2000  Device Operator: HEALTH PROFESSIONAL
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 6 YR -145 DAYS (5.6 YR)  Manufacture Date (H4): 01-Nov-1994
Expiration Date: Single Use (H5): N  Device Usage (H8): R

Event Description (B5):
Mfr 08-JUN-2000: IT WAS REPORTED THAT: OUTPUT WAS LOW. FURTHER INVESTIGATION BY FIELD SERVICE FOUND THAT THE INTERNAL ENERGY DETECTOR DID NOT REGISTER ANY OUTPUT ENERGY. NO INJURIES WERE REPORTED.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: N  Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
08-JUN-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. ATTEMPTS AT ACQUIRING PRODUCT FOR EVALUATION ARE ON-GOING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** OMNIPULSE - MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

### REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Occupation:** 401 - BIOMEDICAL ENGINEER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Details

**MFR Report No:** 1419951-2000-00007  
**Mfr Name:** TRIMEDYNE, INC.  
**Date Received:** 15-Jun-2000

- **Event Date (B3):** 21-Mar-2000  
- **Report Date (B4):** 18-May-2000  
- **Report Date (F8):** 18-May-2000  
- **Date Mfr Rec'd (G4):** 18-May-2000

- **Event Report Type:** MALFUNCTION
- **Event Outcome (B2):**
- **Reporter Occupation (E3):** OTHER
- **Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):** 3 YR 0 DAYS (3 YR)  
**Manufacture Date (H4):** 01-Jun-1997

- **Expiration Date:** Single Use (H5): N  
- **Device Usage (H8):** R

**Event Description (B5):**

Mfr 22-JUN-2000: IT WAS REPORTED VIA FAX: "A" OR "B" OUTPUT ENERGY TOO LOW AND POWER ENERGY FAIL ERROR MESSAGES DISPLAYED ON SCREEN. FURTHER INVESTIGATION BY FIELD SERVICE FOUND THE INTERNAL LOCAL LOOP DETECTOR WAS NOT FUNCTIONING. NO INJURIES REPORTED.

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.  
**Address:** 2801 BARRANCA RD  
IRVINE, CA 92606  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

22-JUN-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. EVAL SUMMARY: NOTE: THE FOLLOWING INFO IS CONSIDERED TO BE CONFIDENTIAL. THE REPORTED DETECTOR WAS RETURNED TO TRIMEDYNE FOR EVAL. TESTING FOUND THAT THE (LOCAL LOOP) DETECTOR FAILED TO ADEQUATELY DETECT LASER OUTPUT ENERGY. TRIMEDYNE WILL CONTINUE TO MONITOR REPORTED EVENTS TO DETECT ANY TRENDS.
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>OMNIPULSE - MAX HOLMIUM LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER SYSTEM</td>
</tr>
<tr>
<td>Device Type</td>
<td>1210-VHP</td>
</tr>
<tr>
<td>Catalog</td>
<td>1210-VHP</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
</tr>
<tr>
<td>International:</td>
</tr>
<tr>
<td>Fax:</td>
</tr>
</tbody>
</table>

Occupation: OTHER

Health Professional: No
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-2000-00008  Mfr Name: TRIMEDYNE, INC.  Date Received: 22-Jun-2000

Event Date (B3): 11-May-2000  Event Report Type: MALFUNCTION
Report Date (B4): 27-May-2000  Event Outcome (B2):
Report Date (F8): 27-May-2000  Reporter Occupation (E3): OTHER
Date Mfr Rec'd (G4): 27-May-2000  Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 1 YR -65 DAYS (10 MO)  Manufacture Date (H4): 01-Aug-1999
Expiration Date:

Device Usage (H8): R

Event Description (B5):
Mfr 29-JUN-2000: IT WAS REPORTED: BAD SMELL COMING FROM LASER.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
29-JUN-2000: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. RESULT: OPTICS ASSEMBLY HAD THERMAL DAMAGE DUE TO BACK-SCATTER OF LASER ENERGY. CONCLUSION: POSSIBLE CAUSE IS LASER FIBER THAT WAS DAMAGED DUE TO MISHANDLING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNIPULSE - MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
EVENT DESCRIPTION (B5):

Mfr 21-JUL-2000: IT WAS REPORTED THAT DURING SET-UP TO TEST FIRE DEVICE, THE DEVICE WAS ATTACHED TO THE LASER AND POWER TURNED ON. A POP WAS HEARD AND THE FIBER BROKE CLOSE TO THE TIP. THE SURGICAL ASSISTANT RECEIVED A BURN TO THE RIGHT FLANK AT WAIST LEVEL. IT BURNED A HOLE IN SURGICAL SCRUBS. BURN WAS MINOR AND TREATED WITH AN APPLICATION OF TOPICAL OINTMENT. NO SERIOUS INJURIES WERE REPORTED.

Concomitant Medical Products:

NA

Device Available for Evaluation:  N

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):

Correction/Removal No (H9):  NA

Additional Mfr Narrative (H10 & H11):

21-JUL-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. ATTEMPTS AT ACQUIRING PRODUCT FOR EVALUATION ARE ON-GOING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TAPERTIP RESPONSIBLE HANDPIECE-30 DEGREE W/SMA CON
- **Device Type:** LASER FIBER
- **Device Type:** 20402-SMA
- **Catalog:** 20402-SMA
- **Serial:** (*confidential*)
- **Lot:** 16314
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**

- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2000-00010
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 14-Jun-2000
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 14-Jun-2000
Event Outcome (B2):

Date Mfr Rec'd (G4): 14-Jun-2000
Event Location (F12): HOSPITAL
Report Source (G3): USER FACILITY

Event Description (B5):
Mfr 21-JUL-2000: IT WAS REPORTED: "BURNED TIP" REPORTER SAID THAT DURING AN ARTHROSCOPY PROCEDURE PHYSICIAN BEGAN LASING AT 40 PPS, 40 WATTS, SINGLE PULSE FOR 20 SECONDS. PHYSICIAN ASKED FOR AN INCREASE OF POWER TO 27 PPS. 70 WATTS, SINGLE PULSE AND LASED FOR 8 TO 10 SECONDS, WHEN A FLASH AND SMOKE CAME FROM THE DEVICE. INSPECTION OF THE DEVICE SHOWED IT WAS BURNT BETWEEN HANDPIECE AND TIP. NO INJURIES WERE REPORTED.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
21-JUL-2000: THE MANUFACTURER COMPLETED ALL OF THE INFO ON THIS FORM. ATTEMPTS AT ACQUIRING PRODUCT FOR EVALUATION ARE ON-GOING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNITIP 20-DEGREE SWITCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20475-HP
- **Catalog:** 20475-HP
- **Serial:** (*confidential*)
- **Lot:** 16017
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)

Health Professional: No

EMAIL: (b) (6)

Phone: (b) (6)

International:

Fax:

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2000-00011</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>17-Jul-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Jun-2000</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Jun-2000</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Jun-2000</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>2801 BARRANCA RD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92606</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>2 YR 170 DAYS (30 MO)</td>
<td>Manufacture Date (H4): 01-Jan-1998</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 24-JUL-2000: &quot;FOOTSWITCH IS STICKING ON.&quot; REPORTER SAID PHYSICIAN WAS IN PROCEDURE (URINARY PROCEDURE) WHEN PHYSICIAN REMOVED THEIR FEET FROM THE PEDAL AND THE FOOTSWITCH WAS STUCK IN THE ON POSITION. PHYSICIAN HIT THE STOP BUTTON AND LASING STOPPED. NO INJURIES WERE REPORTED.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Adverse Event (B1): Problem (B1): | Y |
| Event Location (F12): | HOSPITAL |
| Report Source (G3): | THIRD PARTY SERVICE PROVIDER |

Remedial Action (H7): Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

24-JUL-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. CONCLUSION: REPORTED EVENT IS INCONSISTENT WITH PRODUCT EVALUATION. REPORTED FAILURE WOULD NOT BE POSSIBLE WITH CUT WIRES OBSERVED. REPORTED DEVICE WAS RETURNED TO TRIMEDYNE FOR EVAL. INVESTIGATION AND TESTING OF THE DEVICE FOUND THE FOLLOWING: STRAIN RELIEF WAS PULLED OUT FROM METAL CONNECTOR. A PIECE OF BLACK TAPE INSIDE METAL CONNECTOR AROUND GREEN GROUND WIRE, WHICH WAS (EVIDENCE OF TAMPERING). CABLE IS CUT: WIRES CUT ON INSIDE OF CABLE APPROXIMATELY 1-FOOT FROM THE FOOTSWITCH HOUSING, APPEARS TO BE RUN OVER BY CASTER. FOOTSWITCH WILL NOT OPERATE OR WILL OPERATE INTERMITTENTLY WITH A DAMAGED CABLE. REPORTED EVENT IS INCONSISTENT WITH FINDINGS. NO EVIDENCE OF FOOTSWITCH HAVING BEEN STUCK. POSSIBLE CAUSE IS ABUSE.

**DEVICE INFORMATION:**

- **Brand:** OMNIPULSE-MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>16-Aug-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>1419951-2000-00013</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>17-Jul-2000</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>18-Jul-2000</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>18-Jul-2000</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Jul-2000</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>AMBULATORY SURGICAL FACILITY</td>
</tr>
<tr>
<td>Reporter Source (G3):</td>
<td>USER FACILITY</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>2801 BARRANCA RD.</td>
</tr>
<tr>
<td></td>
<td>P.O. BOX 57001</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92606</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>1 YR -155 DAYS (7 MO)</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Jan-2000</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Feb-2004</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
</tbody>
</table>

Recd: 338
Page: 678
Date Last Updated: 11/2/2010 9:17 AM
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 16350
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 14JA9951-2000-00014
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 21-Jul-2000
Report Date (B4): 21-Jul-2000
Report Date (F8): 21-Jul-2000
Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Date Mfr Rec'd (G4): 21-Jul-2000
Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Event Outcome (B2):
Report Date (F8): 21-Jul-2000
Event Location (F12): AMBULATORY SURGICAL FACILITY
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 1 YR -155 DAYS (7 MO)
Manufacture Date (H4): 01-Jan-2000
Expiration Date: 01-Feb-2004
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 25-AUG-2000: IT WAS REPORTED: "FIBER SHATTERED". REPORTER SAID ON FRIDAY MORNING JULY 21, 5 TO 10 MINUTES INTO A RIGHT KNEE ENDOSCOPY CASE, THE HANDPIECE WITH FIBER ASSEMBLY SHATTERED. NO INJURIES WERE REPORTED.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):

Recd: 339
Page: 680
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 16350
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-2000-00015</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 28-Jul-2000</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 28-Jul-2000</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 2801 BARRANCA ROAD</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92606</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9): NA</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNIPULSE-MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Report Date (B4): 12-Aug-2000
Event Date (B3): 10-Aug-2000

MFR Report No: 1419951-2000-00016
Mfr Name: TRIMEDYNE, INC.

Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Event Location (F12): HOSPITAL
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Device Age (F9): 3 YR 0 DAYS (3 YR)
Manufacture Date (H4): 01-Jun-1997

Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 21-SEP-2000: IT WAS REPORTED THAT AFTER CUSTOMER PERFORMED THE PREVENTATIVE MAINTENANCE, THEIR LASER KEPT SHUTTING DOWN AND DISPLAYED "A" AND SOMETIMES "B" OUTPUT ENERGY TOO LOW ERROR MESSAGES. FURTHER INVESTIGATION BY FIELD SERVICE FOUND THE INTERNAL LOCAL LOOP DETECTOR WAS NOT FUNCTIONING. NO INJURIES WERE REPORTED.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
IRVINE, CA 92606 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
21-SEP-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. SECTION F10, EXPLANATION FOR PT CODE - NO PT INVOLVEMENT. EVAL SUMMARY: TESTING OF THE REPORTED LOCAL LOOP DETECTOR FOUND THAT THE DETECTOR FAILED TO ADEQUATELY DETECT LASER OUTPUT ENERGY.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OMNIPULSE-MAX HOLMIUM LASER
Device Type: LASER SYSTEM
Device Type: 1210-VHP
Catalog: 1210-VHP
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Email: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1419951-2000-00017</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 28-Sep-2000</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 03-Oct-2000</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 03-Oct-2000</td>
<td>Device Operator: OTHER</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3): USER FACILITY</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 0 YR 120 DAYS (4 MO)</td>
<td>Manufacture Date (H4): 01-May-2000</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 09-NOV-2000: IT WAS REPORTED THAT FOOTPEDAL WAS STUCK IN THE "ON" POSITION. NO INJURIES WERE REPORTED.

**Concomitant Medical Products:**

NA

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

Correction/Removal No (H9): NA

**Additional Mfr Narrative (H10 & H11):**

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OMNIPULSE-MAX HOLMIUM LASER
Device Type: LASER SYSTEM
Device Type: 1210-VHP
Catalog: 1210-VHP
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)
Health Professional: No

EMAIL: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Occupation: 401 - BIOMEDICAL ENGINEER
MAUDE EVENT REPORT (FOI)

Sort by

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Expiration Date: Device Usage (H8): R</td>
<td>Expiration Date: Device Usage (H8): R</td>
<td>Expiration Date: Device Usage (H8): R</td>
<td>Expiration Date: Device Usage (H8): R</td>
<td>Device Usage (H8): R</td>
<td>Device Usage (H8): R</td>
<td>Device Usage (H8): R</td>
<td>Device Usage (H8): R</td>
</tr>
</tbody>
</table>

Event Description (B5):


Concomitant Medical Products:

TRIMEDYNE 20021-M 550 MICRON BARE FIBER.

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD
         IRVINE, CA 92606
         UNITED STATES
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
11-OCT-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. MANUFACTURER'S WARNINGS INCLUDED IN THE PROFESSIONAL USE INFO MANUAL ACCOMPANYING THIS PARTICULAR LASER SYSTEM STATE THAT: "FLASH' FIRE CAN OCCUR. GENERAL INHALATION ANESTHETICS THAT ARE INFLAMMABLE MUST NOT BE USED. OXYGEN LEVELS IN THE DIRECT OPERATIVE AREA MUST NOT BE HIGHER THAN 50.%"

DEVICE INFORMATION:

Brand: OMNIPULSE-MAX HOLMIUM LASER
Device Type: LASER SYSTEM
Device Type: 1210-VHP
Catalog: 1210-VHP
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)
Health Professional: No

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-2000-00019  Mfr Name: TRIMEDYNE, INC.

Date Received: 05-Oct-2000

Event Date (B3): 06-Sep-2000
Report Date (B4): 06-Sep-2000
Report Date (F8): 05-Oct-2000
Date Mfr Rec'd (G4): 06-Sep-2000

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y  Problem (B1): N
Event Location (F12): HOSPITAL
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 6 YR -182 DAYS (5.5 YR)
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

TRIMEDYNE OMNIPULSE-MAX HOLMIUM LASER MODEL

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):

11-OCT-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. MFR'S WARNINGS INCLUDED IN THE PROFESSIONAL USE INFO MANUAL ACCOMPANYING THIS PARTICULAR LASER SYSTEM STATE THAT: "FLASH' FIRE CAN OCCUR. GENERAL INHALATION ANESTHETIC THAT ARE INFLAMMABLE MUST NOT BE USED. OXYGEN LEVELS IN THE DIRECT OPERATIVE AREA MUST NOT BE HIGHER THAN 50%.”

DEVICE INFORMATION:

Brand: TRIMEDYNE 20021-M 550 MICRON BARE FIBER
Device Type: LASER FIBER
Device Type: 20021-M 550
Catalog: 20021-M 550
Serial: (*confidential*)
Lot: UNK
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

EMAIL:
Phone: (b) (6)
International: (b) (6)
Fax: 

Occupation: OTHER

Health Professional: No
MAUDE EVENT REPORT (FOI)
SORTED BY

Date Received

MFR Report No: 1419951-2000-00020 Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 27-Oct-2000 Event Report Type: MALFUNCTION
Report Date (F8): 28-Nov-2000 Reporter Occupation (E3): OTHER
Date Mfr Rec'd (G4): 31-Oct-2000 Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y

Event Location (F12): HOSPITAL Report Source (G3): COMPANY REPRESENTATIVE
Report Date (F8): 31-Oct-2000

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA RD.
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
08-DEC-2000: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM.
CDRH  
MAUDE EVENT REPORT (FOI)  
SORTED BY  

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: RESPOSABLE 550 MICRON HOLMIUM FIBER WITH FLAT TIP  
Device Type: LASER FIBER  
Device Type: 20021-M  
Catalog: 20021-M  
Serial: (*confidential*)  
Lot: 17089  
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:  
Address:  
EMAIL:  
Phone:  
International:  
Fax:  

Health Professional: Yes  
Occupation: OTHER

Recd: 345  
Page: 693  
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2000-00021</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>03-Jan-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>05-Dec-2000</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 1 YR -35 DAYS (11 MO)
Manufacture Date (H4): 01-Jan-2000
Expiration Date: 01-Feb-2000
Single Use (H5): N
Device Usage (H8): R

Concomitant Medical Products:

NA

Mfr Name: TRIMEDYNE, INC.
Address: 2801 BARRANCA ROAD
                   IRVINE, CA 92606
                   UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>20472-HP OMNI REPLACEMENT FIBER ASSEMBLY</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>20472-HP</td>
</tr>
<tr>
<td>Catalog</td>
<td>20472-HP</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>16354</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

| Reprocessed & Reused | N/A |

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Address</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>HEALTH PROFESSIONAL</td>
<td>No</td>
</tr>
<tr>
<td>EMAIL</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>(*)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td>OTHER</td>
</tr>
<tr>
<td>Recd</td>
<td>346</td>
</tr>
<tr>
<td>Page</td>
<td>695</td>
</tr>
<tr>
<td>Date Last Updated</td>
<td>11/2/2010 9:17 AM</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

|----------------|---------------------|-----------|----------------|--------------|

**Event Date (B3):** 05-Jun-2001  
**Report Date (B4):** 05-Jun-2001  
**Report Date (F8):** 21-Jun-2001  
**Mfr Name:** TRIMEDYNE, INC.  
**Address:** 15091 BAKE PKWY.  
**IRVINE, CA 92618**  
**UNITED STATES**  
**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** Yes  
**Correction/Removal No (H9):** NA  
**Additional Mfr Narrative (H10 & H11):**


**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Location (F12):** USER FACILITY  
**Report Source (G3):** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):** 01-Sep-2000  
**Expiration Date:** 01-Sep-2004  
**Single Use (H5):** N  
**Device Usage (H8):** I

**Event Description (B5):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** TAPERTIP RESPOSABLE HANDPIECE - 30 DEGREE
- **Device Type:** LASER FIBER
- **Device Type:** 20402-M
- **Catalog:** 20402-M
- **Serial:** (*confidential*)
- **Lot:** 17066
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER

**EMAIL:**
- Phone: (*)
- International:
- Fax:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2001-00003</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received:</th>
<th>29-Aug-2001</th>
</tr>
</thead>
</table>

**Event Date (B3):** 18-Jul-2001  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y

**Report Date (B4):** 26-Jul-2001  
**Event Outcome (B2):**  
**Event Location (F12):** Report Source (G3): USER FACILITY

**Date Mfr Rec'd (G4):** 30-Jul-2001  
**Reporter Occupation (E3):** OTHER  
**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Mar-2001

**Expiration Date:** 01-Mar-2005  
**Single Use (H5):** N  
**Device Usage (H8):** R

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Mfr Name:** TRIMEDYNE, INC.
**Address:** 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER  
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 17512
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [d] (6)
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**

Health Professional: No

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2001-00004</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>11-Sep-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-Jun-2001</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Jun-2001</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>14-Aug-2001</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Apr-1999</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Apr-2003</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 24-SEP-2001: IT WAS REPORTED THAT THE FIBER STOPPED WORKING IN THE MIDDLE OF THE CASE. THE FIBER HAD BEEN USED TWO TIMES PREVIOUSLY. THE PT WAS SENT HOME AND INSTRUCTED TO RETURN TO COMPLETE THE PROCEDURE. NO INJURIES WERE REPORTED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15091 BAKE PKWY.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20005
- **Catalog:** 20005
- **Serial:** (*confidential*)
- **Lot:** 15048
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** (*)
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>17-Aug-2001</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>17-Aug-2001</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (B8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Aug-2001</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1419951-2001-00005</td>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** OMNITIP 35 MM SIDE FIRING LASER NEEDLE
- **Device Type:** LASER FIBER
- **Device Type:** 20373-HP
- **Catalog:** 20373-HP
- **Serial:** (*confidential*)
- **Lot:** 17634
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**

**Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2001-00007</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-Aug-2001</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Aug-2001</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Sep-2001</td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>21-Sep-2001</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Feb-2001
Expiration Date: 01-Feb-2005
Single Use (H5): N
Device Usage (H8): *

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 25-OCT-2001:

Recd: 351  Page: 704  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200SMA
- **Catalog:** B200SMA
- **Serial:** (*confidential*)
- **Lot:** 17307
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:**
- **Address:**
- **Health Professional:** Unknown
- **Occupation:** UNK - UNKNOWN
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

Event Date (B3): 27-Aug-2001
Event Report Type: MALFUNCTION
Event Outcome (B2):

Report Date (B4): 28-Aug-2001
Reporter Occupation (E3): UNK - UNKNOWN
Device Operator: HEALTH PROFESSIONAL

Date Mfr Rec'd (G4): 21-Sep-2001
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Feb-2001
Expiration Date: 01-Feb-2005
Single Use (H5): N
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92606
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 25-OCT-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200SMA
- **Catalog:** B200SMA
- **Serial:** (*confidential*)
- **Lot:** 17307
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [b] (b)
- **Address:** [b] (b)
- **Health Professional:** Unknown

- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:** Fax:

Occupation: UNK - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3)</th>
<th>Event Report Type</th>
<th>Adverse Event (B1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-Oct-2001</td>
<td>MALFUNCTION</td>
<td>Problem (B1): Y</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (B4)</th>
<th>Event Outcome (B2)</th>
<th>Event Location (F12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-Oct-2001</td>
<td>OTHER SERIOUS</td>
<td></td>
</tr>
</tbody>
</table>

| MFR Report No: 1419951-2001-00010 | Mfr Name: TRIMEDYNE, INC. |

| Date Mfr Rec'd (G4): 02-Nov-2001 | Device Operator: HEALTH PROFESSIONAL |

| Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |

<table>
<thead>
<tr>
<th>Device Age (F9): 01-Jul-2001</th>
<th>Single Use (H5): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expunction Date: 01-Aug-2005</td>
<td></td>
</tr>
</tbody>
</table>


Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** RESPONSABLE OMNITIP 20-DEGREE SWITCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20475M-HP
- **Catalog:** 20475M-HP
- **Serial:** (*confidential*)
- **Lot:** 17717
- **Other ID:** NA

### Reprocessed & Reused: N/A

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>(b) (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

- **Health Professional:** No
- **Occupation:** OTHER

**EMAIL:**

**Phone:** (b) (b)

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2001-00011
Mfr Name: TRIMEDYNE, INC.
Report Date (B4): 19-Dec-2001
Event Date (B3): 01-Oct-1999
Report Date (F8): 20-Nov-2000
Date Mfr Rec'd (G4): 31-Dec-2001
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL
Event Description (B5):

Concomitant Medical Products:
Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** OMNIPULSE MAX
- **Device Type:** LASER
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** 600 - ATTORNEY
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-2002-00001</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
</table>

**Event**

- **Event Date (B3):** 14-Jan-2002
- **Report Date (B4):** 14-Feb-2002
- **Report Date (F8):** 15-Jan-2002
- **Date Mfr Rec’d (G4):** 14-Feb-2002

**Device**

- **Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
- **Device Age (F9):** 01-Jul-2001
- **Expiration Date:** 01-Jul-2005
- **Device Usage (H8):** R

**Event Description (B5):**

Mfr 22-FEB-2002: IT WAS REPORTED THAT "... PLUGGED IN TIP AND FRIED. TIP BURNED AND ITS ELEMENTS SHOT OUT." WITH TIP INSERTED INTO THE JOINT, UPON IMMEDIATE USE, THE "FILAMENT SHOT OUT TIP". THREE-QUARTERS OF AN INCH OF FIBER BROKE FROM THE TIP. THE PIECE WAS RETRIEVED FROM THE PATIENT, AND NO INJURY TO PATIENT WAS REPORTED DUE TO THE INCIDENT. A NEW 20475M-HP WAS USED TO COMPLETE THE PROCEDURE.

**Concomitant Medical Products:**

- **NA**

**Mfr Name:** TRIMEDYNE, INC.

**Address:**

15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Date Last Updated:** 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** RESPONSABLE OMNITIP 20-DEGREE SWITCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20475M-HP
- **Catalog:** 20475M-HP
- **Serial:** (*confidential*)
- **Lot:** 17694
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [b] (6)
- **Address:** [b] (6)
- **Health Professional:** Yes
- **EMAIL:** [b] (6)
- **Phone:** [b] (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 15-Feb-2002</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8): 18-Feb-2002</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 18-Feb-2002</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 31-Oct-2005</td>
<td>Manufacture Date (H4): 01-Oct-2001</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 31-Oct-2005</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 21-MAR-2002: IT WAS REPORTED THAT DURING THE PROCEDURE THE FIBER TIP BROKE OFF IN THE PT, BUT THEY WERE ABLE TO RETRIEVE IT. THE DEVICE WAS USED IN A PRIOR PROCEDURE, THIS BEING THE SECOND USE. ANOTHER 20475M-HP WAS USED TO COMPLETE THE PROCEDURE. NO INJURY TO THE PT WAS REPORTED.

**Concomitant Medical Products:**
NA

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>RESPONSABLE OMNITIP 20-DEGREE SWITCHABLE TIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>20475M-HP</td>
</tr>
<tr>
<td>Catalog</td>
<td>20475M-HP</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>17835</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>[b) (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b) (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>Unknown</td>
</tr>
<tr>
<td>Occupation</td>
<td>OTHER</td>
</tr>
</tbody>
</table>

EMAIL: [b) (6)
Phone: [b) (6)
International: [b) (b)
Fax: [b) (b)
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-2002-00003  Mfr Name: TRIMEDYNE, INC.

Report Date (B4): 10-Apr-2002  Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 12-Mar-2002  Reporter Occupation (E3): OTHER
Date Mfr Rec'd (G4): 12-Mar-2002  Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Aug-2001  Single Use (H5): N
Expiration Date: 31-Aug-2005  Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
17-APR-2002: H6: DIMENSIONAL EVALUATION. EVAL SUMMARY: A VISUAL AND DIMENSIONAL EXAMINATION WAS PERFORMED ON THE RETURNED PRODCT. PROXIMAL END: THE FIBER SURFACE APPEARED TO HAVE SURFACE PITS AND WHITE PARTICLE INSIDE THE PROXIMAL END. DISTAL END: THE FIBER TIP APPEARED TO BE FRACTURED APPROXIMATELY 1.02 INCHES FROM THE DISTAL END. METAL SHAFT: INSIDE THE TIP APPEARED TO BE BURNED AND MELTED WITH BLACK RESIDUE. THE SHAFT APPEARED TO HAVE NO KINKS OR TO BE DAMAGED ON EITHER THE EXTERIOR OR INTERIOR. THESE OBSERVATIONS WERE MADE AFTER THE SHAFT WAS REMOVED AND SECTIONED NEAR THE 30-DEGREE BEND AREA, WHERE DAMAGE APPEARED TO OCCUR. RETRIEVED FIBER PIECE RETURNED BY THE CUSTOMER. THE FIBER PIECE WAS 0.135 INCHES LONG, AND APPEARED TO BE BLACK OR BURNED. POSSIBLE CAUSE: ALL MEASURED DIMENSIONS WERE WITHIN SPECIFICATION; THEREFORE, CAUSE IS UNKNOWN.

DEVICE INFORMATION:

- **Brand:** RESPOSABLE OMNITIP 30-DEGREE SWITHCHABLE TIP
- **Device Type:** LASER FIBER
- **Device Type:** 20476M-HP
- **Catalog:** 20476M-HP
- **Serial:** (*confidential*)
- **Lot:** 17754
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:** (b) (b)
- **Fax:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** OTHER

Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**

Mfr 03-JUN-2002: IT WAS REPORTED THAT THE PHYSICIAN WAS LASING FOR ONLY A SHORT TIME, WHEN SUDDENLY THE FIBER BENT OR BROKE TO APPROXIMATELY A 45-DEGREE ANGLE NEAR THE CONNECTOR. SMALL SPARKS WERE SEEN, AND LASING WAS IMMEDIATELY STOPPED. THE FIBER WAS STILL ATTACHED, BUT THE INSULATION APPEARED TO BE STRIPPED AWAY. NO BROKEN FIBER PIECES SEPARATED FROM THE DEVICE, AND THERE WAS NO INJURY TO THE PATIENT OR STAFF.

**Concomitant Medical Products:**

NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Recd: 358 Page: 718
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 17890
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 04-Apr-2002 | Event Report Type: | MALFUNCTION |
| Report Date (B4): | 28-May-2002 |
| Event Date (B2): | 04-Apr-2002 |
| Event Location (F12): | |
| Event Outcome (B2): | OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) |
| Reporter Occupation (E3): | OTHER |
| Device Operator: | HEALTH PROFESSIONAL |
| MFR Report No: | 1419951-2002-00005 |
| Mfr Name: | TRIMEDYNE, INC. |
| Report Date (F8): | 28-May-2002 |
| Date Mfr Rec'd (G4): | 21-May-2002 |
| Mfr Name: | TRIMEDYNE, INC. |
| Address: | 15091 BAKE PARKWAY |
| IRVINE, CA 92618 |
| UNITED STATES |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): | 31-Oct-2005 |
| Expiration Date: | 31-Oct-2005 |
| Manufacture Date (H4): | 01-Oct-2001 |
| Single Use (H5): | Y |
| Device Usage (H8): | U |

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 15091 BAKE PARKWAY

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNITIP 30CM SIDE FIRING SWITCH TIP W SUCTION/IRRIGATION
- **Device Type:** LASER FIBER
- **Catalog:** 20371-HP
- **Serial:** (*confidential*)
- **Lot:** 17825
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 12-Jul-2002

**MFR Report No:** 1419951-2002-00007

**Mfr Name:** TRIMEDYNE, INC.

**Event Date (B3):** 10-Jun-2002

**Report Date (B4):** 12-Jul-2002

**Report Date (F8):** 18-Jun-2002

**Mfr Report No:** LASER RENTALS

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 15091 BAKE PKWY.

IRVINE, CA 92618

UNITED STATES

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Event Location (F12):** REPORTER OCCUPATION (E3): HEALTH PROFESSIONAL

**Device Operator:** HEALTH PROFESSIONAL

**Report Source (G3):** LASER RENTALS

**Device Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** 01-Feb-2002

**Expiration Date:** 31-Dec-2005

**Device Usage (H8):** I

**Manufacture Date (H4):** 01-Feb-2002

**Single Use (H5):** N

**Device Evaluated by Manufacturer (H3):** Yes

**Device Available for Evaluation:** R

**Concomitant Medical Products:** NA

**Mfr 19-JUL-2002:** IT WAS REPORTED THAT THE DEVICE WAS BEING USED TO LASER STONES IN THE KIDNEY, WHEN THE FIBER MISFIRED IN THE CENTER OF THE FIBER AND WHERE IT INSERTS INTO THE SCOPE. FLASHING WAS SEEN, AND LASING WAS STOPPED IMMEDIATELY. THE PROCEDURE WAS COMPLETED USING A DIFFERENT 200-MICRON FIBER (MODEL UNKNOWN). NO INJURIES.

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** FLEXMAX 200 SERIES HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** G200
- **Catalog:** G200
- **Serial:** (*confidential*)
- **Lot:** 17896
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER

**EMAIL:** [redacted]
**Phone:** [redacted]
**International:** [redacted]
**Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

Report Date (B4): 23-Oct-2002
Report Date (F8): 24-Sep-2002
Report Date (G4): 23-Oct-2002

Event Date (B3): 23-Sep-2002
Event Report Type: OTHER
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): CONSUMER

Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Oct-2001
Expiration Date: 31-Oct-2005
Single Use (H5): N
Device Usage (H8): R

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H3):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

Event Description (B5):

Date Last Updated: 11/2/2010 9:17 AM
Recd: 361 Page: 724
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** HO:YAG OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type:** LASER FIBER
- **Device Type:** 20470-HP
- **Catalog:** 20470-HP
- **Serial:** (*confidential*)
- **Lot:** 17810
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:** (b) (6)
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2002-00010</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Nov-2002</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>03-Dec-2002</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Report Date (F4):</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jul-2002</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Expiration Date:</td>
<td>30-Jun-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15091 BAKE PARKWAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Additional Mfr Narrative (H10 & H11): | 13-DEC-2002:
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 200 MICRON HOLMIUM FIBER WITH FLAT TIP
Device Type: LASER FIBER
Device Type: B200
Catalog: B200
Serial: (*confidential*)
Lot: 204018
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: No

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER

Date Last Updated: 11/2/2010  9:17 AM
Recd: 362  Page: 727
MAUDE EVENT REPORT (FOI)

EVENT REPORT

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2003-00002
Mfr Name: TRIMEDYNE, INC.
Event Date (B3): 15-Oct-2002
Report Date (B4): 13-Jan-2003
Report Date (F8): 13-Jan-2003
Date Mfr Rec'd (G4): 13-Jan-2003
Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8): UNK - UNKNOWN
Event Location (F12): Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: REPORTER
Report Source (G3): USER FACILITY
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Feb-2002
Expiration Date: 28-Feb-2006
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 23-JAN-2003:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** RESPONSABLE OMNITIP SWITCHABLE TIP - 30 DEGREES
- **Device Type:** LASER FIBER
- **Device Type:** 20476M-HP
- **Catalog:** 20476M-HP
- **Serial:** (*confidential*)
- **Lot:** 17913
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Unknown
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Occupation:** UNK - UNKNOWN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2003-00006
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 16-Jun-2003
Report Date (B4): 01-Aug-2003
Report Date (F8): 29-Aug-2003
Date Mfr Rec'd (G4): 31-Jul-2003

Event Report Type: OTHER
Event Outcome (B2):

Adverse Event (B1): Problem (B1): Y

MFR Report No: 1419951-2003-00006

Event Location (F12): HOSPITAL
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL
Reporter Occupation (E3): 002 - NURSE

Device Age (F9): 0 YR 180 DAYS (6 MO)
Manufacture Date (H4): 01-Dec-2002
Expiration Date: 30-Nov-2006

Single Use (H5): N
Device Usage (H8): R

Remedial Action (H7): Yes
Correction/Removal No (H9): NA

Event Description (B5):
Mfr 08-SEP-2003: IT WAS REPORTED (IN WRITING) ON MEDWATCH 3500A FORM THAT "TRIMEDYNE OMNI SWITCHTIP LASER - SIDE FIRING - HANDPIECE SMOLDERED AND MELTED DURING USE WHILE SURGEON HOLDING IN HIS HAND. MELTED ABOVE HIS HAND." THE BOXES "PRODUCT PROBLEM" AND "REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE" WERE BOTH CHECKED. IT WAS ALSO REPORTED (IN WRITING) IN A SEPARATE REPORT THAT "HANDPIECE MELTED DURING PROCEDURE." IN THIS REPORT, THERE WAS NO DEATH OR SERIOUS INJURY INVOLVED, THE DEVICE WAS RESTERILIZED USING STERRAD, AND WAS USED AT A POWER SETTING OF 60 WATTS, 5 HERTZ, 1.5 JOULES. NEITHER REPORT PROVIDED SPECIFIC INFORMATION THAT WOULD INDICATE THAT ANY INJURIES RESULTED FROM THE USE OF THE DEVICE MENTIONED HEREIN. THE ABOVE INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
COHERENT LASER USED.

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3):

Recd: 364 Page: 730 Date Last Updated: 11/2/2010 9:17 AM

DEVICE INFORMATION:

Brand: 20471-HP OMNI MULTIUSE HANDLEPIECE WITH FIBER ASSY
Device Type: LASER FIBER
Device Type: 20471-HP
Catalog: 20471-HP
Serial: (*confidential*)
Lot: 209012
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)
SORTED BY
Date Received 19-Sep-2003

MFR Report No: 1419951-2003-00007
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 09-May-2003
Report Date (B4): 18-Sep-2003
Report Date (F8): 09-May-2003
Date Mfr Rec’d (G4): 09-May-2003

Event Report Type: MALFUNCTION
Event Outcome (B2): 
Report Date (F8): OTHER
Device Operator: OTHER

Adverse Event (B1): Problem (B1): Y
Event Location (F12): USER FACILITY
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-May-2001
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>OMNIPULSE JUNIOR -HOLMIUM YAG LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER SYSTEM</td>
</tr>
<tr>
<td>Device Type</td>
<td>1230-30</td>
</tr>
<tr>
<td>Catalog</td>
<td>1230-30</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

| Name:                     | [b] [b]                              |
| Address:                 | [b] [b]                              |
| Health Professional:     | No                                   |
| EMAIL:                   |                                       |
| Phone:                   | (*)                                  |
| International:           |                                      |
| Fax:                     |                                       |
| Occupation:              | OTHER                                |

Date Last Updated: 11/2/2010 9:17 AM

Recd: 365

Page: 733
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2003-00008</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received:</th>
<th>02-Oct-2003</th>
</tr>
</thead>
</table>

**Event Date (B3):** 10-Sep-2003  
**Report Date (B4):** 02-Oct-2003  
**Report Date (F8):** 10-Sep-2003  
**Date Mfr Rec'd (G4):** 10-Sep-2003

**Event Type:** MALFUNCTION

**Event Outcome (B2):**  
**Reporter Occupation (E3):** OTHER

**Device Operator:** INVALID DATA

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** 01-Feb-2000

**Expiration Date:** Single Use (H5): N  
Device Usage (H8): R

**Event Description (B5):**
Mfr 10-OCT-2003: DURING A UROLOGICAL PROCEDURE, IT SEEMS THE FIBER COUPLER CAUGHT ON FIRE AND MELTED.

**Concomitant Medical Products:**

**Mfr Name:** TRIMEDYNE, INC.  
**Address:** 15091 BAKE PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**  
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
10-OCT-2003:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OMNIPULSE MAX HOLMIUM LASER
- **Device Type:** LASER SYSTEM
- **Device Type:** 1210-VHP
- **Catalog:** 1210-VHP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Occupation:** OTHER

**Date Last Updated:** 11/2/2010  9:17 AM

Recd: 366   Page: 735   Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Jan-2003</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td>14-Oct-2003</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>14-Oct-2003</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Feb-2006</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
</tbody>
</table>

| Event Description (B5): | Mfr 29-OCT-2003: IT WAS REPORTED THAT LASING BEAM WAS EXITING A SIDE-FIRING DEVICE AT OTHER THAN 180 DEGREES OPPOSITE THE WHITE INDICATOR MARK. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE. |

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): NA
Correction/Removal No (H9): NA

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
POSSIBLE CAUSE(S): SINCE IT APPEARS THAT THIS DEVICE HAS BEEN USED MULTIPLE TIMES, AND SINCE THE REPORTER OF THIS COMPLAINT HAS INDICATED THAT THE DEVICES USED WITH THIS DEVICE WERE TESTED ACCORDING TO LABELING INSTRUCTIONS BEFORE USE; THEREFORE, IT APPEARS THAT THIS DEVICE WAS MODIFIED BY THE REPORTER OF THIS COMPLAINT OR ONE OF THEIR STAFF BETWEEN THE VERY LAST USE AND ITS PRIOR USE, WHICH IS CONTRARY TO THE INSTRUCTIONS FOR USE. THE REPORTER OF THIS COMPLAINT DID NOT REPLACE THIS DEVICE ALTHOUGH CORROSION WAS EVIDENT INSIDE THE DEVICE, ACCORDING TO LABELED INSTRUCTIONS FOR USE. THE REPORTER OF THIS COMPLAINT REPORTED THAT THEY USED A STERILIZATION PROCESS THAT IS NOT ONE OF THE RECOMMENDED STERILIZATION PROCESSES ACCORDING TO THE INSTRUCTIONS FOR USE.

DEVICE INFORMATION:
- Brand: 20470-HP OMNI MULTIUSE HANDPIECE WITH FIBER ASSY
- Device Type: LASER FIBER
- Device Type: 20470-HP
- Catalog: 20470-HP
- Serial: (*confidential*)
- Lot: 17972
- Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: [b] (6)
- Address: [b] (6)
- Health Professional: Yes
- EMAIL: (*)
- Phone: (*)
- International:
- Fax:
- Occupation: 001 - PHYSICIAN

Recd: 367
Page: 737
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>18-Dec-2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>07-Apr-2004</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>26-Mar-2004</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Mar-2004</td>
</tr>
</tbody>
</table>

**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Event Location (F12):** Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

**Device Name:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Manufacture Date (H4):** 01-Jun-2003  
**Single Use (H5):** N  
**Device Usage (H8):** R

**Event Description (B5):**  
Mfr 20-OCT-2004: DURING A URETER STONE REMOVAL PROCEDURE, THE LASER FIBER BROKE RESULTING IN AN UNCONTROLLED RELEASE OF ENERGY. THERE WAS NO INJURY TO PT, STAFF OR PHYSICIAN. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

**Concomitant Medical Products:**  
NA

**Mfr Name:** TRIMEDYNE, INC.  
**Address:** 15091 BAKE PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**  
**Correction/Removal No (H9):** NA  
**Additional Mfr Narrative (H10 & H11):**  
20-OCT-2004: THE PRODUCT HAS NOT BEEN VERIFIED AND HAS NOT BEEN RETURNED TO THE MFR FOR EVAL.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** B200 - 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200
- **Catalog:** B200
- **Serial:** (*confidential*)
- **Lot:** 301008
- **Other ID:** NA

  Reprocessed & Reused: **N**

 REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **International:** [Redacted]
- **Phone:** (*

  HEALTH PROFESSIONAL: Yes

  OCCUPATION: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 11-Mar-2004  
Report Date (B4): 22-Apr-2004  
Date Mfr Rec’d (G4): 24-Mar-2004  
Event Report Type: MALFUNCTION  
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
Reporter Occupation (E3): 002 - NURSE  
Device Operator: HEALTH PROFESSIONAL  
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
Device Age (F9): Manufacture Date (H4): 01-Jan-2004  
Expiration Date: 01-Nov-2007  
Single Use (H5): N  
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Device Available for Evaluation: R  
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200
- **Catalog:** B200
- **Serial:** (*confidential*)
- **Lot:** 308022
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** 
- **Address:** 
- **Health Professional:** Yes

- **Email:** 
- **Phone:** (b) (6)
- **International:** 
- **Fax:** 

**Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2004-00007</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>18-Jun-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>28-Apr-2004</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): -</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>01-Jun-2004</td>
<td>Device Operator:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Unk:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: HO: YAG TAPERTIP -30 DEGREES
Device Type: LASER FIBER
Device Type: 20402-M
Catalog: 20402-M
Serial: (*confidential*)
Lot: 
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: 
Address: 
EMAIL: 
Phone: 
International: 
Fax: 

Health Professional: No Answer
Occupation: -
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
1419951-2004-00008
Mfr Name: TRIMEDYNE, INC.
03-Aug-2004

Event Date (B3): 30-Jun-2004
Report Date (B4): 03-Aug-2004
Report Date (F8): 06-Jul-2004
Date Mfr Rec'd (G4): 03-Aug-2004

Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Event Outcome (B2):
Event Location (F12):
Report Source (G3): USER FACILITY

Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-May-2004
Expiration Date: 01-Apr-2008

Single Use (H5): N
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUN-2005: EVALUATION SUMMARY POSSIBLE CAUSES: THE FIBER MAY HAVE CONTAINED A CONTAMINANT THAT RESULTED IN A CORE FRACTURE WHEN SUBJECTED TO HIGH ENERGY; THE FIBER MAY HAVE BEEN DAMAGED DURING VENDOR MANUFACTURE, SHIPPING AND HANDLING, OR DURING DEVICE MANUFACTURE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** RESPOSABLE OMNI TIP SWITCHABLE TIP-30 DEGREES
- **Device Type:** LASER FIBER
- **Device Type:** 20476M-HP
- **Catalog:** 20476M-HP
- **Serial:** (*confidential*)
- **Lot:** 307025
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** MARY LOU YABES
- **Address:** [redacted]
- **Health Professional:** Unknown

- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]

**Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2004-00011</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received:</th>
<th>05-Oct-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>07-Sep-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Oct-2004</td>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Sep-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1419951-2004-00011</td>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td>Date Received:</td>
<td>05-Oct-2004</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>07-Sep-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Oct-2004</td>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Sep-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: TRIMEDYNE, INC.
Address: 05091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
31-AUG-2007: THE PRODUCT WAS NOT RETURNED TO THE MANUFACTURER FOR EVALUATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** FLEXMAX 365 SERIES HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** B365
- **Catalog:** B365
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2004-00012</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>28-Sep-2004</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>29-Sep-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-2004</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Jul-2008</td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
</tbody>
</table>

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
01-NOV-2004: H6: THE PRODUCT WAS NOT RETURNED TO THE MFR FOR EVALUATION.

Date Last Updated: 11/2/2010 9:17 AM
CDRH MAUDE EVENT REPORT (FOI)

SORTED BY

02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

  Brand: FLEXMAX 365 SERIES HOLMIUM LASER FIBER
  Device Type: LASER FIBER
  Device Type: B365
  Catalog: B365
  Serial: (*confidential*)
  Lot: 405033
  Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

  Name: [b] (b)
  Address: [b] (b)
  Email: [b] (b)
  Phone: [b] (b)
  International: [b] (b)
  Fax: [b] (b)

Health Professional: No

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2004-00013
Mfr Name: TRIMEDYNE, INC.
Event Date (B3): 28-Sep-2004
Event Report Type: MALFUNCTION
Report Date (B4): 25-Oct-2004
Event Outcome (B2):
Date Mfr Rec’d (G4): 29-Sep-2004
MFR Report No: 1419951-2004-00013
Event Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Problem (B1): Y
Report Date (F8): OTHER
Event Location (F12):
Report Source (G3): USER FACILITY
Device Operator:
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2004
Expiration Date: 01-Jul-2008
Single Use (H5): N
Device Usage (H8): I
Event Description (B5):
Mfr 06-SEP-2007: IT WAS REPORTED THAT THE LASER FIBER BROKE AND FIRED PAST THE TECHNICIAN'S HEAD. THE ABOVE INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3):
Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-SEP-2007: THE PRODUCT WAS NOT RETURNED TO THE MANUFACTURER FOR EVALUATION.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: FLEXMAX 365 SERIES HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: B365
Catalog: B365
Serial: (*confidential*)
Lot: 405033
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *(b)(6)*
Address: *(b)(6)*

Health Professional: No

EMAIL: *(b)(6)*
Phone: *(b)(6)*
International: *(b)(6)*
Fax: *(b)(6)*

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Description (B5):
Mfr 02-DEC-2004: IT WAS REPORTED THAT A SCRUB NURSE RECEIVED A MINOR BURN DURING THE PROCEDURE. THE SCRUB NURSE'S HAND WAS NEAR THE FIBER WHEN IT BEGAN TO MAKE A POPPING SOUND. NURSE NOTICED A VERY SMALL BLISTER AT THE BASE OF THE PALM OF THEIR HAND.

Concomitant Medical Products:
TRIMEDYNE RESPONSABLE OMNITIP SWITCHABLE TIP-30

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-DEC-2004: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. THE PRODUCT WAS NOT RETURNED TO THE MFR FOR EVAL.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: HO:YAG OMNI MULTIUSE HANDPIECE WITH FIBER ASSEMBLY
- **Device Type**: LASER FIBER
- **Device Type**: 20470-HP
- **Catalog**: 20470-HP
- **Serial**: (*confidential*)
- **Lot**: 404009
- **Other ID**: NA

- **Reprocessed & Reused**: N

REPORTER INFORMATION:

- **Name**: [Redacted]
- **Address**: [Redacted]

- **Email**: [Redacted]
- **Phone**: [Redacted]
- **International**: [Redacted]
- **Fax**: [Redacted]

- **Health Professional**: No
- **Occupation**: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 02-Jun-2005</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Date Received: 27-Jul-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporter Date (F8):</td>
<td>Reporter Occupation (E3):  OTHER</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 15091 BAKE PARKWAY</td>
<td>Address: 15091 BAKE PARKWAY</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 15091 BAKE PARKWAY</td>
<td>Address: 15091 BAKE PARKWAY</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 28-Jun-2005</td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 01-Feb-2008</td>
<td>Expiration Date: 01-Feb-2008</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 15091 BAKE PARKWAY</td>
<td>Address: 15091 BAKE PARKWAY</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 28-Jun-2005</td>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 01-Feb-2008</td>
<td>Expiration Date: 01-Feb-2008</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
</tr>
<tr>
<td>Address: 15091 BAKE PARKWAY</td>
<td>Address: 15091 BAKE PARKWAY</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): Mfr 29-SEP-2006: IT WAS REPORTED THAT BLACK MATERIAL CAME OUT OF THE TIP AND DEPOSITED INTO THE KNEE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td>Device Available for Evaluation: R</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7): Correction/Removal No (H9):</td>
<td>Remedial Action (H7): Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** RESPOSABLE OMNITIP SWITCHABLE TIP 30 DEGREES
- **Device Type:** LASER FIBER
- **Device Type:** 20476M-HP
- **Catalog:** 20476M-HP
- **Serial:** (*confidential*)
- **Lot:** 312009
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No
- **Occupation:** OTHER

EMAIL: (b) (b)

Phone: (b) (b)

International: 

Fax: 

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-2005-00002  Mfr Name: TRIMEDYNE, INC.  Date Received: 27-Jul-2005

Report Date (F8):
Date Mfr Rec'd (G4): 28-Jun-2005  Reporter Occupation (E3): Other
MFR Report No: LASER RENTAL COMPANY  Report Source (G3): LASER RENTAL COMPANY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  Device Operator: HEALTH PROFESSIONAL
Device Age (F9): Manufacture Date (H4): 01-Mar-2004
Expiration Date: 01-Mar-2008  Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 29-SEP-2006: IT WAS REPORTED THAT BLACK MATERIAL AND "SILICONE TIP" CAME OUT OF THE TIP AND DEPOSITED INTO THE KNEE.

Concomitant Medical Products: NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R  Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** RESPONSABLE OMNI TIP SWITCHABLE TIP - 30 DEGREES
- **Device Type:** LASER FIBER
- **Device Type:** 20476M-HP
- **Catalog:** 20476M-HP
- **Serial:** (*confidential*)
- **Lot:** 312016
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
1419951-2005-00005
Mfr Name: TRIMEDYNE, INC.

Date Mfr Rec'd (G4): 18-Aug-2005

Event Description (B5):
Mfr 02-NOV-2005: IT WAS REPORTED THAT THE CONNECTOR BLEW UP AFTER THE DEVICE WAS PLUGGED INTO THE LASER. THE DEVICE WAS NOT USED ON A PT. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Device Type:</th>
<th>LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type:</td>
<td>20470-HP</td>
</tr>
<tr>
<td>Catalog:</td>
<td>20470-HP</td>
</tr>
<tr>
<td>Serial:</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot:</td>
<td>411037</td>
</tr>
<tr>
<td>Other ID:</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: No

EMAIL: (b) (6)
Phone: (b) (6)
International: Fax: 

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

#### DATE RECEIVED
14-Oct-2005

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Mfr Name:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Event Outcome (B2):</th>
<th>Event Location (F12):</th>
<th>Reporter Occupation (E3):</th>
<th>Event Description (B5):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Device Age (F9):</th>
<th>Expiration Date:</th>
<th>Manufacture Date (H4):</th>
<th>Single Use (H5):</th>
<th>Device Usage (H8):</th>
<th>Device Available for Evaluation:</th>
<th>Device Evaluated by Manufacturer (H3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>01-Aug-2005</td>
<td>01-Aug-2009</td>
<td>01-Aug-2005</td>
<td>N</td>
<td>R</td>
<td>R</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**

NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 15091 BAKE PKWY.

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** HO:YAG TAPER TIP 30 DEGREES (SMA CONNECTOR)
- **Device Type:** LASER FIBER
- **Device Type:** 20402-SMA
- **Catalog:** 20402-SMA
- **Serial:** (*confidential*)
- **Lot:** 505017
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

MFR Report No: 1419951-2005-00007 Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 30-Aug-2005 Event Report Type: MALFUNCTION
Report Date (F8): Event Location (F12):
Date Mfr Rec'd (G4): 30-Aug-2005 Reporter Occupation (E3): 002 - NURSE

MFR Report No: 1419951-2005-00007 Mfr Name: TRIMEDYNE, INC.

Adverse Event (B1): Problem (B1): Y
Event Date (B3): 30-Aug-2005
Report Date (B4): 13-Oct-2005
Event Outcome (B2):
Date Mfr Rec'd (G4): 30-Aug-2005

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-APR-2006:

Event Description (B5):
POPPING NOISE AND THEN SAW THAT THE LASER FIBER WAS BROKEN. THIS INCIDENT OCCURRED IN THE LAST MONTH. THIS INFORMATION IS
DOCUMENTED AS REPORTED TO TRIMEDYNE

Concomitant Medical Products:
NA

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Manufacture Date (H4):
Single Use (H5): N
Device Usage (H8): I

Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Date Received: 14-Oct-2005

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** HO:YAG TAPER TIP 30 DEGREES (SMA CONNECTOR)
- **Device Type:** LASER FIBER
- **Device Type:** 20402-SMA
- **Catalog:** 20402-SMA
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-2005-00008</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
<th>Date Received 14-Oct-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 30-Aug-2005</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 13-Oct-2005</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 30-Aug-2005</td>
<td>Device Operator: UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device not Returned to Manufacturer</td>
</tr>
<tr>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): |

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-APR-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>HO:YAG TAPER TIP 30 DEGREES (SMA CONNECTOR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>20402-SMA</td>
</tr>
<tr>
<td>Catalog</td>
<td>20402-SMA</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>UNK</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

Health Professional: Yes

<table>
<thead>
<tr>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>International:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fax:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 14-Sep-2005
Report Date (B4): 04-Nov-2005
Report Date (F8): 14-Sep-2005
Date Mfr Rec'd (G4): 14-Sep-2005

Event Report Type: MALFUNCTION
Event Outcome (B2):

Adverse Event (B1): Problem (B1): Y

Event Location (F12):
Report Source (G3): DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date: 01-Aug-2009

Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 10-OCT-2006: IT WAS REPORTED THAT AT 111KJ, THE FIBER BROKE WHERE IT MEETS THE HANDLE. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: VAPORMAX HO: YAG SIDE FIRING HANDPIECE
- **Device Type**: LASER FIBER
- **Device Type**: 20440-SMA
- **Catalog**: 20440-SMA
- **Serial**: (*confidential*)
- **Lot**: R504036
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: [redacted]
- **Address**: [redacted]
- **Health Professional**: No
- **Other ID**: NA

- **EMAIL**: [redacted]
- **Phone**: [redacted]
- **International**: [redacted]
- **Fax**: [redacted]

**Occupation**: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1419951-2005-00010

Date Received: 1419951-2005-00010

Mfr Name: TRIMEDYNE, INC.

Date Mfr Rec'd (G4): 15-Sep-2005

Event Date (B3): 15-Sep-2005

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Event Outcome (B2): Reporter Occupation (E3): OTHER

Event Location (F12): Report Source (G3): DISTRIBUTOR

Event Description (B5):
Mfr 05-OCT-2006: IT WAS REPORTED THAT THE DEVICE BLEW OFF THE TIP INTO THE PATIENT AFTER 70KJ AND 30 MINUTES OF LASING. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VAPOMAX HO:YAG SIDE FIRING HANDPIECE
- **Device Type:** LASER FIBER
- **Device Type:** 20440-SMA
- **Catalog:** 20440-SMA
- **Serial:** (*confidential*)
- **Lot:** R504006
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-2006-00002</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Date (B3):</strong> 22-Nov-2005</td>
<td><strong>Event Report Type:</strong> MALFUNCTION</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong> 11-May-2006</td>
<td><strong>Event Outcome (B2):</strong></td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td><strong>Reporter Occupation (E3):</strong> OTHER</td>
</tr>
<tr>
<td><strong>Date Mfr Rec'd (G4):</strong> 04-May-2006</td>
<td><strong>Device Operator:</strong> HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td><strong>Report Source (G3):</strong> USER FACILITY</td>
</tr>
<tr>
<td><strong>Event Description (B5):</strong></td>
<td><strong>Adverse Event (B1):</strong> Problem (B1): Y</td>
</tr>
<tr>
<td>Mfr 17-MAY-2006: THE TIP BROKE OFF INSIDE WOUND BEFORE LASER WAS FIRED. SURGEON ISN'T SURE WHETHER HE RETRIEVED THE ENTIRE TIP OR PART OF THE TIP. DEVICE WAS DISCARDED.</td>
<td></td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**
NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 15091 BAKE PKWY.

IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
17-MAY-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OMNITIP SWITCHABLE TIP - 30 DEGREES
- **Device Type:** LASER FIBER
- **Device Type:** 20476-HP
- **Catalog:** 20476-HP
- **Serial:** (*confidential*)
- **Lot:** 501029
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1419951-2006-00003</th>
<th>Mfr Name: TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 18-Apr-2006</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 11-May-2006</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8): 18-Apr-2006</td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 18-Apr-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (AN)-YAG (LLO)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Apr-2006</td>
</tr>
<tr>
<td>Expiration Date: 01-Mar-2010</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8): I</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 17-MAY-2006: THE DISTAL SHAFT SNAPPED AT THE BUTTERFLY JUNCTION WITHOUT APPARENT CAUSE APPROXIMATELY TEN MINUTES INTO PROCEDURE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 15091 BAKE PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
17-MAY-2006: ANALYSIS: TO DUPLICATE THE REPORTED EVENT, THE PEEK TUBING WAS BENT MORE THAN 45 DEGREES. THE FIRST PRECAUTION LISTED IN THE INSTRUCTIONS FOR USE STATES THAT THE PRODUCT SHOULD NOT BE SUBJECTED TO SEVERE ANGLE BENDS, DROPS, OR EXCESSIVE FORCE, WHICH MAY RESULT IN BREAKS OR FRACTURES. IT APPEARS THAT THE FIBER BREAK WAS DUE TO USER ERROR. PROBABLE CAUSE: FIBER SUBJECTED TO SEVERE ANGLE BENDS.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: VAPORMAX - HO:YAG SIDE FIRING HANDPIECE
- **Device Type**: LASER FIBER
- **Device Type**: 20442-SMA
- **Catalog**: 20442-SMA
- **Serial**: (*confidential*)
- **Lot**: 601085
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: (b) (6)
- **Address**: (b) (6)
- **Health Professional**: No
- **Email**: (b) (6)
- **Phone**: (b) (6)
- **International**: (b) (6)
- **Fax**: (b) (6)
- **Occupation**: OTHER
MAUDE EVENT REPORT (FOI)

Sorted by

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>1419951-2006-00005</td>
<td>14-Mar-2006</td>
<td>MALFUNCTION</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>

Report Date (B4): 29-Jun-2006

Event Outcome (B2):

Reporter Occupation (E3): 002 - NURSE

Event Location (F12):

Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Date Mfr Rec'd (G4): 17-Mar-2006

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Oct-2005

Expiration Date: 01-Oct-2009

Single Use (H5): N

Device Usage (H8): R

Event Description (B5):

Mfr 20-JUL-2006: IT WAS REPORTED THAT THERE WAS A FIBER BREAK. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:

NA

Mfr Name: TRIMEDYNE, INC.

Address: 25901 COMMERCE CENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9): Additional Mfr Narrative (H10 & H11):

CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HO: YAG TAPER TIP -30 DEGREES (SMA CONNECTOR)
- **Device Type:** LASER FIBER
- **Device Type:** 20402-SMA
- **Catalog:** 20402-SMA
- **Serial:** (*confidential*)
- **Lot:** 509003
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 002 - NURSE

Recd: 386
Page: 775
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
1419951-2006-00006
Mfr Name: TRIMEDYNE, INC.

Date: 29-Jun-2006
Event Date (B3): 12-Apr-2006
Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL
Report Date (B4): 29-Jun-2006
Event Location (F12):
Report Source (G3): LASER RENTAL COMPANY

Date Mfr Rec'd (G4): 12-Apr-2006
MFR Report No: 1419951-2006-00006

Event Description (B5):
Mfr 20-JUL-2006: IT WAS REPORTED THAT THE TIP OF THE CAME OFF DURING THE PROCEDURE. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCE CENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
20-JUL-2006: A VISUAL EXAMINATION WAS PERFORMED ON THE RETURN PRODUCT. PROXIMAL END: NO DEFECT WAS FOUND. DISTAL END: FUSED GLASS/ FIBER AND TIP ARE BROKEN OFF AND SEPARATED NEXT TO THE METAL SHAFT. THE METAL SHAFT IS BENT. THE CUSTOMER DID NOT RETURN THE PIECE THAT BROKEN OFF DURING THE PROCEDURE. POSSIBLE CAUSE(S): TIP/SHAFT UNDERWENT EXCESSIVE FORCE DURING INSERTION AND/OR REMOVAL OF DEVICE FROM SCOPE SYSTEM; DEVICE ADHESIVE ON DISTAL TIP LOOSENED DURING USE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VAPORMAX-HO: YAG SIDE FIRING HANDPIECE
- **Device Type:** LASER FIBER
- **Device Type:** 20440
- **Catalog:** 20440
- **Serial:** (*confidential*)
- **Lot:** 502030
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** 
- **Fax:** 
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2006-00007
Mfr Name: TRIMEDYNE, INC.
Report Date (B4): 10-Jul-2006
Event Date (B3): 21-Dec-2005
Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER
Reporter Occupation (E3): Device Operator: UNKNOWN
Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): FOREIGN, DISTRIBUTOR
Report Date (F8): 10-Jul-2006
Date Mfr Rec'd (G4): 16-Feb-2006
MFR Report No: 1419951-2006-00007
Report Date (B4): 10-Jul-2006

Event Description (B5):
Mfr 31-DEC-2007: IT WAS REPORTED "NOT WORKING WELL AT OPERATIVE END. RED GLOWING AREA 1 METRE FROM MACHINE AND SMELL OF ELECTRICAL BURNING. BROKE AFTER 10 SECONDS." THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
31-DEC-2007: EVALUATION SUMMARY: A VISUAL EXAMINATION WAS PERFORMED ON THE RETURNED PRODUCT. DISTAL END: NO DEFECT WAS FOUND. FIBER IS STRIPPED AND CLEAVED. PROXIMAL END: OPTICAL SLEEVE SURFACE WAS SLIGHTLY PITTED. FIBER IS BROKEN AND SEPARATED 63 INCHES FROM PROXIMIAL END. FIBER APPEARS TO BE MECHANICALLY BROKEN. LENGTH OF DISTAL END: 59 INCHES. LENGTH OF PROXIMAL END: 63 INCHES. POSSIBLE CAUSE(S): FIBER BENT BEYOND MAXIMUM SPECIFIED BEND RADIUS; FIBER CLAMPED WITH SHARP OBJECT CONTRARY TO INSTRUCTIONS FOR USE.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP (SMA CONNECTOR)
- **Device Type:** LASER FIBER
- **Device Type:** B200SMA
- **Catalog:** B200SMA
- **Serial:** (*confidential*)
- **Lot:** 506041
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: OTHER
## MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Report

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2006-00009</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-Dec-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Jul-2006</td>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Feb-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jul-2005</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Jun-2009</td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 18-SEP-2006: IT WAS REPORTED &quot;NOT WORKING WELL AT OPERATIVE END. RED GLOWING AREA 1 METER FROM MACHINE AND SMELL OF ELECTRICAL BURNING. BROKE AFTER 10 SECONDS.&quot; THIS INFORMATION IS DOCUMENTED AS REPORTED TO MFR.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>18-SEP-2006:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date Last Updated:** 11/2/2010 9:17 AM

---

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 25901 COMMERCENTRE DR.  
LAKE FOREST, CA 92630  
UNITED STATES
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP (SMA CONNECTOR)
- **Device Type:** LASER FIBER
- **Device Type:** B200SMA
- **Catalog:** B200SMA
- **Serial:** (*confidential*)
- **Lot:** 505041
- **Other ID:** NA

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2006-00011</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received</td>
<td>28-Aug-2006</td>
<td>Event Date (B3):</td>
<td>09-Aug-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Event Report:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
<td>Reporter Location (F12):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Address:</td>
<td>25901 COMMERCE DR</td>
<td>Date Mfr Rec'd (G4):</td>
<td>09-Aug-2006</td>
</tr>
<tr>
<td>LAKE FOREST, CA 92630</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Code:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>01-Apr-2006</td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Mar-2010</td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 03-NOV-2006: IT WAS REPORTED THAT THE FIBER BROKE. THE CUSTOMER WAS NOT AWARE OF ENERGY EXITING AT THE BREAK. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 390 Page: 782 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


APPROXIMATELY 0.060 INCHES FROM THE DISTAL END OF THE FIBER AFTER SEPARATION (END CONNECTED TO LASER CONNECTOR), THERE IS CYLINDRICAL INDENTATION APPROXIMATELY 0.005 INCHES IN WIDTH, CONSISTENT WITH A MARK MADE BY A CLAMP OR OTHER HARD OBJECT IN THE OUTER BUFFER OF FIBER. LENGTH OF FIBER WITH PROXIMAL CONNECTOR: 84.5 INCHES. LENGTH OF SEPARATED FIBER: FIBER: 35.5 INCHES.

POSSIBLE CAUSE(S): FIBER CLAMPED WITH HARD OBJECT DURING USE, CONTRARY TO DEVICE INSTRUCTIONS FOR USE; FIBER BENT BEYOND MAXIMUM BEND RADIUS, CONTRARY TO DEVICE INSTRUCTIONS FOR USE.

DEVICE INFORMATION:

- **Brand:** FLEXMAX 365 SERIES HOLMIUM LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** B365
- **Catalog:** B365
- **Serial:** (*confidential*)
- **Lot:** 601058
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Email:** 
- **Phone:** (b) (b)
- **International:** 
- **Fax:** 

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 07-Sep-2006

MFR Report No: 1419951-2006-00012

Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 21-Mar-2006
Report Date (B4): 07-Sep-2006
Report Date (F8): 23-Aug-2006
Mfr Report No: FOREIGN, DISTRIBUTOR
Report Source (G3): HEALTH PROFESSIONAL

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): FOREIGN, DISTRIBUTOR

Device Age (F9): Manufacture Date (H4): 01-Oct-2004
Expiration Date: 01-Aug-2008
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
OMNIPULSE MAX HO: YAG LASER SYSTEM

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007: EVALUATION BASED UPON THREE PHOTOGRAPHS OF DEVICE PROVIDED BY DISTRIBUTOR. EVALUATION SUMMARY: AN EVALUATION WAS PERFORMED BASED ONLY ON THREE PHOTOGRAPHS PROVIDED BY THE DISTRIBUTOR. PROXIMAL END: NO VISIBLE PROBLEMS ARE PRESENT WITH THE PROXIMAL CONNECTOR OF THE DEVICE. DISTAL END: THE FIBER BUFFER IS STRIPPED BACK APPROXIMATELY 3-4 MM FROM THE DISTAL END. THE FIBER BUFFER AND BLACK OVERCOAT SHRINK TUBING WERE EXPOSED TO EXCESSIVE TEMPERATURES (ABOVE 200 DEGREES C) OVER THE DISTAL 3-4CM OF FIBER, CAUSING MELTING OF AND POSSIBLE BURNING OF THE FIBER BUFFER AND BLACK OVERCOAT. POSSIBLE CAUSE(S): FIBER MAY HAVE BEEN USED WITH ELEVATED OXYGEN CONCENTRATIONS OR IN THE PRESENCE OF FLAMMABLE ANESTHETICS, CONTRARY TO INSTRUCTIONS FOR USE, IN A BRONCHOSCOPIC PROCEDURE, ACCORDING TO THE DISTRIBUTOR.

DEVICE INFORMATION:
- Brand: 550 MICRON FLEXMAX HOLMIUM FIBER WITH FLAT TIP
- Device Type: LASER FIBER
- Device Type: 20021-M
- Catalog: 20021-M
- Serial: (*confidential*)
- Lot: 406027
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: [REDACTED]
- Address: [REDACTED]
- EMAIL: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]

Health Professional: No

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2006-00013</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Aug-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Sep-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Aug-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1419951-2006-00013</td>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>16-Aug-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Sep-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Aug-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Jul-2006
Expiration Date: 01-Mar-2010

Event Description (B5):
Mfr 02-JUL-2007: IT WAS REPORTED THAT THE TIP SEPARATED AND WAS RETRIEVED FROM THE PT. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products: NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200
- **Catalog:** B200
- **Serial:** (*confidential*)
- **Lot:** 601051
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

**Occupation:** OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 14-Sep-2006

MFR Report No: 1419951-2006-00014
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 14-Aug-2006
Report Date (B4): 12-Sep-2006
Report Date (F8): 16-Aug-2006

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: REPORTER OCCUPATION

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Jul-2006
Expiration Date: 01-Mar-2010

Single Use (H5): N
Device Usage (H8): I

Event Description (B5):
Mfr 02-JUL-2007: IT WAS REPORTED THAT THE FIBER BROKE OUTSIDE OF PT WHILE LASING. EMERGENCY STOP WAS HIT. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 200 MICRON HOLMIUM FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200
- **Catalog:** B200
- **Serial:** (*confidential*)
- **Lot:** 601051
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 14-Sep-2006

MFR Report No: 1419951-2006-00015
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 18-Jul-2006
Report Date (B4): 12-Sep-2006
Report Date (F8): 18-Aug-2006
Date Mfr Rec'd (G4): 18-Aug-2006

Event Report Type: MALFUNCTION
Event Report Type: MALFUNCTION
Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): Event Location (F12): Report Location (G12): USER FACILITY
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-May-2004
Expiry Date: 01-May-2008

Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 14-DEC-2007: IT WAS REPORTED ON A MEDWATCH 3500A FORM, "HOLMIUM LASER FIBER B365 BROKE DURING LASER LITHOTRIPSY WHILE BEING USED BY SURGEON. THE STONE WAS PARTIALLY IMBEDDED INTO THE WALL OF THE URETER. FIBER WAS REPLACED DURING THE PROCEDURE. NO INJURY TO PT. SURGEON NOTED THAT HE TORQUED THE DEVICE POTENTIALLY CONTRIBUTING TO FIBER BREAKAGE. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: FLEXMAX 365 SERIES HOLMIUM LASER FIBER
Device Type: LASER FIBER
Device Type: B365
Catalog: B365
Serial: (*confidential*)
Lot: 403039
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: Unknown

EMAIL: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 30-Apr-2007

MFR Report No: 1419951-2007-00001
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 03-Apr-2007
Report Date (B4): 25-Apr-2007
Report Date (F8): 30-Apr-2007
Date Mfr Rec'd (G4): 30-Apr-2007

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 19-Dec-2006
Expiration Date: 01-Nov-2010
Single Use (H5): N
Device Usage (H8): I

Event Description (B5):
Mfr 03-MAY-2007: BLEW OUT SIDE OF FIBER, MIDDLE OF FIBER ASSEMBLY. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
03-MAY-2007: EVAL SUMMARY: NOTE: THE FOLLOWING INFORMATION IS CONSIDERED TO BE CONFIDENTIAL. A VISUAL EXAMINATION WAS PERFORMED ON THE RETURNED PRODUCT. FIBER ASSEMBLY: PROXIMAL END: NO DEFECT WAS FOUND ON FIBER SURFACE AND OPTICAL SLEEVE SURFACE. DISTAL END: NO DEFECT WAS FOUND ON FIBER SURFACE. WHITE PARTICLES ARE PRESENT INSIDE THE METAL CONNECTOR. THE FIBER IS BROKEN AND SEPARATED 58.5 INCHES FROM THE DISTAL END. THE WHITE PROTECTOR TUBING IS HOLDING THE SEPARATED FIBER PIECES. AT THE POINT OF BREAKAGE, THE WHITE PROTECTOR TUBING HAS CLAMP MARKS NEXT TO THE BREAK POINT. THE FIBER HAS A BLACK RESIDUE, ALSO INSIDE THE WHITE PROTECTOR TUBING. CUSTOMER DID NOT SEND HANDPIECE FOR EVAL. POSSIBLE CAUSE: FIBER CLAMPED WITH CLAMP MID-FIBER, OR FIBER BENT BEYOND MINIMUM BEND RADIUS, CONTRARY TO INSTRUCTIONS FOR USE, CAUSING FIBER TO FRACTURE.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>OMNI MULTIUSE HANDPIECE WITH FIBER ASSY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type:</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type:</td>
<td>20470-HP</td>
</tr>
<tr>
<td>Catalog</td>
<td>20470-HP</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>607014</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>[b] (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>No</td>
</tr>
<tr>
<td>Occupation:</td>
<td>OTHER</td>
</tr>
<tr>
<td>EMAIL:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>International:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2007-00002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 05-Dec-2006

**Report Date (B4):** 17-May-2007

**Report Date (F8):** 17-Apr-2007

**Date Mfr Rec'd (G4):** 17-Apr-2007

**Event Report Type:** MALFUNCTION

**Event Description (B5):**
Mfr 14-JUN-2007: FIBER BROKEN 3 INCHES FROM HANDLE. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

**Concomitant Medical Products:**
NA

**Mfr Name:** TRIMEDYNE, INC.

**Address:** 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
14-JUN-2007: NOTE: THE MFR COMPLETED ALL OF THE INFO ON THIS FORM. REPORTER HAS INDICATED THAT DEVICE WILL BE RETURNED FOR EVAL, BUT AS OF THE DATE OF THIS REPORT, DEVICE HAS NOT BEEN RECEIVED. OTHER FIRM REFERENCE NUMBER:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** 200 MICRON FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200SMA
- **Catalog:** B200SMA
- **Serial:** (*confidential*)
- **Lot:** 508027
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 05-Dec-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 17-May-2007</td>
</tr>
<tr>
<td>Report Date (F8): 17-Apr-2007</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 17-Apr-2007</td>
</tr>
<tr>
<td>MFR Report No: 1419951-2007-00003</td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
</tr>
</tbody>
</table>

Event Report Type: MALFUNCTION
Event Date (B3): 05-Dec-2006
Report Date (B4): 17-May-2007
Report Date (F8): 17-Apr-2007
Date Mfr Rec'd (G4): 17-Apr-2007
MFR Report No: 1419951-2007-00003
Mfr Name: TRIMEDYNE, INC.

Adverse Event (B1):
Problem (B1): Y
Event Location (F12):
Report Source (G3):
FOREIGN, DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 03-May-2006
Expiration Date: 01-Apr-2010
Single Use (H5): N
Device Usage (H8): I

Event Description (B5):
Mfr 14-JUN-2007: FIBER BROKEN 3 INCHES FROM HANDLE. THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE.
Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
14-JUN-2007: THIS REPORT INVOLVES TWO UNITS OF THE SAME MODEL AND LOT NUMBER WITH THE SAME REPORTED PROBLEM. REPORTER HAS INDICATED THAT SUBJECT DEVICES WILL BE RETURNED FOR EVAL, BUT AS OF THE DATE OF THIS REPORT, DEVICES HAVE NOT BEEN RECEIVED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** 200 MICRON FIBER WITH FLAT TIP
- **Device Type:** LASER FIBER
- **Device Type:** B200SMA
- **Catalog:** B200SMA
- **Serial:** (*confidential*)
- **Lot:** 509033
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1419951-2007-00010</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>02-Nov-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>13-Sep-2007</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Sep-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 29-Jun-2007
Expiration Date: 30-Apr-2011
Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 18-DEC-2007: "FIBER WIRE WAS BROKEN ON REMOVAL FROM PACKAGE." THIS INFO IS DOCUMENTED AS REPORTED TO TRIMEDYNE. UPON INITIAL RECEIPT OF THIS COMPLAINT, IT WAS DETERMINED TO NOT BE REPORTABLE. HOWEVER, AFTER RETURNED PRODUCT EVAL ON 10/15/2007, IT WAS DETERMINED TO BE REPORTABLE.

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR
LAKE FOREST, CA 92630
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** OMNI MULTIUSE HANDPIECE WITH FIBER ASSY
- **Device Type:** LASER FIBER
- **Device Type:** 20471-HP
- **Catalog:** 20471-HP
- **Serial:** (*confidential*)
- **Lot:** 609046
- **Other ID:** NA

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** OTHER

**Health Professional:** No
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>1419951-2008-00003</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>10-Jan-2008</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Mar-2008</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>11-Jan-2008</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>26-Dec-2007</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Apr-2011</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>25901 COMMERCENTRE DR LAKE FOREST, CA 92630 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: TRIMEDYNE, INC.
Address: 25901 COMMERCENTRE DR LAKE FOREST, CA 92630 UNITED STATES

Date Last Updated: 11/2/2010 9:17 AM
Recd: 399
Page: 800
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HO:YAG TAPERTIP - 30 DEGREE (SMA CONNECTOR)
- **Device Type:** LASER FIBER 20402-SMA
- **Catalog:** 20402-SMA
- **Serial:** (*confidential*)
- **Lot:** 709012
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No

- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:**

- **Occupation:** OTHER
<table>
<thead>
<tr>
<th>Event Date (B3): 20-May-2008</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 11-Jul-2008</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 403 - MEDICAL EQUIPMENT COMPANY TECHNICIAN/REPRESENTATIVE</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 25-Feb-2008</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 01-Apr-2011</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 11-JUL-2008: IT WAS REPORTED THAT, "THE PROCEDURE DID NOT GO WELL DUE TO THE FACT THAT THE FIBER BROKE AT THE END OF THE HAND PIECE. THE DOCTOR HAD BEEN LASING FOR ABOUT 10,000 JOULES WHEN THE FIBER SNAPPED. THE POP STARTLED THE PHYSICIAN, WHO DID GET A BURN MARK ON HIS RIGHT HAND GLOVE, BUT NO BURN MARKS TO HIS SKIN. ALL INDICATIONS ARE THAT THE DOCTOR HAD THE FIBER UNDER HIS PALM WHILE HOLDING THE HAND PIECE AND MAY HAVE PUT TOO MUCH PRESSURE ON THE STRESS JOINT OF THE FIBER. THIS IS WHAT WE BELIEVE CAUSED IT TO BREAK. THE PHYSICIAN FINISHED THE CASE WITH A TRADITIONAL TURP. "THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

**Concomitant Medical Products:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
11-JUL-2008: FIBEROPTIC BREAK/SEPARATION. NO CONSEQUENCES OR IMPACT TO PATIENT

DEVICE INFORMATION:

- **Brand:** VAPORMAX(TM) LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 20440
- **Catalog:** 20440
- **Serial:** (*confidential*)
- **Lot:** 712006
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Occupation:** 403 - MEDICAL EQUIPMENT COMPANY TECHNICIAN/REPRESENTATIVE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Description (B5):
Mfr 18-JUL-2008: IT WAS REPORTED THAT DURING A KNEE ARTHROSCOPY PROCEDURE, "WHILE RUNNING ON HOLMIUM LASER, HANDPIECE CAUGHT ON FIRE. THERE WAS A BEAM OR OUTPUT SEEN. THE DOCTOR DID ASK TO TURN UP THE RATE TO 3.5 AND THAT IS WHEN THE HANDLE PIECE STARTED ON FIRE." REPORTER INDICATED THAT THE AREA THAT MELTED WAS "BLACK PIECE NEAR WHERE THE TIP CONNECTS TO THE HANDPIECE." REPORTER PROVIDED THE FOLLOWING ADDITIONAL INFORMATION: NO PATIENT, USER OR OTHER PERSON WAS INJURED. THEY WERE USING BOTH A REUSABLE FIBER (SWITCHABLE TIP) AND A REUSABLE HANDPIECE/FIBER ASSEMBLY. BOTH DEVICES HAD BEEN USED MULTIPLE TIMES. NO PRE-TESTING OF DEVICES BEFORE USE. AT THE END OF THE PROCEDURE A "SPARK" AND "FLAME" WERE SEEN; THEY IMMEDIATELY REMOVED THE DEVICES FROM THE AREA AND EXTINGUISHED THE FIBER. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

### Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>25901 COMMERCENTRE DRIVE</td>
</tr>
<tr>
<td></td>
<td>LAKE FOREST, CA 92630</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

### Remedial Action (H7):
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11):  
18-JUL-2008: NO CONSEQUENCE OR IMPACT TO PATIENT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNI(TM) MULTIUSE HANDPIECE
- **Device Type:** LASER FIBER
- **Device Type:** 20471-HP
- **Catalog:** 20471-HP
- **Serial:** (*confidential*)
- **Lot:** 609046
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1419951-2008-00008
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 18-Jun-2008
Report Date (B4): 29-Oct-2008
Report Date (F8): 29-Aug-2008
Date Mfr Rec'd (G4): 29-Aug-2008

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 18-JUL-2008: IT WAS REPORTED THAT DURING A KNEE ARTHROSCOPY PROCEDURE, "WHILE RUNNING ON HOLMIUM LASER, HANDPIECE CAUGHT ON FIRE. THERE WAS A BEAM OR OUTPUT SEEN. THE DOCTOR DID ASK TO TURN UP THE RATE TO 3.5 AND THAT IS WHEN THE HANDLE PIECE STARTED ON FIRE." REPORTER INDICATED THAT THE AREA THAT MELTED WAS "BLACK PIECE NEAR WHERE THE TIP CONNECTS TO THE HANDPIECE." REPORTER PROVIDED THE FOLLOWING ADDITIONAL INFORMATION: NO PATIENT, USER OR OTHER PERSON WAS INJURED. THEY WERE USING BOTH A REUSABLE FIBER (SWITCHABLE TIP) AND A REUSABLE HANDPIECE/FIBER ASSEMBLY. BOTH DEVICES HAD BEEN USED MULTIPLE TIMES - SWITCHABLE TIP REPORTED TO HAVE BEEN USED "LESS THAN 25 TIMES". NO PRE-TESTING OF DEVICES BEFORE USE. AT THE END OF THE PROCEDURE A "SPARK" AND "FLAME" WERE SEEN; THEY IMMEDIATELY REMOVED THE DEVICES FROM THE AREA AND EXTINGUISHED THE FIBER. THIS INFORMATION IS DOCUMENTED AS REPORTED TO TRIMEDYNE.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-JUL-2008: NO CONSEQUENCE OR IMPACT TO PATIENT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OMNITIP SWITCHABLE TIP
Device Type: LASER FIBER
Device Type: 20475M-HP
Catalog: 20475M-HP
Serial: (*confidential*)
Lot: 703042
Other ID: 

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health Professional: No

EMAIL: [b] (b)
Phone: [b] (b)
International: 
Fax: 

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1519132-2000-00056</th>
<th>Mfr Name:</th>
<th>CIRCON VIDEO</th>
<th>Date Received:</th>
<th>17-Nov-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Nov-2000</td>
<td>Event Report Type:</td>
<td>*</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Nov-2000</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td>Device Usage (H8):</td>
<td>*</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 30-NOV-2000: LASER FIBER REPORTEDLY BROKE AT TIP WHILE DEFLECTED 75CM FROM TIP. THE DOCTOR WAS BURNED WHILE USING LASER FIBER THROUGH A SHEATH.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: INNOVAQUARTZ</td>
<td>Address: SOUTH 32ND STREET PHOENIX, AZ 85040 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>30-NOV-2000:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INNOVAQUARTZ LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>HFO200DSSM-S</td>
</tr>
<tr>
<td>Catalog</td>
<td>HFO200DSSM-S</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NI</td>
</tr>
<tr>
<td>Other ID</td>
<td>NI</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *
Address: [b] [b]

Health Professional: No Information

EMAIL: [b] [b]
Phone: [b] [b]
International: 
Fax: 

Occupation: NI - NO INFORMATION
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 07-Jul-1998
Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Date (B3): 15-Jun-1998
Event Report Type: DEATH
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y
Event Location (F12): NOT APPLICABLE
Report Source (G3): COMPANY REPRESENTATIVE

MFR Report No: 1527736-1998-02520
MFR Report No:

Report Date (B4): 07-Jul-1998
Report Date (F8):
Date Mfr Rec'd (G4): 07-Jul-1998

Report Date (F8):
Date Mfr Rec'd (G4):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Dec-1997
Expiration Date: 22-Nov-2002

Product Code:
Device Age (F9):
Expiration Date:

Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 

Date Last Updated: 11/2/2010 9:17 AM
Recd: 404
Page: 810
Date Last Updated: 11/2/2010 9:17 AM
Recd: 404
Page: 810

Concomitant Medical Products:
UNK

Mfr Name: INDIGO MEDICAL, INC.
Address: 10123 ALLIANCE RD.
CINCINNATI, OH 45242
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3):

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 

Date Last Updated: 11/2/2010 9:17 AM
Recd: 404
Page: 810
DEVICE INFORMATION:

- **Brand:** INDIGO 1 CM FIBER
- **Device Type:** LASER-SURGERY DEVICE
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** K48R6T
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (b)
- **Address:** (b) (b)

**Health Professional:** Yes

**EMAIL:**

**Phone:** (b) (b)

**International:**

**Fax:**

**Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-02728</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>07-Aug-1998</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>07-Aug-1998</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Aug-1998</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Recd:</td>
<td>405</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date:</td>
<td>09-Sep-1998</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Jun-1998

**Expiration Date:** 01-May-2003

**Single Use (H5):** Y

**Device Usage (H8):** U

**Event Description (B5):**


**Concomitant Medical Products:**

UNK

**Mfr Name:** INDIGO MEDICAL

**Address:** 10123 ALLIANCE RD.

CINCINNATI, OH 45242

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):** 14-SEP-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO 1 CM FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** L4AA2A
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTEER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** No Information
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-02729</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received:</th>
<th>14-Sep-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>13-Aug-1998</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>13-Aug-1998</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Device Usage (H8): U</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INDIGO MEDICAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>10123 ALLIANCE RD. CINCINNATI, OH 45242 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>15-SEP-1998:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO 1 CM FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1527736-1998-02825</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
</table>

**Date Received**
02-Oct-1998

**Event Date (B3):** 27-Jul-1998
**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Report Date (B4):** 04-Aug-1998

**Report Date (F8):**

**Date Mfr Rec'd (G4):** 04-Aug-1998

**Event Location (F12):** OTHER

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-Apr-1998

**Expiration Date:** 24-Mar-2003

**Single Use (H5):** Y

**Device Usage (H8):** U

**Event Description (B5):**
08/21/1998 DURING THE EVAL OF THE RETURNED PRODUCT, THE HEAT MARKER WAS OBSERVED TO BE DAMAGED.

**Concomitant Medical Products:**
UNK

**Mfr Name:** ETHICON ENDO-SURGERY - ALB
**Address:** 3801 UNIVERSITY BLVD., SE
ALBUQUERQUE, NM 87125
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER
**Correction/Removal No (H9):** NA
06-OCT-1998: A1,2,3,4; B6,7; D10: INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFO. H6; DAMAGED HEAT SHRINK MARKER/BROKEN FIBER. THE ANALYSIS RESULTS CONFIRMED THAT THE FIBER HAD MULTIPLE BREAKS, ONE AT 9MM AND THE OTHER AT 14MM FROM THE DISTAL TIP. IT WAS ALSO NOTED THAT THE HEAT SHRINK MARKER WAS DAMAGED AT 34MM FROM THE DISTAL TIP. NO TESTING COULD BE PERFORMED DUE TO THE CONDITION OF THE RETURNED FIBER. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAD OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND CO DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IS FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN. THE INFO CO PROVIDED IS COMPILED, MONITORED AND REVIEWED BY UPPER MANAGEMENT ON A ROUTINE BASIS FOR ANY ASSOCIATED TRENDS.

DEVICE INFORMATION:

- **Brand**: INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type**: LASER-SURGERY DEVICE
- **Catalog**: LF001
- **Serial**: (*confidential*)
- **Lot**: L49X6U
- **Other ID**: NA
- **Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: [redacted]
- **Address**: [redacted]
- **Email**: [redacted]
- **Phone**: (*)
- **International**: [redacted]
- **Fax**: [redacted]
- **Health Professional**: No
- **Occupation**: OTHER

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-03041</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received:</th>
<th>22-Oct-1998</th>
</tr>
</thead>
</table>

**Event Date (B3):** 08-Sep-1998

**Report Date (B4):** 15-Oct-1998

**Report Date (F8):**

**Date Mfr Rec'd (G4):** 15-Oct-1998

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Adverse Event (B1):**

**Problem (B1):** Y

**Report Date (B4):** 15-Oct-1998

**Event Location (F12):** NOT APPLICABLE

**Reporter Occupation (E3):** 002 - NURSE

**Device Operator:** HEALTH PROFESSIONAL

**Device Usage (H8):** U

**Manufacture Date (H4):**

**Expiration Date:** Single Use (H5): Y

**Device Age (F9):**

**Device Evaluated by Manufacturer (H3):** Yes

**Device Available for Evaluation:** Y

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Mfr 29-OCT-1998:** IT WAS REPORTED BY THE REP THE DEVICE WAS USED DURING AN INTERSTITIAL LASER COAGULATION. IT WAS REPORTED THE "SURGEON FIRST FIBER REC'D BLACK BODY." THE SECOND FIBER RESULTED IN DIFFUSER FAULT. THE THIRD FIBER WAS OK. IT WAS USED AND FINISHED THE CASE. THERE WAS NO CONSEQUENCE TO THE PT. 10/15/98 - DURING THE FAILURE INVESTIGATION OF THE ORIGINAL EVENT DESCRIPTION, THE HEAT SHRINK TUBING OF THE DEVICE WAS OBSERVED TO BE DAMAGED AND AS SUCH IS CONSIDERED A MALFUNCTION.

**Concomitant Medical Products:**

**Mfr Name:** INDIGO MEDICAL

**Address:** 10123 ALLIANCE RD.
CINCINNATI, OH 45242
UNITED STATES

**Remedial Action by Manufacturer (H3):**

**Correction/Removal No (H9):** NA

**Report Source (G3):** COMPANY REPRESENTATIVE

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

---

Recd: 408 Page: 818 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
29-OCT-1998: SENT 10/19/1998. A1,2,3,4; B6,7; D10: INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFO. D6: DEVICE RETURNED WITH NO LOT IDENTIFICATION. H6; BROKEN HEAT SHRINK TUBING MATERIAL. INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER: THE ANALYSIS RESULTS CONFIRMED THAT THE FIBER WAS RETURNED BROKEN APPROX 2.2 CM FROM THE DISTAL TIP. NO TESTING COULD BE PERFORMED DUE TO THE CONDITION OF THE RETURNED FIBER. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAD OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND CO HAS DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IS FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN.

DEVICE INFORMATION:

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Email:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-03155</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>13-Oct-1998</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Received: 28-Oct-1998

Event Location (F12): NOT APPLICABLE

Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Jul-1998

Expiration Date: 20-Jun-2003

Single Use (H5): Y

Device Usage (H8): U

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

03-NOV-1998: SENT 10/28/1998. A1,2,3,4; B6,7; D10:E1,2,3: INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFO. INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER; NO CONCLUSION COULD BE REACHED BASED ON THE ANALYSIS RESULTS AS TO WHAT MAY HAVE CAUSED THE REPORTED INCIDENT. THE FIBER WAS RETURNED WITH THE HEAT SHRINK MARKER TORN 65MM FROM THE DISTAL POINT. WHILE CO WAS UNABLE TO RE-CREATE THE EVENT, CO HAS DOCUMENTED THE CIRCUMSTANCES AS THEY WERE REPORTED TO IT. IN ADDITION, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED OF THIS INCIDENT.

**DEVICE INFORMATION:**

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** L4AN2K
- **Other ID:** 37861

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** No Information
- **Phone:** (*)
- **International:**
- **Fax:**
- **EMAIL:**
- **Occupation:** UNK - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 21-Aug-1998 |
| Event Report Type: | MALFUNCTION |
| Report Date (B4): | 31-Aug-1998 |
| Event Outcome (B2): | OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) |
| Event Location (F12): | NOT APPLICABLE |
| Concomitant Medical Products: | UNK |
| Mfr Name: | ETHICON ENDO-SURGERY, INC. |
| Mfr Report No: | 1527736-1998-03156 |
| Device Operator: | HEALTH PROFESSIONAL |
| Reporter Occupation (E3): | OTHER |
| Report Source (G3): | COMPANY REPRESENTATIVE |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Date Mfr Rec'd (G4): | 31-Aug-1998 |
| Report Date (F8): | 28-Oct-1998 |
| Report Date (G4): | 31-Aug-1998 |
| Mfr Name: | INDIGO MEDICAL |
| Address: | 10123 ALLIANCE RD CINCINNATI, OH 45242 UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |
| Remedial Action (H7): | OTHER |
| Correction/Removal No (H9): | NA |
| Date Received: | 28-Oct-1998 |
| Date Mfr Rec'd (G4): | 31-Aug-1998 |
| Device Age (F9): | Manufacture Date (H4): 01-May-1998 |
| Expiration Date: | 11-Apr-2003 |
| Single Use (H5): | Y |
| Device Usage (H8): | U |
| Date Last Updated: | 11/2/2010  9:17 AMRecd:  410 Page:  822 |
| Date Last Updated: | 11/2/2010  9:17 AMRecd:  410 Page:  822 |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
03-NOV-1998: SENT 10/26/1998. A1,2,3,4; B6,7; D10: INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFO. DIFFUSER TIP BENT AND HEAT SHRINK MARKET CRACKED. INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER: THE ANALYSIS RESULTS CONFIRMED THAT BOTH FIBERS WERE RETURNED WITH THE INNER GLASS CORE BROKEN AT THE DIFFUSER TIP. NO TESTING COULD BE PERFORMED DUE TO THE CONDITION OF THE RETURNED FIBER. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAD OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND CO HAS DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IS FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN.

DEVICE INFORMATION:

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Device Type:** NA
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** L4A242
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **EMAIL:** 
- **Phone:** (*)
- **International:** 
- **Fax:** 

Health Professional: No

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-03246</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received: 30-Oct-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Aug-1998</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>04-Sep-1998</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): UNK - UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Sep-1998</td>
<td>Event Location (F12): NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 04-NOV-1998: IT WAS REPORTED BY THE REP THE DEVICE WAS USED DURING AN INTERSTITIAL LASER COAGULATION. IT WAS REPORTED OUT OF A BOX FAILURE ON THE LASER. DURING THE CASE, CO CONTINUED TO HAVE CONNECT FIBER MESSAGE ON THE LASER. THERE WAS NO CONSEQUENCE TO THE PT. 09/04/1998 DURING THE COMPLAINT ANALYSIS, THE HEAT SHRINK MARKER ON FIBER #41274 WAS OBSERVED TO BE TORN, IN AND OF ITSELF CONSIDERED A MALFUNCTION.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ETHICON ENDO-SURGERY - ALB</td>
<td>Address: 3801 UNIVERSITY BLVD., SE ALBUQUERQUE, NM 87125 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7): OTHER</td>
<td>Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

04-NOV-1998: DEVICE-1 DATE SENT: 10/30/1998. A1,2,4; B6,7; D10; E1,2,3: INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFO D5,6; H4: INFO NOT AVAILABLE. H6; BROKEN FIBER AND TORN HEAT SHRINK MARKER, FIBER #41274. INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER: THE ANALYSIS RESULTS CONFIRMED THAT THE FIBERS WERE RETURNED BROKEN APPROX 7 TO 11 MM FROM THE DIATAL TIPS. NO TESTING COULD BE PERFORMED DUE TO THE CONDITION OF THE RETURNED FIBERS. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAS OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND CO HAS DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IF FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN.

### DEVICE INFORMATION:

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

### Reporter Information:

<table>
<thead>
<tr>
<th>Name</th>
<th>*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td><a href="6">b</a></td>
</tr>
<tr>
<td>Health Professional</td>
<td>No Information</td>
</tr>
<tr>
<td>EMAIL</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>(*)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td>UNK - UNKNOWN</td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>02-Nov-2010</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-03310</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>30-Sep-1998</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
<th>UNK</th>
</tr>
</thead>
</table>

| Mfr Name: ETHICON ENDO-SURGERY - ALB |
| Address: 3801 UNIVERSITY BLVD., SE |
| ALBUQUERQUE, NM 87125 |
| UNITED STATES |

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Date Last Updated: 11/2/2010 9:17 AM

Recd: 412 Page: 826
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
12-NOV-1998: DATE SENT 11/02/98. A1,2,4; B6,7; D10; INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFO. H6; BROKEN FIBER AND TORN HEAT SHRINK MARKER, FIBER #36778. INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER: THE ANALYSIS RESULTS CONFIRMED THAT THE FIBER WAS RETURNED BROKEN APPROX 1.3 CM FROM THE DISTAL TIP "DIFFUSE FAULT" ERROR OCCURRED DURING FUNCTIONALITY TEST. NO TESTING COULD BE PERFORMED DUE TO THE CONDITION OF THE RETURNED FIBER. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAD OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND CO HAS DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IS FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN.

**DEVICE INFORMATION:**
- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** 36778
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:**
- **Address:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Occupation:** OTHER

---

**Revised on:** 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 11-Nov-1998

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-03440</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
</table>

Event Date (B3): 08-Oct-1998
Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Location (F12): NOT APPLICABLE
Event Location (F12): NOT APPLICABLE
Mfr Name: ETHICON ENDO-SURGERY, INC.
Address: 3801 UNIVERSITY BLV., SE. ALBUQUERQUE, NM 87125 UNITED STATES
Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Adverse Event (B1): Problem (B1): Y
Event Description (B5):

Concomitant Medical Products:
UNK

Device Operator: HEALTH PROFESSIONAL
Report Source (G3): COMPANY REPRESENTATIVE
Report Date (F8): UNK - UNKNOWN
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Expiration Date: Single Use (H5): Y
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Device Type:** NA
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**

**Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1527736-1998-03585
Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Date (B3): 09-Oct-1998
Report Date (B4): 13-Oct-1998
Report Date (F8): 13-Oct-1998
Date Mfr Rec’d (G4): 13-Oct-1998

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): UNK - UNKNOWN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): NOT APPLICABLE
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Manufacture Date (H4):
Single Use (H5): Y
Device Usage (H8): U

Event Description (B5):

Concomitant Medical Products:
UNK

Mfr Name: ETHICON ENDO-SURGERY - ALB
Address: 3801 UNIVERSITY BLVD, SE
ALBUQUERQUE, NM 87125
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
23-NOV-1998: DATE SENT 11/17/98. A1,2,4;B6,7;D10; E2,3: INFO NOT PROVIDED DURING INITIAL CONTACT. FOLLOW UP LETTER SENT TO FACILITY REQUESTING ADD'L INFO. D5; H4: INFO NOT AVAILABLE. H6: BROKEN FIBER AND TORN HEAT SHRINK MARKER, FIBER #19720. INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER: THE ANALYSIS RESULTS CONFIRMED THAT THE FIBER WAS RETURNED BROKEN APPROX 17 MM FROM THE DISTAL TIP. "DIFFUSER FAULT" ERROR VERIFIED DURING FUNCTIONALITY TESTING. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAD OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND CO HAS DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IS FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN.

DEVICE INFORMATION:
- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** 19720
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** *
- **Address:** [b] (6)
- **Health Professional:** No Information
- **Email:** (*)
- **Phone:** (*)
- **International:**
- **Fax:**

**Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1527736-1998-03939</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 13-Nov-1998</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Adverse Event (B1):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 13-Nov-1998</td>
<td>Problem (B1): Y</td>
</tr>
</tbody>
</table>

| Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): 01-Jul-1998 |
| Expiration Date: 20-Jun-2003 |
| Manufacture Date (H4): 01-Jul-1998 |
| Single Use (H5): Y |
| Device Usage (H8): U |

Event Description (B5):

Concomitant Medical Products:
UNK

Mfr Name: ETHICON ENDO-SURGERY - ALB
Address: 3801 UNIVERSITY BLVD., SE.
ALBUQUERQUE, NM 87125
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
14-DEC-1998: DATE SENT: 12/7/98. A1,2,4; B6,7; D10; E2,3: INFO NOT PROVIDED DURING INITIAL CONTACT. F/U LETTER SENT TO FACILITY REQUESTING ADD'L INFO. H6: BROKEN FIBER, DAMAGED HEAT SHRINK MARKER, FIBER #35983.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** L4AN2K
- **Other ID:** NA

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** [redacted]
- **Phone:** (*)
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN
### MAUDE EVENT REPORT (FOI)

#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>13-Nov-1998</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>13-Nov-1998</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY - ALB</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Address:</td>
<td>3801 UNIVERSITY BLVD., SE</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ALBUQUERQUE, NM 87125</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
15-DEC-1998: DATE SENT: 12/07/1998. A1,2,4; B6,7; D10; E2,3: INFORMATION NOT PROVIDED DURING INITIAL CONTACT. FOLLOW UP LETTER SENT TO FACILITY REQUESTING ADDITIONAL INFORMATION. H6: BROKEN FIBER, TORN HEAT SHRINK MARKER ON FIBER B. THE ANALYSIS RESULTS CONFIRMED THAT THE FIBERS WERE RETURNED BROKEN APPROXIMATELY 23 MM AND 25 MM FROM THE DISTAL TIP. TESTING CONFIRMED "DIFFUSER FAULT" ERROR MESSAGES WITH BOTH FIBERS. TORN HEAT SHRINK MARKER AT FIRST DEPTH MARKER. WHILE NO CONCLUSION COULD BE REACHED AS TO HOW THIS DAMAGE HAD OCCURRED, THE APPROPRIATE ENGINEERING PERSONNEL HAVE BEEN NOTIFIED AND THE CO HAS DOCUMENTED THE REPORTED CIRCUMSTANCES AND ANALYSIS RESULTS. IF THE DISTAL DIFFUSER TIP IS FLEXED EXTENSIVELY OR USED IN COMBINATION WITH THE CYSTOSCOPE BRIDGE, THE DIFFUSER TIP MAY BECOME BROKEN.

DEVICE INFORMATION:

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** L4AL01
- **Other ID:** NA

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (6)
- **Email:** *
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>20-Nov-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>20-Nov-1998</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>20-Nov-1998</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>20-Nov-1998</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jul-1998</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY - ALB</td>
</tr>
<tr>
<td>Address:</td>
<td>3801 UNIVERSITY BLVD., SE ALBUQUERQUE, NM 87125 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
Device Type: LASER-SURGERY DEVICES
Catalog: LF001
Serial: (*confidential*)
Lot: L4AT5K
Other ID: NA
Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *
Address: [b] (6)
Health Professional: No Information

EMAIL: 
Phone: (*)
International: 
Fax: 

Occupation: UNK - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-1998-04086</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received: 15-Dec-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>13-Nov-1998</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): UNK - UNKNOWN</td>
<td>Event Location (F12): NOT APPLICABLE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manuf Date (H4):</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8): U</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:
UNK

Mfr Name: ETHICON ENDO-SURGERY - ALB
Address: 3801 UNIVERSITY BLVD., SE.
ALBUQUERQUE, NM 87125
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 18-DEC-1998:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Masked]
- **Address:** [Masked]
- **EMAIL:** [Masked]
- **Phone:** (*)
- **International:** [Masked]
- **Fax:** [Masked]
- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 08-Jun-1999
Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Problem (B1): Y
Event Location (F12): NOT APPLICABLE
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Event Description (B5):
Mfr 16-JUL-1999: IT WAS REPORTED BY THE REP THE DEVICE WAS USED IN AN INDIGO LASER COAGULATION CASE. THE REP REPORTED AFTER THE FIRST TREATMENT THE LASER READ FIBER FAULT. DR. REMOVED THE FIBER FROM THE PATIENT AND CYSTOSCOPE TO INSPECT. THE CONICAL TIP AND TREATMENT ZONE OF THE FIBER HAD BROKEN AWAY FROM THE FIBER. IT APPEARED THE CAPSULE OR OUTER SHEATH HAD PULLED AWAY. DR. COULD SEE IT IN THE PATIENT STICKING OUT OF THE PROSTATE. DR WAS ABEL TO USE AN INSTRUMENT TO REMOVE IT FROM THE PATIENT. A NEW FIBER WAS OPENED TO COMPLETE THE PROCEDURE. THERE WAS NO CONSEQUENCE TO THE PATIENT.

Concomitant Medical Products:
UNK

Mfr Name: ETHICON ENDO-SURGERY - ALB
Address: 3801 UNIVERSITY BLVD SE
          ALBUQUERQUE, NM 87125
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INDIGO FIBEROPTIC TEMPERATURE SENSING FIBER
- **Device Type:** LASER-SURGERY DEVICES
- **Device Type:** NA
- **Catalog:** LF001
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2002-01468</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received</th>
<th>15-Jul-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-May-2002</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>23-May-2002</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>23-May-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:
UNK

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand: INDIGO LASEROPTIC LASER TREATMENT SYSTEM
   Device Type: LASER-SURGERY DEVICES-REUSABLE
   Device Type: NA
   Catalog: LS83E
   Serial: (*confidential*)
   Lot: NA
   Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

   Name:  
   Address:  
   EMAIL:  
   Phone: (*)
   International:  
   Fax:  
   Occupation: OTHER

Recd: 420  Page: 844  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2004-01357</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received</th>
<th>11-May-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date B3:</td>
<td>14-Apr-2004</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date F8:</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location F12:</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Mfr Name: ETHICON ENDO SURGERY, INC. (CINCINNATI)</td>
<td>Address:</td>
<td>CINCINNATI, OH</td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>18-Feb-2006</td>
<td>Manufacture Date H4:</td>
<td>01-Mar-2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 14-MAY-2004: DURING AN ILS PROCEDURE THE LF002 FIBER WAS EXCHANGED 4 TIMES DUE TO BLACKBODY ERRORS, A 5TH FIBER WAS USED TO COMPLETE THE CASE. GROSS HEMATURIA POST-OP. THE PT WAS ADMITTED TO THE HOSPITAL DUE TO CLOT RETENTION REQUIRING CONTINUOUS BLADDER IRRIGATION.

Concomitant Medical Products:
UNK

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

14-MAY-2004: H3: EVALUATION SUMMARY: A TOTAL OF 5 FIBERS WERE RETURNED FOR EVALUATION. IT WAS CONFIRMED THAT 2 FIBERS EXHIBITED BLACK BODY WARNING MESSAGE DURING USE AND CHARRING TYPICALLY SEEM WITH BLACK BODY ERRORS; ONE FIBER EXHIBITED A REPLACE FIBER WARNING MESSAGE DURING USE AND NO EVIDENCE OF CHARRING, AND 2 FIBERS WERE RETURNED WITH CORRUPTED MEMORY MAKING IT IMPOSSIBLE TO CONFIRM IF ANY ERROR CODES WERE EXHIBITED DURING USE, HOWEVER THERE WAS NO EVIDENCE OF CHARRING ON EITHER FIBER. NEITHER OF THE TWO FIBERS WITH CORRUPTION OF THE MEMORY EXHIBITED ANY BLACK BODY ERRORS DURING EVALUATION TESTING. THE CORRUPTION OF MEMORY IS UNRELATED TO THE REPORTED EVENT. PER THE OPERATOR'S MANUAL: POSSIBLE CAUSES OF BLACK BODY WARNING MESSAGE INCLUDE OVERHEATING OF THE FIBEROPTIC OR SURROUNDING TISSUE AT THE TREATMENT SITE. THE CUSTOMER IS INSTRUCTED TO REPLACED THE FIBEROPTIC AND MOVE TO THE NEXT TREATMENT SITE. FIBERS WITH DEBRIS ON THE PROXIMAL FACE ARE AUTOMATICALLY DETECTED BY THE LASER AND THE MESSAGE "REPLACE FIBER" IS DISPLAYED.

**DEVICE INFORMATION:**

- **Brand:** INDIGO OPTIMA TISSUE ADAPTIVE FIBER
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT
- **Catalog:** LF002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** OTHER

**Date Last Updated:** 11/2/2010 9:17 AM
## MAUDE EVENT REPORT (FOI)
### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2004-03207</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>30-Jun-2003</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>26-Aug-2004</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr rec'd (G4):</td>
<td>26-Aug-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO SURGERY, INC. (CINCINNATI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>* CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**
- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT
- **Catalog:** LS83E
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2004-03698</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received</th>
<th>19-Oct-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Oct-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Oct-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr rec'd (G4):</td>
<td>01-Oct-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8): U</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 16-AUG-2007: IT WAS REPORTED THAT THE LASER FAILED DURING PREPARATION FOR A CASE. THE DEVICE GAVE AN ERROR CODE. THERE WAS NO PT CONSEQUENCE. THE CASE WAS RESCHEDULED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO SURGERY, INC.</td>
<td>Address:</td>
<td>* CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INDIGO OPTIMA LASER SYSTEM
Device Type: LASER-SURGERY DEVICE
Catalog: LS83R
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: *

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2004-03924</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received</th>
<th>03-Nov-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Oct-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>22-Oct-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Oct-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO SURGERY, INC.(CINCINNATI)</td>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>* CINCINNATI, OH * UNITED STATES</td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER-SURGERY DEVICES - REUSABLE
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** (UNK)
- **International:**
- **Fax:**

- **Health Professional:** No

- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2004-04263</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>29-Oct-2004</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>29-Oct-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 29-NOV-2004: IT WAS REPORTED BY THE SALES REP THAT SHE WAS CONTACTED BY THE DOCTOR BECAUSE THE PT WENT IN FOR RECTAL SURGERY TWO DAYS AFTER HAVING A PPH PRECEDURE PERFORMED WITH THE LASER. THE RECTAL SURGERY WAS DONE DUE TO URINE LEAKING INTO THE RECTUM AND A COLOSTOMY BAG WAS NEEDED. IT IS UNK AT THIS TIME IF THIS ADDITIONAL SURGERY WAS MADE NECESSARY DUE TO THE PPH PROCEDURE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC. (CINCINNATI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>*CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>29-NOV-2004: EVAL SUMMARY: THE LASER WAS NOT RETURNED FOR EVAL OF THIS EVENT. THERE IS NO INFO AT THIS TIME TO INDICATE THAT THE DEVICE REPORTED WAS DIRECTLY INVOLVED IN THE REPORTED INCIDENT AND WILL BE DOCUMENTED AT THIS TIME AS A STAND ALONE EVENT. IF ADDITIONAL INFO IS RECEIVED A SUPPLEMENTAL REPORT WILL BE FILED AT THAT TIME.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPTIMA LASER SYSTEM
Device Type: LASER POWERED SURGICAL INSTRUMENT
Catalog: LS83F
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

Date: 15-Dec-2004

MFR Report No: 1527736-2004-04744

Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Date (B3): 24-Nov-2004

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Event Location (F12): NOT APPLICABLE

Event Operator: HEALTH PROFESSIONAL

Mfr Report No: 1527736-2004-04744

Date Mfr Rec'd (G4): 30-Nov-2004

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Device Evaluated by Manufacturer (H3): No

Additional Mfr Narrative (H10 & H11): 12-DEC-2006:

Mfr 12-DEC-2006: IT WAS REPORTED THAT THE DOCTOR WAS PERFORMING AN ILC PROCEDURE AND THE DOCTOR RECEIVED BLACKBODY ERRORS WITH A TOTAL OF FOUR LASER FIBERS. ADD'L TREATMENTS WERE NEEDED; HOWEVER, THE DOCTOR DECIDED TO STOP THE CASE. THE PT WILL BE RESCHEDULED FOR ADD'L TREATMENTS. NO PT CONSEQUENCE OCCURRED.

Concomitant Medical Products:

LASER

Mfr Name: ETHICON ENDO SURGERY, INC.(CINCINNATI)

Address: *

CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11): 12-DEC-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

## DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>ASSEMBLY, DIFFUSER FIBER AND PACKAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER POWERED SURGICAL INSTRUMENT</td>
</tr>
<tr>
<td>Catalog</td>
<td>LF002</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NI</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

## REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>No</td>
</tr>
<tr>
<td>Occupation</td>
<td>OTHER</td>
</tr>
</tbody>
</table>

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 11-Jan-2005

| Event Date (B3): 23-Dec-2004 | Event Report Type: MALFUNCTION |
| Report Date (B4): 30-Dec-2004 | Event Outcome (B2): |
| Report Date (F8): | Reporter Occupation (E3): 303 - MEDICAL ASSISTANT |
| Date Mfr Rec’d (G4): 30-Dec-2004 | Device Operator: HEALTH PROFESSIONAL |
| MFR Report No: 1527736-2005-00172 | Mfr Name: ETHICON ENDO-SURGERY, INC. |
| Adverse Event (B1): Problem (B1): Y |
| Event Location (F12): NOT APPLICABLE |
| Reporter Occupation (E3): 303 - MEDICAL ASSISTANT |
| Device Operator: HEALTH PROFESSIONAL |
| Event Description (B5): |
| Concomitant Medical Products: |
| TREATMENT FIBER |
| Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI) |
| Address: * CINCINNATI, OH * UNITED STATES |
| Device Available for Evaluation: Y |
| Device Evaluated by Manufacturer (H3): No |
| Remedial Action (H7): OTHER |
| Correction/Removal No (H9): NA |
| Additional Mfr Narrative (H10 & H11): |
| 18-JAN-2005: H6: INFORMATION ANTICIPATED, BUT UNAVAILABLE AT THIS TIME. |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES-REUSABLE
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No Information
- **Occupation:** 303 - MEDICAL ASSISTANT

- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

DATE RECEIVED

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 1527736-2005-00217

Event Date (B3): 07-Jan-2005
Report Date (B4): 07-Jan-2005

Event Report Type: MALFUNCTION

Adverse Event (B1):

Problem (B1): Y

Event Outcome (B2):

Event Location (F12): NOT APPLICABLE

Report Source (G3): COMPANY REPRESENTATIVE

Mfr Name: ETHICON ENDO-SURGERY, INC.

Date Mfr Rec'd (G4): 07-Jan-2005

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Operator: HEALTH PROFESSIONAL

Device Usage (H8): U

Event Description (B5):

Mfr 03-FEB-2005: IT WAS REPORTED THAT THE LASER GAVE A CURRENT LIMIT EXCEEDED ERROR DURING THE CASE. CUSTOMER CYCLED POWER AND TRIED A NEW FIBER AND THEY COULD NOT CLEAR THE ERROR. THEY HAD TO ABORT THE CASE.

Concomitant Medical Products:

UNK

Mfr Name: ETHICON ENDO SURGERY, INC. (CINCINNATI)

Address: CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
03-FEB-2005: H6: INFORMATION ANTICIPATED, BUT UNAVAILABLE AT THIS TIME.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER-SURGERY DEVICES - REUSABLE
Device Type: LASER
Device Type: NA
Catalog: LS83E
Serial: (*confidential*)
Lot: NA
Other ID: NA
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-00713</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received</td>
<td>15-Feb-2005</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Date (B3):** 01-Aug-2004  
**Report Date (B4):** 02-Sep-2004  
**Report Date (F8):** 02-Sep-2004  
**Date Mfr Rec'd (G4):** 02-Sep-2004  

**Event Report Type:** INJURY  
**Event Report Type:** INJURY  
**Event Outcome (B2):**  
**Reporter Occupation (E3):** 001 - PHYSICIAN  
**Device Operator:** HEALTH PROFESSIONAL  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:**  
**Device Usage (H8):** I  

**Event Description (B5):**  

**Concomitant Medical Products:**  
LASER  

**Mfr Name:** ETHICON ENDO SURGERY, INC.(CINCINNATI)  
**Address:**  
CINCINNATI, OH  
UNITED STATES  

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer  

**Remedial Action (H7):** OTHER  
**Correction/Removal No (H9):** NA  
**Additional Mfr Narrative (H10 & H11):**  
17-FEB-2005: H4: INFORMATION NOT AVAILABLE AS DEVICE IS NOT BEING RETURNED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>INDIGO OPTIMA TISSUE ADAPTIVE FIBER</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER POWERED SURGICAL INSTRUMENT</td>
</tr>
<tr>
<td>Catalog</td>
<td>LF002</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>UNK</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Address</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Phone</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Professional</td>
<td>Yes</td>
</tr>
<tr>
<td>Occupation</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

[b] (b): Redacted information
<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-00714</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Mfr Rec'd (G4):</th>
<th>02-Sep-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Aug-2004</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Sep-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Sep-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>LASER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO SURGERY, INC. (CINCINNATI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>* CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>17-FEB-2005: H4, INFORMATION NOT AVAILABLE AS DEVICE IS NOT BEING RETURNED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA TISSUE ADAPTIVE FIBER
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT
- **Catalog:** LF002
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**Date Last Updated:** 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-00753</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received: 16-Feb-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Feb-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Feb-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Feb-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DIFFUSER TEMPERATURE SENSING FIBER.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO SURGERY, INC.(CINCINNATI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>*</td>
<td>CINCINNATI, OH *</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPTIMA LASER SYSTEM
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [红acted]
- **Address:** [红acted]
- **Email:** [红acted]
- **Phone:** [红acted]
- **International:** [红acted]
- **Fax:** [红acted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-01221</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
</tr>
<tr>
<td>Date Received:</td>
<td>16-Mar-2005</td>
</tr>
</tbody>
</table>

| Event Date (B3):              | 04-Jun-2004         |
| Report Date (B4):             | 21-Feb-2005         |
| Report Date (F8):             |                     |
| Date Mfr Rec'd (G4):          | 21-Feb-2005         |

- **Event Report Type:** INJURY
- **Event Outcome (B2):** HOSPITALIZATION
- **Adverse Event (B1):** Y
- **Problem (B1):** Y
- **Event Location (F12):** NOT APPLICABLE
- **Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

- **Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
- **Device Age (F9):** Manufacture Date (H4):
- **Expiration Date:** Single Use (H5): N
- **Device Usage (H8):** R

**Event Description (B5):**

Mfr 18-MAR-2005: THE LASER DISPLAYED MESSAGE: WIPE FIBER END. THE FIBER WAS WIPED AND RESULTED IN MESSAGE: HIGH LASER CURRENT. THE REP TRIED ANOTHER FIBER WITH THE SAME RESULT. THE DOCTOR USED A COMPETITOR'S DEVICE TO DO A TUNA MICROWAVE PROCEDURE TO COMPLETE THE CASE WITH NO INTERVENTION OR PATIENT CONSEQUENCE. PATIENT WAS RELEASED IN NORMAL POST OP CONDITION.

**Concomitant Medical Products:**

- FIBER

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES - REUSABLE
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 28-Feb-2005 |
| Report Date (B4): | 28-Feb-2005 |
| Report Date (F8): | 28-Feb-2005 |
| Date Mfr Rec'd (G4): | 28-Feb-2005 |

**Event Description (B5):**
Mfr 25-MAR-2005: DURING THE PROCEDURE THE TEMPERATURE WOULD NOT GO ABOVE 30 WITH THE DIFFUSER TIP FIBER. A SECOND FIBER WAS TRIED CAUSING THE SAME PROBLEM. THE SECOND FIBER WAS TRIED AGAIN AND THE TEMPERATURE QUICKLY ROSE ABOVE 90 DEGREES AND THEN THE POWER DROPPED TO 0. THE CASE WAS THEN ABORTED. THE PT IS TO BE RESCHEDULED NEXT MONTH.

**Concomitant Medical Products:**
- FIBER

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER-POWERED SURGICAL INSTRUMENT
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 05-Oct-2004 |
| Report Date (B4): | 22-Feb-2005 |
| Reporter Occupation (E3): | HEALTH PROFESSIONAL |
| Device Age (F9): | N |
| Device Usage (H8): | U |
| Event Description (B5): |

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC.
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: LASER-SURGERY DEVICES-REUSABLE
Device Type: LASER
Device Type: NA
Catalog: LS83F
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: No
Occupation: OTHER
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-01271</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received:</th>
<th>21-Mar-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>16-Mar-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Mar-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):**

**Expiration Date:**

**Single Use (H5):** N

**Device Usage (H8):** R

**Event Description (B5):**

Mfr 28-MAR-2005: SYSTEM IS DISPLAYING ALEXANDRITE ERROR AS SOON AS THE FIBER IS PLUGGED IN. 4 FIBERS WITH THE SAME RESULT. THE DOCTOR STOPPED THE PROCEDURE. NO REPORTED PATIENT CONSEQUENCE.

**Concomitant Medical Products:**

- FIBER

**Mfr Name:** ETHICON ENDO-SURGERY, INC.

**Address:** CINCINNATI, OH UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):** 28-MAR-2005: H4, 6: INFORMATION ANTICIPATED, BUT UNAVAILABLE AT THIS TIME.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: LASER-SURGERY DEVICES-REUSABLE
- Device Type: LASER
- Catalog: LS83F
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [Redacted]
- Address: [Redacted]
- Health Professional: Yes
- Occupation: 001 - PHYSICIAN

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>10-Jan-2005</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>22-Feb-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Feb-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1527736-2005-01272</td>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.(CINCINNATI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES-REUSABLE
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:** (b) (6)
- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-01274</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received:</th>
<th>21-Mar-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jan-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>22-Feb-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Feb-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 29-MAR-2005: RECEIVED AN E0008 LASER CURRENT OUT OF RANGE ERROR DURING THE CASE. THEY CHANGED FIBERS AND CYCLED POWERED THREE TIMES AND KEPT RECEIVING THE ERROR. THE REP. HAD TO BRING IN THIS DEMO LASER TO COMPLETE THE CASE. NO PATIENT CONSEQUENCE WAS REPORTED. THE UNIT WILL BE SENT IN FOR REPAIR. THE FIBER WILL NOT BE RETURNED FOR ANALYSIS.

Concomitant Medical Products:
- FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC.
Address: *
* CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** LASER-SURGERY DEVICES-REUSABLE
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Email:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 10-Jan-2005</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 22-Feb-2005</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td>Report Source (G3): COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 22-Feb-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Manufacture Date (H4):**

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Event Description (B5):**


**Concomitant Medical Products:**

FIBER

**Mfr Name:** ETHICON ENDO-SURGERY, INC.

**Address:** *

CINCINNATI, OH *

UNITED STATES
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES-REUSABLE
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-01715</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received</th>
<th>14-Apr-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>23-Dec-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>23-Dec-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>23-Dec-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIBER</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES-REUSABLE
- **Device Type:** LASER
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:** 
- **Phone:** (b) (b)
- **International:** 
- **Fax:** 
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 24-Mar-2005</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 24-Mar-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 24-Mar-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 22-APR-2005: LASER DISPLAYED ERROR CODE E000D, MARKER LASER CURRENT (SW) WHEN POWERED ON. THE ERROR COULD NOT BE CLEAR AND THE PROCEDURE WAS CANCELLED. NO PT CONSEQUENCE REPORTED.

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)
Address: *
CINCYNATI, OH *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES -REUSABLE
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**

  [b]  [b]

  [b]  [b]

- **EMAIL:**
- **Phone:**

  [b]  [b]

  [b]  [b]

- **International:**
- **Fax:**

  [b]  [b]

- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 1527736-2005-01722
Mfr Name: ETHICON ENDO-SURGERY, INC. 14-Apr-2005

Event Date (B3): 05-Mar-2005
Report Date (B4): 28-Mar-2005
Report Date (F8): 28-Mar-2005
Date Mfr Rec'd (G4): 28-Mar-2005

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): NOT APPLICABLE
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL

Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 19-APR-2005: IT WAS REPORTED THAT A PT INVOLVED IN CLINICAL PROTOCOL # CM-01-0008 PRESENTED TO THE EMERGENCY ROOM 5 DAYS POST ILC PROCEDURE WITH INABILITY TO VOID FOR 24 HOURS. THE ILC PROCEDURE WAS COMPLETED UNEVENTFULLY. FOLEY CATHETER WAS REMOVED IN 2005, AND AT VOIDING TRIAL PATIENT HAD 100CC OF URINE RESIDUAL. OVER THE LAST 24 HOURS, THE PT HAS HAD NOCTURIA X8 WITH INABILITY TO EMPTY BLADDER. THE POSTVOID RESIDUAL REVEALED 400 CC OF URINE. THE PT WAS PLACED ON 3 DAYS OF ANTIBIOTICS AND CLEAN INTEMITTENT CATHETERIZATION. THE PT WAS DISCHARGED THE FOLLOWING DAY WITH INSTRUCTIONS TO RETURN TO THE CLINIC IN 4 DAYS FOR FLOW RATE/RESIDUAL URINE CHECK. THE PT WAS DISCHARGED IN AN IMPROVED CONDITION.

Concomitant Medical Products:
FIBER.

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
19-APR-2005: D4; H4: INFORMATION IS UNAVAILABLE; DEVICE WAS NOT RETURNED FOR EVALUATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INDIGO OPTIMA LASER SYSTEM
- **Device Type**: LASER-SURGERY DEVICES - REUSABLE
- **Catalog**: LS83F
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA
- **Reprocessed & Reused**: N

REPORTER INFORMATION:

- **Name**: (b) (6)
- **Address**: (b) (b)
- **Health Professional**: No
- **Occupation**: OTHER
- **Phone**: (UNK)
- **Fax**: 
- **EMAIL**: 

Date Last Updated: 11/2/2010  9:17 AM
Recd: 441  Page: 886
MAUDE EVENT REPORT (FOI)

Date Received
1527736-2005-01792

Event Date (B3): 12-Apr-2005
Report Date (B4): 21-Apr-2005
Report Date (F8):
Date Mfr Rec'd (G4): 21-Apr-2005

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator:

Mfr Name: ETHICON ENDO-SURGERY, INC.

Adverse Event (B1): Problem (B1): Y
Event Location (F12): NOT APPLICABLE
Report Source (G3): USER FACILITY, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 28-APR-2005: IT WAS REPORTED BY THE SALES REP THAT ON THE FIFTH TREATMENT THE LASER SHUT DOWN. THE UNIT COULDN'T BE TURNED BACK ON. THE CASE WAS COMPLETED WITH THE SALES REPS LASER AND A NEW FIBER. NO PT CONSEQUENCE. DEVICE BEING RETURNED FOR SERVICE.

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER-SURGERY DEVICES-REUSABLE
Device Type: LASER
Device Type: NA
Catalog: LS83F
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] [6]
Address: *

Health Professional: No

EMAIL: [b] [6]
Phone: [b] [6]
International:
Fax:

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-Apr-2005</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (B4):</th>
<th>Event Outcome (B2):</th>
</tr>
</thead>
<tbody>
<tr>
<td>22-Apr-2005</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (F8):</th>
<th>Reporter Occupation (E3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>22-Apr-2005</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Mfr Rec'd (G4):</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>22-Apr-2005</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Device Age (F9):</th>
</tr>
</thead>
<tbody>
<tr>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Expiration Date:</th>
<th>Single Use (H5):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Usage (H8):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>U</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 17-MAY-2005: DURING AN ILC PROCEDURE, THE DOCTOR RECEIVED AN E0008 ERROR ON THE FIRST STICK. THE DOCTOR TRIED TO USE ANOTHER FIBER AND RECEIVED ANOTHER E0008 ERROR. THE DOCTOR DECIDED TO USE A BOVI AND PERFORM A TURP TO COMPLETE THE CASE WITH NO PATIENT CONSEQUENCE.

**Concomitant Medical Products:**

- FIBER

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

17-MAY-2005: H4, 6: INFORMATION ANTICIPATED, BUT UNAVAILABLE AT THIS TIME.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INDIGO OPTIMA LASER SYSTEM
Device Type: LASER-SURGERY DEVICES - REUSABLE
Device Type: NA
Catalog: LS83F
Serial: (*confidential*)
Lot: NI
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: No

EMAIL: [redacted]
Phone: (UNK)
International:
Fax:

Occupation: OTHER
## MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1527736-2005-02209</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received: 17-May-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 02-May-2005</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 16-May-2005</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12): NOT APPLICABLE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 16-May-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4):

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** U

**Event Description (B5):**

Mfr 25-MAY-2005: IT WAS REPORTED BY THE SALES REP. THAT THEY RECEIVED AN E0113 HIGH LASER CURRENT (HW) ERROR DURING THE CASE. THE CASE WAS COMPLETED WITH AN 830E INDIGO LASER. NO PT CONSEQUENCE WAS REPORTED.

**Concomitant Medical Products:**

FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)

Address: *

CINCINNATI, OH *

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand:</th>
<th>LASER-SURGERY DEVICES-REUSABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type:</td>
<td>LASER</td>
</tr>
<tr>
<td>Device Type:</td>
<td>NA</td>
</tr>
<tr>
<td>Catalog:</td>
<td>LS83F</td>
</tr>
<tr>
<td>Serial:</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot:</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID:</td>
<td>NA</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused:</td>
<td>N</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

| Name:          | [b] [b] [b] |
| Address:       | [b] [b] [b] |
| Health Professional: | Yes |
| EMAIL:         | [b] [b] [b] |
| Phone:         | [b] [b] [b] |
| International: |                  |
| Fax:           |                  |
| Occupation:    | 001 - PHYSICIAN |
| Date Last Updated: | 11/2/2010 9:17 AM |

Reprocessed & Reused: N

02-Nov-2010  9:17 AM

Recd: 444 Page: 892
MFR Report No: 1527736-2005-02216  Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Date (B3): 27-Apr-2005  Event Report Type: MALFUNCTION  Adverse Event (B1):  Problem (B1): Y
Report Date (B4): 27-Apr-2005  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8): 27-Apr-2005  Reporter Occupation (E3): OTHER
Date Mfr Rec'd (G4): 27-Apr-2005  Device Operator: HEALTH PROFESSIONAL

Event Description (B5):

Concomitant Medical Products:
FIBER
Mfr Name: ETHICON ENDO-SURGERY, INC.
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R  Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER  Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER-SURGERY DEVICES - REUSABLE
- **Device Type:** LASER, NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]

Health Professional: No

EMAIL: [redacted]

Phone: [redacted]

International: [redacted]

Fax: [redacted]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 1527736-2005-03122
Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Date (B3): 22-Apr-2005
Report Date (B4): 29-Jun-2005
Report Date (F8): 29-Jun-2005
Date Mfr Rec'd (G4): 29-Jun-2005

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): NOT APPLICABLE
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Expiration Date: Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 27-JUL-2005: IT WAS REPORTED THAT THEY RECEIVED AN E000D ERROR AS SOON AS THEY INSERTED THE FIBER. THE CASE COULD NOT BE COMPLETED. THE FIBER OPENED FOR THE CASE WAS DISPOSED OF SO IT WILL NOT BE RETURNED FOR ANALYSIS.

Concomitant Medical Products:
FIBER.

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1527736-2005-03804

Mfr Name: ETHICON ENDO-SURGERY, INC.

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 14-OCT-2005: IT WAS REPORTED BY THE CUSTOMER THAT THERE WAS A BURNING SMELL IN TREAT MODE. THIS UNIT WAS JUST RECEIVED BACK FROM JABIL. THIS UNIT IS USED FOR TESTING FIBERS AND IS NOT FOR PATIENT USE.

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INDIGO OPTIMA
- **Device Type**: LASER-SURGERY DEVICES - REUSABLE
- **Catalog**: E05524
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: [REDACTED]
- **Address**: [REDACTED]
- **EMAIL**: [REDACTED]
- **Phone**: [REDACTED]
- **International**: [REDACTED]
- **Fax**: [REDACTED]

Health Professional: No

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 1527736-2005-04032  Mfr Name: ETHICON ENDO-SURGERY, INC. 02-Sep-2005

Event Date (B3): 09-Aug-2005  Event Report Type: MALFUNCTION  Adverse Event (B1):  Problem (B1): Y

Event Location (F12): NOT APPLICABLE  Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL

Problem (B1): Y

Report Date (B4): 19-Aug-2005  Event Outcome (B2):

Event Description (B5):

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Single Use (H5): N
Device Usage (H8): U
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-04181</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received</th>
<th>13-Sep-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>25-Aug-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>25-Aug-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 30-JAN-2006: RECEIVED AN E0008 LASER CURRENT OUT OF RANGE ERROR ON DEMO LASER DURING THE CASE. THEY CHANGED FIBERS AND CYCLED POWER AND THE ERROR CLEARED. NO PATIENT CONSEQUENCE WAS REPORTED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>fiber</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO SURGERY, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 449 Page: 901 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: INDIGO OPTIMA LASER SYSTEM
Device Type: LASER
Device Type: NA
Catalog: LS83F
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Health Professional: No
Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-04185</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Aug-2005</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 30-JAN-2006: THE CUSTOMER RECEIVED AN E000D MARKER LASER CURRENT ERROR. THE CUSTOMER CHANGED FIBERS AND STILL RECEIVED THE SAME ERROR. THEY CYCLED POWER AND THE ERROR PERSISTED. THE CASE WILL BE RESCHEDULED AT AN UNKNOWN DATE. THE LASER WILL BE SENT IN FOR REPAIR.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>FIBER</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ETHICON ENDO SURGERY, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: CINCINNATI, OH * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7): OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Received: 13-Sep-2005
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received:** 15-Oct-2003

**Event Date (B3):** 15-Oct-2003

**Report Date (B4):** 15-Oct-2003

**Mfr Name:** ETHICON ENDO-SURGERY, INC.

**Event Report Type:** INJURY

**Adverse Event (B1):** Y

**Problem (B1):** N

**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Event Location (F12):** NOT APPLICABLE

**Report Source (G3):** HEALTH_professional, USER FACILITY, COMPANY REPRESENTATIVE

**Device Operator:** HEALTH PROFESSIONAL

**Report Date (B4):** 15-Oct-2003

**MFR Report No:** 152776-2005-04197

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Code (G1):**

**Device Age (F9):** Manufacture Date (H4): 01-Sep-2004

**Single Use (H5):** Y

**Expiration Date:** 01-Jul-2006

**Device Usage (H8):** U

**Event Description (B5):**


**Concomitant Medical Products:**

LASER

**Mfr Name:** ETHICON ENDO-SURGERY, INC.(CINCINNATI)

**Address:**

CINCINNATI, OH *
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

Recd: 451

Page: 905

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
16-SEP-2005: RECEIVED NOTICE OF LITIGATION FROM CORPORATE COUNSEL. COMPLAINT ALLEGES THAT PATIENT "SUFFERED INJURY TO AREAS OF THEIR BODY UNRELATED TO THE PROSTATE" AS A RESULT OF NEGLIGENCE OF THE PHYSICIAN. COMPLAINT FURTHER ALLEGES THAT DEVICE WAS DEFECTIVE AND PATIENT DID NOT CONSENT TO PRESENCE OF SALES REPRESENTATIVE. COMPLAINT FURTHER STATES PATIENT SUFFERED A RUPTURED COLON REQUIRING COLOSTOMY. SURGEON INDICATED TO THE SALES REP THAT HE DID NOT BELIEVE THE COLON RUPTURE OCCURRED DURING THE ILC PROCEDURE. SURGEON ALSO INDICATED THIS PATIENT HAD A PRIOR HISTORY OF HEALTH RELATED ISSUES. THE FIBER NOT THE LASER WAS RETURNED FROM THIS EVENT TO BE EVALUATED.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INDIGO OPTIMA TISSUE ADAPTIVE FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER POWERED SURGICAL INSTRUMENT</td>
</tr>
<tr>
<td>Catalog</td>
<td>LF002</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>03H059</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>(a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>(a)</td>
</tr>
</tbody>
</table>

Health Professional: Yes

Occupation: 001 - PHYSICIAN

EMAIL: (a)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Aug-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>02-Nov-2010</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>16-Aug-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Aug-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC. (CINCINNATI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Address:</td>
<td>*CINCINNATI, OH *UNITED STATES</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>14-DEC-2005:</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

- FIBER

**Mfr Name:** ETHICON ENDO-SURGERY, INC. (CINCINNATI)

**Address:** *CINCINNATI, OH *UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer:** Yes

**Remedial Action:** OTHER

**Correction/Removal:** NA

**Additional Mfr Narrative:** 14-DEC-2005:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INDIGO OPTIMA LASER SYSTEM
- **Device Type**: LASER
- **Catalog**: LS83F
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: [Redacted]
- **Address**: [Redacted]
- **Health Professional**: No Information

- **Email**: [Redacted]
- **Phone**: [Redacted]
- **International**: [Redacted]
- **Fax**: [Redacted]

**Occupation**: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>26-Jul-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>09-Sep-2005</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>09-Sep-2005</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>09-Sep-2005</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>1527736-2005-04439</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Mar-2008</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Apr-2005</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>21-NOV-2005:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** R OPTIMA* FIBER
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT
- **Catalog:** LF002
- **Serial:** (*confidential*)
- **Lot:** Y4528F
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Aug-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>22-Sep-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>22-Sep-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 03-NOV-2005: IT WAS REPORTED BY THE SALES REP. THAT HER DEMO LASER POWERED ON AND THEN SHUT OFF AFTER A FEW SECONDS. SHE TRIED CYCLING POWER A COUPLE OF TIMES AND THE SAME THING HAPPENED. AFTER A FEW ATTEMPTS AT THIS, THE LASER SOULDN'T EVEN POWER ON AT ALL. THE CASE COULD NOT BE COMPLETED AND WAS RESCHEDULED. THE LASER WILL BE SENT IN FOR REPAIR.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>FIBER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.(CINCINNATI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>*</td>
<td>CINCINNATI, OH *</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td>Recd:</td>
<td>454</td>
<td>Page:</td>
</tr>
</tbody>
</table>

DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

EMAIL: [b] (6)

Phone: [b] (6)

International: [b] (6)

Fax: [b] (6)
### MAUDE EVENT REPORT (FOI)
#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-04495</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>22-Aug-2005</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>22-Sep-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>22-Aug-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):**

**Single Use (H5):** N

**Device Usage (H8):** U

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Event Description (B5):**

**Concomitant Medical Products:**

**Mfr Name:** ETHICON ENDO SURGERY, INC. (CINCINNATI)

**Address:**

* CINCINNATI, OH *

UNITED STATES

**Device Available for Evaluation:**

**Device Evaluated by Manufacturer:**

**Remedial Action:**

**Correction/Removal No:** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:
- **Brand**: OPTIMA INDIGO LASER SYSTEM
- **Device Type**: LASER
- **Catalog**: LS83F
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Health Professional**: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: 

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| MFR Report No: | 1527736-2005-04920 | Mfr Name: | ETHICON ENDO-SURGERY, INC. | Date Received: | 19-Oct-2005 |
| Event Date (B3): | 29-Sep-2005 | Event Report Type: | MALFUNCTION | Adverse Event (B1): | Problem (B1): Y |
| Report Date (B4): | 29-Sep-2005 | Event Outcome (B2): | | Event Location (F12): | NOT APPLICABLE |
| Report Date (F8): | | Reporter Occupation (E3): | OTHER | Report Source (G3): | COMPANY REPRESENTATIVE |
| Date Mfr Rec’d (G4): | 29-Sep-2005 | Device Operator: | HEALTH PROFESSIONAL |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) | Device Age (F9): |
| Expiration Date: | | Manufacture Date (H4): |
| | | Single Use (H5): N |
| | | Device Usage (H8): U |

Event Description (B5):
Mfr 18-SEP-2006: IT WAS REPORTED THAT DURING AN INSERVICE SESSION, A FIBER WAS INSERTED AND THE DEVICE WAS TURNED ON, BUT THERE WAS NO DISPLAY. THE REP HEARD A CLICK AND SAW A RED MARKER BEAM. A SECOND FIBER WAS TRIED WITH THE SAME RESULTS. THE INSERVICE WAS THEN STOPPED. THERE WAS NO PATIENT INVOLVEMENT.

Concomitant Medical Products:
- FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)

Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
18-SEP-2006: INFORMATION ANTICIPATED, BUT UNAVAILABLE AT THIS TIME.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER-SURGERY DEVICES - REUSABLE
- **Device Type:** NA
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NI
- **Other ID:** NA
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>07-Sep-2005</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>31-Oct-2005</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC.</td>
<td>Date Mfr Rec'd (G4):</td>
<td>31-Oct-2005</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Event Description (B5):

Concomitant Medical Products:
FIBER

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
03-OCT-2006: THIS SITE COULD NOT PERFORM THE INCOMING TEMPERATURE MEASUREMENTS DUE TO THE UNIT GAVE W0118: ALEXANDRITE RMS ERROR WHEN BOOTING UP WITH A DIFFUSER FIBER. DURING INCOMING F2, THE UNIT FAILED STEP VA130 (FLUOR. SENSOR VOLTAGE CALIBRATION: 2.207). DURING DISASSEMBLY, IT WAS NOTICED THAT 7 PINS FROM THE OPTICAL BENCH WERE NOT SOLDERED ON TO THE SENSOR BOARD ASSEMBLY WHICH CAUSED THE UNIT TO HAVE ALEXANDRITE RMS ERROR AND FAILED STEP VA130 OF THE INCOMING F2. REFLOWED SENSOR BOARD ASSEMBLY TO CORRECT THE ISSUE. THE ANALYSIS SITE CALIBRATED THE CONTROLLER BOARD AND VERIFIED THE UNIT ALREADY HAS SOFTWARE VERSION TO 1.9. PER SERVICE MANUAL, PROTOCOL 04-E-0006 WAS PERFORMED. THE TEMPERATURE ACCURACY AND TREATMENT LASER POWER LEVELS WERE WITHIN SPECIFICATIONS FOR THIS PRODUCT. PERFORMED ANNUAL CALIBRATION AND ELECTRICAL SAFETY TEST. THE LASER WAS TESTED AND MET DESIGN SPECIFICATIONS.

DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:** (b) (b)
- **Fax:** (b) (b)

- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1527736-2005-05590</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 20-Sep-2005</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (B4): 20-Sep-2005</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8): 20-Sep-2005</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 20-Sep-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td></td>
<td>Event Location (F12): NOT APPLICABLE</td>
</tr>
<tr>
<td></td>
<td>Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): Single Use (H5): Device Usage (H8): *

Event Description (B5):

Concomitant Medical Products:
- FIBER

Mfr Name: ETHICON ENDO-SURGERY, INC. (CINCINNATI)
Address: CINCINNATI, OH * UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): NA

DEVICE INFORMATION:

Brand: INDIGO OPTIMA LASER SYSTEM
Device Type: LASER
Device Type: NA
Catalog: LS83F
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)
Email: (b) (6)
Phone: (b) (6)
International:
Fax:

Health Professional: Yes
Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2005-05592</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Sep-2005</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>16-Nov-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Nov-2005</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 24-MAY-2006: IN ATTEMPTING TO BEGIN A CASE THE DISPLAY WAS BLACKED OUT. LASER APPEARED TO BE RUNNING, BUT THERE WAS NO DISPLAY. THE SALES REPS DEMO LASER WAS USED TO COMPLETE THE CASE SUCCESSFULLY WITH NO PATIENT CONSEQUENCE. LASER BEING RETURNED FOR REPAIR.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>FIBER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ETHICON ENDO-SURGERY, INC. (CINCINNATI0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CINCINNATI, OH *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recd:</td>
<td>459</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Page:</td>
<td>921</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 1527736-2005-05637</th>
<th>Mfr Name: ETHICON ENDO-SURGERY, INC.</th>
<th>21-Nov-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 18-Nov-2005</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Reporter Location (F12): NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 18-Nov-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Event Location (F12): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4): N</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Remedial Action (H7): OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): U</td>
<td>Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 12-MAY-2006: RECEIVED AN E000D MARKER LASER CURRENT ERROR DURING THE PROCEDURE WITH THE BARE TIP FIBER. THEY REPLACED THE FIBER AND REBOOTED THE SYSTEM AND THE ERROR PERSISTED. THEY HAD TO ABORT THE PROCEDURE AND RESCHEDULE IT FOR A LATER DATE.

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO SURGERY, INC.(CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** INDIGO OPTIMA LASER SYSTEM
- **Device Type:** LASER
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:** (UNK)
- **International:**
- **Fax:**

Health Professional: Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1527736-2006-00114</th>
<th>Mfr Name:</th>
<th>ETHICON ENDO-SURGERY, INC.</th>
<th>Date Received:</th>
<th>10-Jan-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>12-Dec-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Event Location (F12):</td>
<td>NOT APPLICABLE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>12-Dec-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Oct-2003
Expiration Date: 10-Oct-2006

Event Description (B5):
Mfr 17-JAN-2006: NI

Concomitant Medical Products:
LASER

Mfr Name: ETHICON ENDO SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
17-JAN-2006: ANALYSIS RESULTS FOUND THAT THE FIBER WAS RETURNED WITH THE DISTAL 5MM OF THE FIBER TIP MISSING FROM THE FIBER. NO CONCLUSION COULD BE REACHED AS TO HOW THE DAMAGE TO THE FIBER OCCURRED. IF THE DISTAL FIBER TIP IS FLEXED EXTENSIVELY THE FIBER MAY CRACK OR BREAK.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to
the event.

DEVICE INFORMATION:

Brand: OPTIMA BARE TIP CUTTING FIBER
Device Type: LASER POWERED SURGICAL INSTRUMENT
Device Type: NA
Catalog: LF021
Serial: (*confidential*)
Lot: NI
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1527736-2006-00955
Date Report: 03-Mar-2006
Report Date (F8): Omitted
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Date (B3): 22-Nov-2005
Report Date (B4): Omitted
Event Outcome (B2):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1):
Problem (B1): Y
Event Location (F12): NOT APPLICABLE
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): U

Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Description (B5):
Mfr 10-MAR-2006: IT WAS REPORTED BY THE SALES THAT DURING THE CASE ERROR MESSAGE E000D, MARKER LASER CURRENT-CYCLE POWER OCCURRED AFTER COMPLETING TWO AND A HALF STICK SITES. THREE FIBERS WERE TRIED, BUT THE ERROR WAS UNRECOVERABLE. THE CASE WAS ABORTED WITH NO PATIENT CONSEQUENCE. LASER BEING RETURNED FOR REPAIR.

Concomitant Medical Products:
FIBER

Mfr Name: ETHICON ENDO SURGERY, INC. (CINCINNATI)
Address: *
CINCINNATI, OH *
UNITED STATES

Device Available for Evaluation: R

Device Evaluated by Manufacturer (H3): Yes
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>LASER-SURGERY DEVICES- REUSABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Catalog</td>
<td>LS83F</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] [6] (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] [6] (6)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>Yes</td>
</tr>
<tr>
<td>Occupation</td>
<td>002 - NURSE</td>
</tr>
</tbody>
</table>

EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)
# MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>01-Jul-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MFR Report No:</strong></td>
<td>1530517-1999-00001</td>
</tr>
<tr>
<td><strong>Mfr Name:</strong></td>
<td>IHD, INC.</td>
</tr>
<tr>
<td><strong>Event Date (B3):</strong></td>
<td>04-Jun-1999</td>
</tr>
<tr>
<td><strong>Event Report Type:</strong></td>
<td>OTHER</td>
</tr>
<tr>
<td><strong>Adverse Event (B1):</strong></td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong></td>
<td>01-Jul-1999</td>
</tr>
<tr>
<td><strong>Event Outcome (B2):</strong></td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td><strong>Event Location (F12):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date Mfr Rec'd (G4):</strong></td>
<td>07-Jun-1999</td>
</tr>
<tr>
<td><strong>Device Operator:</strong></td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td><strong>Report Source (G3):</strong></td>
<td>DISTRIBUTOR, *</td>
</tr>
<tr>
<td><strong>Product Code:</strong></td>
<td>(SU)-ELECTROSURGICAL, CUTTING &amp; COAGULATION &amp; ACCESSORIES (GEI)</td>
</tr>
<tr>
<td><strong>Device Age (F9):</strong></td>
<td>Manufacture Date (H4): 01-Mar-1999</td>
</tr>
<tr>
<td><strong>Expiration Date:</strong></td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td><strong>Device Usage (H8):</strong></td>
<td>I</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 07-JUL-1999: PT WAS UNDERGOING UVULO-PALATO-PHARYNGO-PLASTY) PROCEDURE. PHYSICIAN COMPLETED LEFT SIDE. WHILE MAKING A CUTTING PASS ON RIGHT SIDE, HE NOTED LOSS OF POWER. LASER TECH NOTED ENERGY STILL BEING PRODUCED AND TRANSMITTED, THEN RESET LASER. PHYSICIAN THEN NOTED BURNS TO LEFT AND RIGHT BUCCAL REGION OF PT'S MOUTH AND COMMISSURE REGION OF PT'S LIP. PROCEDURE WAS DISCONTINUED. PT'S BURNS WERE TREATED WITH BACTITRACIN. DEVICE WAS INSPECTED AND WRINKLES AND BUBBLES WERE NOTED ON SHAFT. TOTAL PROCEDURE TIME WAS 25 MINS. TOTAL LASER ENERGY USED WAS 4.4 KJ. DEVICE WAS RETURNED TO IHD AND EVALUATED. IT WAS DETERMINED FIBER TIP BURNED AND CEASED TO FUNCTION.

**Concomitant Medical Products:**

- STATLASE SDL DIODE LASER.

- **Mfr Name:** IHD, INC.
- **Address:** 11240 CORNELL PARK DR.
  
  STE. 110
  
  CINCINNATI, OH 45242
  
  UNITED STATES

- **Device Available for Evaluation:** Y
- **Device Evaluated by Manufacturer (H3):** Yes
- **Remedial Action (H7):** OTHER
- **Correction/Removal No (H9):**

---

Recd: 463  
Page: 929  
Date Last Updated: 11/2/2010 9:17 AM
07-JUL-1999: IT IS CLEARLY NOTED IN THE INSTRUCTIONS FOR USE FOR THIS DEVICE THAT, "IF DESIRED TISSUE EFFECT IS NOT ACHIEVED AT THIS SETTING (12 WATTS), DISCONTINUE USE". ONCE IT WAS NOTED BY PHYSICIAN THAT TISSUE EFFECT WAS NOT ACHIEVED, LASER WAS RESET AND AN ADD'L ATTEMPT WAS MADE TO CUT TISSUE. IHD, INC HAS OFFERED FACILITY THE OPPORTUNITY TO RECEIVE ADD'L TRAINING IN THE USE OF THIS HANDPIECE. FACILITY HAS ACCEPTED AND A TIME-LINE FOR TRAINING IS BEING DEVELOPED.

DEVICE INFORMATION:

- **Brand:** HYBRID SURGICAL DEVICE (HSD) 10.5 CM CURVED
- **Device Type:** LASER DELIVERY AND ELECTROCAUTERY HANDPIECE
- **Catalog:** 2211-1290
- **Serial:** (*confidential*)
- **Lot:** 0000144
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Mfr Name: ALCON LABORATORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1610287-2000-00005</td>
<td>05-May-2000</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 04-Mar-2000  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):**  
**Event Outcome (B2):**  
**Report Source (G3):** FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE  
**Report Date (B4):** 06-Apr-2000  
**Reporter Occupation (E3):** 500 - RISK MANAGER  
**Device Operator:*** HEALTH PROFESSIONAL  
**Event Description (B5):**  

**Concomitant Medical Products:**  
NI

**Device Code:** (OP)-LASER, OPHTHALMIC (HQF)  
**Device Age (F9):**  
**Manufacture Date (H4):**  
**Single Use (H5):** Y  
**Expiration Date:**  
**Device Usage (H8):** I

**Device Available for Evaluation:*** Y  
**Device Evaluated by Manufacturer (H3):*** Yes  
**Remedial Action (H7):*** OTHER  
**Correction/Removal No (H9):*** NA  
**Additional Mfr Narrative (H10 & H11):**  
10-MAY-2000: H-10: NO SAMPLE HAS BEEN RETURNED FOR EVAL. THERE HAVE BEEN NO OTHER REPORTS ON THIS LOT. CODES PROVIDED BY MFR. THIS REPORT WAS MAILED IN TO FDA ON: 05/05/2000.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INFINITECH ENDOLASER PROBE
- **Device Type**: LASER PROBE
- **Device Type**: I-101-C1
- **Catalog**: NA
- **Serial**: (*confidential*)
- **Lot**: 926002
- **Other ID**: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name**: [Redacted]
- **Address**: [Redacted]
- **Email**: [Redacted]
- **Phone**: (*)
- **International**: [Redacted]
- **Fax**: [Redacted]

**Health Professional**: Unknown

**Occupation**: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1625519-1997-00004</th>
<th>Mfr Name:</th>
<th>LIFESTREAM INT'L, INC.</th>
<th>Date Received:</th>
<th>26-Nov-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Oct-1997</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>0 YR 150 DAYS (5 MO)</td>
<td>Manufacture Date (H4):</td>
<td>01-May-1997</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 04-DEC-1997: DURING EGD WITH LASER ABELATION OF TUMOR, THE LASER FIBER TIP BROKE OFF. LASER FIBER TIP WAS RETRIEVED INTACT FROM ESOPHAGUS AREA USING A SNARE. LASER PROCEDURE WAS TERMINATED FOLLOWING INCIDENT.

**Concomitant Medical Products:**
1997/10/08 GASTROSCOPE, OLYMPUS G1F29 (10/8/97 TO 10/8/97)

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LIGHT TOUCH, MICROCONTACT LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 9S-5601
- **Serial:** (*confidential*)
- **Lot:** 238719
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1625519-1997-00005</th>
<th>Mfr Name:</th>
<th>LIFESTREAM INT'L, INC.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 07-Nov-1997  
**Report Date (B4):** Omitted  
**Report Date (F8):** Omitted  
**Date Mfr Rec'd (G4):** 25-Nov-1997

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:** 
**Device Code:** 
**Device Evaluated by Manufacturer (H3):** Yes

**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): N  
**Event Outcome (B2):**  
**Reporter Occupation (E3):** -  
**Device Operator:**

**Device Usage (H8):** *

**Event Description (B5):**

Unk :

**Concomitant Medical Products:**

**Mfr Name:**
**Address:**

**Device Available for Evaluation:**

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

: ALL INFO CONCERNING INCIDENT AND PROCEDURE (ITEMS A-F) WAS OBTAINED FROM UF/DIST REPORT #5200280000-1997-0004.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td></td>
</tr>
<tr>
<td>Catalog</td>
<td></td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td></td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>EMAIL</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
</tbody>
</table>

Health Professional: No Answer

Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>12-Dec-1997</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Dec-1997</td>
<td>Reporter Occupation (E3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Jan-1998</td>
<td>Device Operator:</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>01-Sep-1997</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Unk :</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

Mfr Name: ,
Address: ,

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
: ALL INFO CONCERNING INCIDENT AND PROCEDURE (ITEMS A-F) WAS OBTAINED FROM REPORT FORM 3500A FROM THE FACILITY.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand:
- Device Type:
- Catalog:
  - Serial: (*confidential*)
  - Lot:
- Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: 
- Address: 
- EMAIL: 
- Phone: 
- International: 
- Fax: 

- Health Professional: No Answer
- Occupation: -
## MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Mfr Name: MYRIAD LASE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>22-Sep-1995</td>
<td>1645365-1995-00003</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8): 22-Sep-1995</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

### Event Description (B5):

Importer 12-OCT-1995: DURING PROSTATE SURGERY BEING PERFORMED ON A MALE PT, A SMALL FRAGMENT OF A GOLD TIP FROM A LASER FIBER FLAKED OFF & REQUIRED REMOVAL. A SECOND LASER FIBER WAS UTILIZED TO COMPLETE THE PROCEDURE. THERE WAS NO REPORT OF ADVERSE CONSEQUENCE TO THE PT AS A RESULT OF THE EVENT.

### Concomitant Medical Products:

- **Mfr Name:** MYRIAD LASE INC.
- **Address:** 4800 SOUTH EAST LOOP 820
  FORREST HILLS, TX 76140
  UNITED STATES

- **Device Available for Evaluation:** R
- **Device Evaluated by Manufacturer (H3):** No Answer

### Remedial Action (H7):

- **Correction/Removal No (H9):**
- **Additional Mfr Narrative (H10 & H11):** 12-OCT-1995:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

    Brand: SIDE FIRE FIBER
    Device Type: LASER FIBER

    Catalog: AA2441900
    Serial: (*confidential*)
    Lot: 25441

    Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1648708-1999-00001</th>
<th>Mfr Name:</th>
<th>TRANSMEDICA INTL., INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received:</td>
<td></td>
<td>15-Apr-1999</td>
<td></td>
</tr>
</tbody>
</table>

**Event Date (B3):** 24-Mar-1999  
**Event Report Type:** MALFUNCTION  
**Event Location (F12):**  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Event Location (F12):**  
**Report Date (B4):** 15-Apr-1999  
**Problem (B1):** Y

**Event Description (B5):**
Mfr 19-APR-1999: BATTERY PACK WAS RE-CHARGING IN BATTERY CHARGER. USER NOTICED THAT SMOKE WAS ORIGINATING FROM DEVICE DURING OPERATION. USER BELIEVED THAT RISK OF FIRE WAS IMMEDIATE.

**Concomitant Medical Products:**

**Device Name:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Usage (H8):** R  
**Manufacture Date (H4):** 01-Jul-1996  
**Expiration Date:**  
**Device Age (F9):**  
**Single Use (H5):** N  
**Device Operator:** PHYSICIAN  
**Report Source (G3):** U.S. MILITARY

**Date Mfr Rec'd (G4):**  
**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** Yes  
**Remedial Action (H7):** REPLACE  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 19-APR-1999;
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- **Brand:** TRANSMEDICA LASER LANCET LB100
- **Device Type:** LASER PERFORATOR
- **Device Type:** LB100/CH100
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **International:** [REDACTED]
- **Phone:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1720381-1997-00001
Mfr Name: FISMA, INC.
Date Mfr Rec’d (G4): 27-May-1997
Mfr 07-JAN-1998: DR. REPORTED SEEING REFLECTED LASER LIGHT WHILE OPERATING THE LASER SLIT LAMP.

Concomitant Medical Products:

Mfr Name: FISMA, INC.
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
07-JAN-1998:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: HGM
- Device Type: LASER SLIT LAMP USED IN OPHTHALMOLOGY
- Device Type: S30-H-A01-1-00
- Catalog: ZEISS 30 LDS SLIT LAMP
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- EMAIL: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
- Health Professional: Yes
- Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1720381-1997-00003
Mfr Name: FISMA, INC.

Event Date (B3): 10-Mar-1997
Report Date (B4): 11-Mar-1997
Report Date (F8):
Date Mfr Rec'd (G4): 11-Mar-1997

Event Report Type: OTHER
Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Location (F12):

Date Received: 30-Dec-1997

Report Date (B4):
Event Date (B3):

Adverse Event (B1): Problem (B1): Y

Event Date (B3): 10-Mar-1997
Report Date (B4): 11-Mar-1997
Report Date (F8): 30-Dec-1997
Date Mfr Rec'd (G4): 11-Mar-1997

Adverse Event (B1):

Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Date Last Updated: 11/2/2010 9:17 AM
Recd: 471 Page: 945

MFR Report No: 1720381-1997-00003
Mfr Name: FISMA, INC.

Event Description (B5):
mfr 07-jan-1998: dr. reported seeing green laser light while operating the laser slit lamp.

Concomitant Medical Products:

Product Code: (OP)-BIOMICROSCOPE, SLIT-LAMP, AC-POWERED (HJO)
Device Age (F9): Manufacture Date (H4): 01-Oct-1996
Expiration Date:

Device Operator: HEALTH PROFESSIONAL

Mfr 07-Jan-1998: DR. REPORTED SEEING GREEN LASER LIGHT WHILE OPERATING THE LASER SLIT LAMP.

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 07-JAN-1998:

Date Last Updated: 11/2/2010 9:17 AM
Recd: 471 Page: 945

Mfr Name: FISMA, INC.
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 07-JAN-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: HGM
Device Type: LASER SLIT LAMP USED IN OPHTHALMOLOGY
Device Type: S12-A-K05-1-00
Catalog: ZEISS DUAL SHUTTER SLIT LAMP
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

[Redacted]

Health Professional: Yes

Occupation: 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1720381-1997-00004</th>
<th>Mfr Name:</th>
<th>FISMA, INC.</th>
<th>Date Received</th>
<th>12-Jan-1998</th>
</tr>
</thead>
</table>

**Event Date (B3):** 19-Aug-1997  
**Report Date (B4):** 19-Aug-1997  
**Report Date (F8):** 19-Aug-1997  
**Date Mfr Rec'd (G4):** 19-Aug-1997

**Date Mfr Rec'd (G4):** 19-Aug-1997

**Device Operator:** HEALTH PROFESSIONAL

**Device Evaluated by Manufacturer (H3):** Yes

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
21-JAN-1998:

---

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):** R

**Event Report Type:** OTHER

**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY

**Problem (B1):** Y

**Event Location (F12):**

**Product Code:** (OP)-BIOMICROSCOPE, SLIT-LAMP, AC-POWERED (HJO)

**Event Description (B5):**
Mfr 21-JAN-1998: TWO DRS, SAID THEY WERE ABLE TO SEE REFLECTED LASER LIGHT DURING OPERATION OF THE SLIT LAMP.

**Manufacture Date (H4):** 01-Sep-1996

**Single Use (H5):** N

**Concomitant Medical Products:**

---

**Mfr Name:** FISMA, INC.  
**Address:** 3959 WEST 1820 SOUTH  
SALT LAKE CITY, UT 84104  
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Date Last Updated:** 11/2/2010 9:17 AM

---

Recd: 472  
Page: 947  
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HGM
- **Device Type:** LASER SLIT LAMP USED IN OPHTHALMOLOGY
- **Device Type:** S12-A-K01-1-00
- **Catalog:** ZEISS DUAL SHUTTER SLIT LAMP,
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Yes

- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
1720381-1997-00005

Mfr Name: FISMA, INC.

Event Date (B3): 27-May-1997
Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (OP)-BIOMICROSCOPE, SLIT-LAMP, AC-POWERED (HJO)
Device Age (F9):
Expiration Date:
Device Usage (H8): R

Event Description (B5):
Mfr 21-JAN-1998: DR REPORTED SEEING LASER LIGHT WHILE OPERATING THE LASER SLIT LAMP.

Concomitant Medical Products:

Mfr Name: FISMA, INC.
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
21-JAN-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** HGM
- **Device Type:** LASER SLIT LAMP USED IN OPHTHALMOLOGY
- **Device Type:** DSL030-100-A
- **Catalog:** ZEISS 30 LDS SLIT LAMP
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]

- **Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1720381-1997-00006
Mfr Name: FISMA, INC.
12-Jan-1998

Event Date (B3): 15-Oct-1997
Report Date (B4): 15-Oct-1997
Report Date (F8): 15-Oct-1997
Date Mfr Rec'd (G4): 15-Oct-1997
Product Code: (OP)-OPHTHALMOSCOPE, AC-POWERED (HLI)
Device Age (F9): 01-Sep-1994
Expiration Date: N
Device Usage (H8): R

Event Description (B5):
Mfr 21-JAN-1998: DR REPORTED SEEING REFLECTED LASER LIGHT WHILE OPERATING THE LASER INDIRECT OPHTHALMOSCOPE.

Concomitant Medical Products:

Mfr Name: FISMA, INC.
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
21-JAN-1998:

Recd: 474
Page: 951
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HGM
- **Device Type:** LASER INDIRECT OPHTHALMOSCOPE
- **Device Type:** DIO190-100-A
- **Catalog:** HGM ACCUSPOT
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

Health Professional: Yes

Occupation: 401 - BIOMEDICAL ENGINEER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1720381-1997-00007</th>
<th>Mfr Name:</th>
<th>FISMA, INC.</th>
<th>Date Received</th>
<th>12-Jan-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Sep-1997</td>
<td>Event Report Type: OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>09-Sep-1997</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>09-Sep-1997</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-BIOMICROSCOPE, SLIT-LAMP, AC-POWERED (HJO)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4): 01-Sep-1996</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: FISMA, INC.
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
21-JAN-1998:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** HGM
- **Device Type:** LASER SLIT LAMP USED IN OPHTHALMOLOGY
- **Device Type:** S30-H-A01-1-00
- **Catalog:** HGM ZEISS 30 LDS
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 401 - BIOMEDICAL ENGINEER
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1720381-1998-00007</th>
<th>Mfr Name:</th>
<th>FISMA, INC.</th>
<th>Date Received</th>
<th>29-Jul-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>FISMA, INC.</td>
<td>Address:</td>
<td>3959 WEST 1820 SOUTH SALT LAKE CITY, UT 84104 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>REPAIR</td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>07-AUG-1998: THE SLIT LAMP ATTACHMENT WHEN RETURNED TO FISMA (MFR) HAD ONE LENS STILL IN PLACE THE OTHER LENS WAS OUT OF THE UNIT. A COMPLETE INVESTIGATION IS UNDER WAY TO DETERMINE THE CAUSE AND A FOLLOW UP REPORT WILL BE SUBMITTED AT ITS CONCLUSION.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** HGM
- **Device Type:** LASER SLIT LAMP ATTACHMENT
- **Device Type:** A01-A-K03-0-02
- **Catalog:** PLANAR F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1720381-1999-00008
Mfr Name: FISMA, INC.

Event Date (B3): 08-Nov-1999
Report Date (B4): 01-Dec-1999
Report Date (F8): 24-Nov-1999
Date Mfr Rec’d (G4): 08-Nov-1999

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): OTHER
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, END PROCEDURE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Mar-1998
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 10-DEC-1999: DIABETIC RETINOPATHY BEING PERFORMED. SHUTTER STUCK IN CLOSED POSITION (VIEW SHUTTER) AND PHYSICIAN FIRED ONCE MORE BEFORE REALIZING PROBLEM. PHYSICIAN STATED THAT HE ELECTED TO END PROCEDURE EVEN THOUGH PT COULD HAVE REC'D "A FEW MORE SHOTS" BUT THE OUTCOME OF PT IS STILL GOOD. PHYSICIAN STATED THAT THE LAST SHOUT "WASN'T NORMAL SEQUENCE" AND THAT "NO FLASH BACK OCCURRED". POWER SET AT 200 MW AND THE DURATION AT 0.1 SECONDS. THE REPORT TO SVC DEPT RECORDED THE EVENT AS "MADE A STRANGE FLASH".

Concomitant Medical Products:

Mfr Name: FISMA
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): REPAIR
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
10-DEC-1999: FIELD SVC FOUND WORN/EXPOSED WIRE THAT CAUSED GROUND FAULT AND FORCE SHUTTER IN THE CLOSED POSITION. WIRE BETWEEN SHUTTER AND SLIT LAMP REPLACED REMEDIED SITUATION.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ZEISS M-150 SHUTTER
Device Type: LASER SLIT LAMP PROTECTION DEVICE (ARGON)
Device Type: S15-A-K03-1-02
Catalog: ZEISS THIN
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

EMAIL:
Phone: (*)
International:
Fax:

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Report Details

**MFR Report No:** 1721279-2004-00002  
**Mfr Name:** SPEXTRANETICS CORP.  
**Date Received:** 12-Nov-2004

**Event Date (B3):** 16-Sep-2004  
**Event Report Type:** DEATH

**Report Date (B4):** 12-Nov-2004  
**Event Outcome (B2):**

**Report Date (F8):** 18-Oct-2004  
**Adverse Event (B1): Problem (B1):** N

**Date Mfr Rec'd (G4):** 18-Oct-2004  
**Event Location (F12):**

**Product Code:** (CV)-PACER LEAD (MFA)  
**Report Source (G3):** HEALTH PROFESSIONAL

**Device Age (F9):**  
**Device Operator:**

**Expiration Date:**  
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Device Usage (H8):** *

**Event Description (B5):**

Unk :

**Concomitant Medical Products:**

**Mfr Name:**

**Address:** ,

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):**

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

: NO INDICATION THAT THE LASER SHEATH CAUSED PT DEATH.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SPECTRANETICS LASER SHEATH II
Device Type: 500-013
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID:

Reprocessed & Reused: Y

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: -
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MFR Report No:** 1721279-2007-00001  **Mfr Name:** SPECTRANETICS CORP.

**Event Date (B3):** 07-Mar-2007  **Event Report Type:** INJURY

**Report Date (B4):** 08-Mar-2007  **Event Outcome (B2):** REQUIRED INTERVENTION

**Report Date (F8):** 08-Mar-2007  **Adverse Event (B1):** Y

**Date Mfr Rec’d (G4):** 08-Mar-2007  **Problem (B1):** N

**Product Code:** (CV)-FIBEROPTIC (LPC)

**Device Operator:** HEALTH PROFESSIONAL

**Event Description (B5):**

Mfr 16-APR-2007: A CORONARY ARTERY WAS PERFORATED DURING LASER ATHERECTOMY CATHETER USE. THE "#7 PROXIMAL" HAD AN 85% OCCLUDED, 4MM LONG ECCENTRIC LESION. FIRST ATTEMPT (AT 45 MJ 25 PULSES/SECOND, 5 SECONDS, 5 PASSES) REDUCED THE OCCLUSION TO 50%. THREE MORE PASSES WERE MADE AT HIGHER LASER POWER (55 MJ, 35 PULSES/SECOND, 5 SECONDS, THREE PASSES) TO REDUCE IT FURTHER, WHEN THE CATHETER PERFORATED THE VESSEAL WALL. VENTRICULAR FIBRILLATION OCCURRED, BUT WAS CONVERTED WITH A DEFIBRILLATOR. VESSEL PERFORATION WAS SEEN ON THE ANGIOGRAM, AND SUCCESSFULLY SEALED WITH A COVERED STENT.

**Concomitant Medical Products:**

**Mfr Name:** THE SPECTRANETICS CORP.

**Address:** 96 TALAMINE CT.

COLORADO SPRINGS, CO 80907

UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

16-APR-2007: THIS APPEARS TO BE A PROCEDURE RELATED OCCURRENCE. THE DOCTOR NOTED THAT HE DID NOT SEE A PRODUCT QUALITY ISSUE WITH THE CATHETER. WE HAVE CONFIRMED THAT THE CATHETER WAS THROWN AWAY, SO IT IS NOT AVAILABLE FOR OUR INSPECTION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** SPECTRANETICS CVX-300 LASER SYSTEM
- **Device Type:** LASER ATERECTOMY CATHETER
- **Device Type:** 120-005
- **Catalog:** 120-005
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:**
- **Address:**
- **Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1721279-2007-00002</th>
<th>Mfr Name: SPECTRANETICS CORP.</th>
<th>Date Received: 11-Apr-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 14-Mar-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): NA - NOT APPLICABLE</td>
<td></td>
</tr>
<tr>
<td>Product Code: (CV)-FIBEROPTIC (LPC)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): 30-Nov-2008</td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td>Expiration Date: 30-Nov-2008</td>
<td>Device Usage (H8): I</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): Mfr 08-NOV-2007:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mfr Name: THE SPECTRANETICS CORPORATION
Address: 96 TALAMINE CT.
COLORADO SPRINGS, CO 80907
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
08-NOV-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SPECTRANETICS CVX-300 LASER SYSTEM
- **Device Type:** LASER AHERECTOMY CATHETER
- **Device Type:** 320-159
- **Catalog:** 320-159
- **Serial:** (*confidential*)
- **Lot:** 842222
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 1725006-2009-00001
Mfr Name: CAO GROUP, INC.

Event Date (B3): 16-Apr-2009
Report Date (B4): 27-May-2009
Report Date (F8): 20-May-2009
Date Mfr Rec'd (G4): 20-May-2009

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 116 - DENTIST
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL, DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Jan-2008
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 14-SEP-2009:

Concomitant Medical Products:

Mfr Name: IVOCLAR VIVADENT
Address: 175 PINEVIEW DRIVE
AMHERST, NY 14228
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): OTHER
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
14-SEP-2009:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ODYSSEY NAVIGATOR DIODE LASER
Device Type: LASER SURGICAL DEVICE
Device Type: 603302
Catalog: 603302
Serial: (*confidential*)
Lot:
Other ID:
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: Yes
EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]
Occupation: 116 - DENTIST
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 1920664-2009-00021</th>
<th>Mfr Name: BAUSCH &amp; LOMB, INC.</th>
<th>Date Received: 12-Jan-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 13-Dec-2008</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 15-Dec-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Feb-2008</td>
</tr>
<tr>
<td></td>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8): U</td>
</tr>
<tr>
<td></td>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Available for Evaluation: Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Evaluated by Manufacturer (H3): No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remedial Action (H7):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correction/Removal No (H9):</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11): 15-JAN-2009:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>ZYOPTIX TREATMENT CARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER TREATMENT CARD</td>
</tr>
<tr>
<td>Device Type</td>
<td>NA</td>
</tr>
<tr>
<td>Catalog</td>
<td>88002150</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>30106081</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [(b) (6)]
Address: [(b) (b)]

Health Professional: Yes

Email: [(b) (6)]
Phone: [(b) (6)]
International: [(b) (6)]
Fax: [(b) (6)]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
1920664-2009-00022
Mfr Name: BAUSCH & LOMB, INC.
Event Date (B3): 10-Dec-2008
Report Date (B4): 15-Dec-2008
Report Date (F8):
Date Mfr Rec'd (G4): 15-Dec-2008
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE
Report Date (B4): 15-Dec-2008
Event Outcome (B2):
OTHER

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Age (F9):
Expiration Date:
Device Usage (H8): U

Event Description (B5):
Mfr 15-JAN-2009: FOLLOW-UP RESULTS FOLLOWING LASIK SURGERY FOUND THAT THE PATIENT'S VISION WAS SIGNIFICANTLY OVERCORRECTED.

Concomitant Medical Products:
NA

Mfr Name: BAUSCH & LOMB, INC.
Address: ROCHESTER, NY 14609
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
15-JAN-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ZYOPTIX TREATMENT CARD
Device Type: LASER TREATMENT CARD
Catalog: 88002150
Serial: (*confidential*)
Lot: 30106081
Other ID: NA
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]
Occupation: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>1920664-2009-00139</th>
<th>Mfr Name:</th>
<th>BAUSCH &amp; LOMB, INC.</th>
<th>Date Received:</th>
<th>18-Jun-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-May-2009</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-May-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)

Device Age (F9): Manufacture Date (H4):
   Single Use (H5): N
Device Usage (H8): U

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: BAUSCH & LOMB
   Address: ROCHESTER, NY 14609 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-JUN-2009:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TECHNOLAS EXCIMER 217A LASER
- **Device Type:** LASER
- **Catalog:** EXC-217A
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER

- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2024567-2000-00002

Mfr Name: DORNIER SURGICAL PRODUCTS, INC.

Event Date (B3): 17-Oct-2000
Report Date (B4): 02-Jan-2002
Date Mfr Rec'd (G4): 24-Aug-2001

Event Report Type: MALFUNCTION
Adverse Event (B1): Y
Problem (B1): N
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Event Location (F12):

Report Date (B4): 11-Feb-2002

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 15-FEB-2002: DOCTOR USING LASER FIBER AND HEARD "POPPING AND BREAKING" RESULTING IN A BURN ON THE PATIENT DRAPE.

Concomitant Medical Products:
NA

Device Available for Evaluation: N

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
15-FEB-2002: MDR WAS NOT FILED WHEN ORIGINALLY REPORTED. AUDIT OF COMPLAINT FILES DISCOVERED SITUATION AND THEREFORE MDR IS BEING FILED. DUE TO DATE OF INCIDENT NO ADDITIONAL INFORMATION IS AVAILABLE. SAMPLE NOT AVAILABLE, NO OTHER PRODUCT FROM LOT OR INVENTORY AVAILABLE FOR EXAMINATION.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER

- **EMAIL:** [redacted]
- **Phone:** (b) (6)
- **Fax:**
- **International:**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>02-May-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>17-Apr-2001</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Apr-2001</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedy Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>02-MAY-2001:</td>
</tr>
</tbody>
</table>

Importer 02-MAY-2001: PHYSICIAN WAS TREATING A PT WITH STONES IN THE BLADDER WITH THE HOLMIUM LASER. THE TIP OF THE FIBER (LIGHTGUIDE) FELL OFF INTO THE BLADDER. THERE WAS NO INJURY TO THE PT. TREATMENT OF THE STONES WAS COMPLETED WITH AN ELECTROHYDRAULIC LITHOTRIPTER.

Concomitant Medical Products:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>DORNIER MEDIZIN LASER GMBH</td>
</tr>
<tr>
<td>Address:</td>
<td>INDUSTRIESTR. 13</td>
</tr>
<tr>
<td></td>
<td>GERMERING,</td>
</tr>
<tr>
<td></td>
<td>GERMANY</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
</tbody>
</table>

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

02-MAY-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER MEDILAS H LASER FIBER
- **Device Type:** LASER FIBER - LIGHTGUIDE
- **Device Type:** LASER - MEDILAS H
- **Catalog:** FIBER - HF1000DSSM-S
- **Serial:** (*confidential*)
- **Lot:** FIBER - 1799L
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2024567-2001-00002
Mfr Name: DORNIER SURGICAL PRODUCTS, INC.

Event Date (B3): 26-Jan-2001
Report Date (B4): 02-Jan-2002
Report Date (F8): 26-Jan-2001
Date Mfr Rec'd (G4): 26-Jan-2001
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Adverse Event (B1): Y
Problem (B1): N
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL
Report Source (G3):
Event Location (F12):

Event Description (B5):
Mfr 13-FEB-2002: LASER FIBER BROKE AND BURNED. BOTH THE DOCTOR'S AND THE NURSE'S BAND IN 2 OR 3 SPOTS.

Concomitant Medical Products:
NA

Mfr Name: DORNIER SURGICAL PRODUCTS
Address: 10027 SOUTH 51ST ST.
PHOENIX, AZ 85044
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-FEB-2002: MDR WAS NOT FILED WHEN ORIGINALLY REPORTED. AUDIT OF COMPLAINT FILES DISCOVERED SITUATION AND THEREFORE, A MDR IS BEING FILED. DUE TO THE DATE OF THE INCIDENT NO ADD'L INFO IS AVAILABLE.

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** A4300-02B/A3800-04A
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** No
- **Occupation:** OTHER
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
Event Date (B3): 22-Mar-2001
Report Date (B4): 02-Jan-2002
Report Date (F8): 24-Aug-2001
Date Mfr Rec'd (G4): 24-Aug-2001

Event Report Type: MALFUNCTION
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Reporter Occupation (E3): NA - NOT APPLICABLE
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Sep-2000
Expiration Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 15-FEB-2002: TIPS ON LASER FIBERS WERE BURNING AND DISCOLORED. CUSTOMER DID NOT FEEL SAFE USING FIBERS AND FELT PRODUCT WAS DEFECTIVE.

Concomitant Medical Products:

Mfr Name: DORNIER SURGICAL PRODUCTS
Address: 10027 SOUTH 51ST ST.
          PHOENIX, AZ 85044
          UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
15-FEB-2002: MDR WAS NOT FILED WHEN ORIGINALLY REPORTED. AUDIT OF COMPLAINT FILES DISCOVERED SITUATION AND THEREFORE AN MDR IS BEING FILED. DUE TO DATE OF INCIDENT NO ADDITIONAL INFORMATION IS AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF0200DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** A3800-01A
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Occupation:** NA - NOT APPLICABLE

Health Professional: No Information
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2024567-2002-00001</th>
<th>Mfr Name:</th>
<th>DORNIER SURGICAL PRODUCTS, INC.</th>
<th>Date Received: 2024567-2002-00001</th>
<th>11-Feb-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Jan-2001</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Feb-2002</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>REPORTER</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Jan-2001</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Age (F9):</td>
<td></td>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expiration Date:</td>
<td></td>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>

Mfr Name: DORNIER SURGICAL PRODUCTS
Address: 10027 SOUTH 51ST ST.
PHOENIX, AZ 85044
UNITED STATES

Concomitant Medical Products:
NA

Device Available for Evaluation: N

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
27-FEB-2002: MDR WAS NOT FILED WHEN ORIGINALLY REPORTED. AUDIT OF COMPLAINT FILES DISCOVERED SITUATION AND THEREFORE MDR IS BEING FILED. THE DATE OF INCIDENT NO ADDITIONAL INFORMATION IS AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** HF 0600 DSSM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b)(6)
- **Address:** (b)(6)
- **Health Professional:** No
- **EMAIL:** (b)(6)
- **Phone:** (b)(6)
- **International:**  
- **Fax:**  
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2028159-1996-00163
Mfr Name: ALCON LABORATORIES
Event Date (B3): 06-Aug-1996
Report Date (B4): 04-Sep-1996
Report Date (F8):
Date Mfr Rec’d (G4): 08-Aug-1996

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): INVALID DATA
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Product Code: (OP)-PHOTOCOAGULATOR AND ACCESSORIES (HQB)
Device Age (F9):
Expiration Date:
Device Usage (H8): R

Manufacture Date (H4):
Single Use (H5): N

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): RECALL
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
07-OCT-1996: THIS PRODUCT HAD BEEN RECALLED. ORIGINAL RETROFIT ON 4/10/96 WAS PERFORMED INCORRECTLY BY FOREIGN FIELD ENGINEER. THE RETROFIT WAS PERFORMED CORRECTLY ON 8/8/96. PT INFO HAS BEEN REQUESTED FROM THE REPORTER BUT HAS NOT BEEN RECEIVED TO DATE. THE MFR'S INTERNAL REFERENCE NUMBER IS 8-8799-96.

Mfr 07-OCT-1996: A POWER SURGE DURING THE PROCEDURE RESULTED IN A STRONGER BURN TO THE RETINA.

Concomitant Medical Products:
UNK

Mfr Name: ALCON LABORATORIES, INC.
Address: 15800 ALTON PKWY
IRVINE, CA 92718
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): RECALL
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
07-OCT-1996: THIS PRODUCT HAD BEEN RECALLED. ORIGINAL RETROFIT ON 4/10/96 WAS PERFORMED INCORRECTLY BY FOREIGN FIELD ENGINEER. THE RETROFIT WAS PERFORMED CORRECTLY ON 8/8/96. PT INFO HAS BEEN REQUESTED FROM THE REPORTER BUT HAS NOT BEEN RECEIVED TO DATE. THE MFR'S INTERNAL REFERENCE NUMBER IS 8-8799-96.

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>OPHTHALAS 532 LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER PHOTOCOAGULATOR</td>
</tr>
<tr>
<td>Device Type</td>
<td>532 LASER</td>
</tr>
<tr>
<td>Catalog</td>
<td>NA</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>UNK</td>
</tr>
<tr>
<td>Other ID</td>
<td>K914334</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>Yes</td>
</tr>
<tr>
<td>EMAIL:</td>
<td></td>
</tr>
<tr>
<td>Phone:</td>
<td>(*)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-1996-00183</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Sep-1996</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>05-Sep-1996</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>05-Sep-1996</td>
<td>Device Operator:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date Received**: 03-Oct-1996

**Mfr Name**: ALCON LABORATORIES, INC.

**Address**: 15800 ALTON PARKWAY

IRVINE, CA 92718

UNITED STATES

**Device Available for Evaluation**: Y

**Device Evaluated by Manufacturer (H3)**: Yes

**Remedial Action (H7)**: REPAIR

**Correction/Removal No (H9)**: NA

**Additional Mfr Narrative (H10 & H11)**:

13-DEC-1996: A COMPANY SERVICE REP CHECKED THE SYSTEM AND IDENTIFIED A DEFECTIVE ATTENUATOR MODULE. A NEW MODULE HAS BEEN ORDERED FOR REPLACEMENT. SYSTEM WILL NOT BE USED UNTIL REPLACEMENT OCCURS. THIS REPORT WAS MAILED IN TO FDA ON: 10/03/96. THE MFR'S INTERNAL REFERENCE NUMBER IS 9-8873-96. DISCLAIMER: THIS INFO IS SUBMITTED PURSUANT TO 21CFR803, IN COMPLIANCE WITH THE MEDICAL DEVICE REPORTING REQUIREMENT AND SHOULD NOT BE CONSIDERED TO BE AN ADMISSION THAT AN ALCON LABORATORIES, INC. PRODUCT IS DEFECTIVE OR HAS CAUSED SERIOUS INJURY.
### DEVICE INFORMATION:

- **Brand:** 3000 LE ND: YAG LASER
- **Device Type:** LASER PHOTODISRUPTER
- **Device Type:** 3000 LE
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** K882772
- **Reprocessed & Reused:** N/A

### REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>11-Nov-1996</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>11-Nov-1996</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>11-Nov-1996</td>
<td>Device Operator:</td>
<td>OTHER</td>
</tr>
</tbody>
</table>

**Adverse Event (B1):** Problem (B1): Y

**Event Location (F12):** INVALID DATA

**Report Source (G3):** FOREIGN, COMPANY REPRESENTATIVE, QA TESTS

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):** Manufacture Date (H4):

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** I

**Event Description (B5):**
Mfr 18-DEC-1996: DURING QUALITY TEST, POWER DISPLAY SHIFTED UNEXPECTEDLY TO HIGHER LEVEL IN READY OR STANDBY MODE. UNIT WAS NOT INSTALLED ON SITE.

**Concomitant Medical Products:** NA

**Mfr Name:** ALCON LABORATORIES, INC.
**Address:** 15800 ALTON PKWY
IRVINE, CA 92718
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):** OTHER
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
18-DEC-1996: H-10: A CO REP CHANGED THE KEYBOARD INTERFACE, S/N 315, REV.L. RESOLVING PROBLEM, PASSING QUALITY TEST. EVALUATION IS NOT COMPLETE AT THIS TIME. THIS REPORT WAS MAILED IN TO FDA ON: 12/11/96. DISCLAIMER: THIS INFO IS SUBMITTED PURSUANT TO 21CFR803, IN COMPLIANCE WITH THE MEDICAL DEVICE REPORTING REQUIREMENT AND SHOULD NOT BE CONSIDERED TO BE AN ADMISSION THAT AN ALCON LABORATORIES, INC. PRODUCT IS DEFECTIVE OR HAS CAUSED SERIOUS INJURY.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532
- **Catalog:** 8065-6786-01
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** 510(K) K914334

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Phone:** (UNK)
- **Fax:**
- **Email:**
- **International:**
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2028159-1998-00201
Mfr Name: ALCON LABORATORIES

Event Date (B3): 17-Jun-1998
Report Date (B4): 17-Jun-1998
Report Date (F8): 17-Jun-1998
Date Mfr Rec'd (G4): 17-Jun-1998

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:

Device Operator:

Event Description (B5):
Mfr 16-JUL-1998: REPORTER NOTED CORNEAL BURN WHILE USING THE LASER FOR AN IRIDOTOMY, FOUND FIBER WAS NOT PUSHED IN ALL THE WAY. DID NOT WANT LASER CHECKED.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):

MFR Report No: 2028159-1998-00201
Report Date (F8): 001 - PHYSICIAN
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Date Last Updated: 11/2/2010 9:17 AM Recd: 493 Page: 989
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OPHTHALAS (A/K) LASER
- **Device Type:** LASER PHOTOCOAGULTOR
- **Device Type:** OPHTH-AK
- **Catalog:** OPHTH-AK
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 22-Oct-1998
Report Date (F8): 23-Oct-1998
Date Mfr Rec'd (G4): 23-Oct-1998

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1):
Problem (B1): Y

Event Location (F12): AMBULATORY SURGICAL FAC
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 27-NOV-1998: REPORTER NOTED UNIT FIRED IN READY MODE. NO PT INJURY REPORTED.

Concomitant Medical Products:
NA

Mfr Name: ALCON LABORATORIES, INC.
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
27-NOV-1998: H-10: A COMPANY SERVICE REP CHECKED THE SYSTEM AND COULD NOT DUPLICATE PROBLEM REPORTED, BUT OBSERVED INTERMITTENT LOW ENERGY BURN. REPLACED "PCB" AND RIBBON CABLES. H-11: PARTIAL INFO IN SECTION F PROVIDED BY CUSTOMER'S INITIAL REPORT. CODES PROVIDED BY MFR. THIS REPORT WAS MAILED IN TO FDA ON: 11/19/98. DISCLAIMER: THIS INFORMATION IS SUBMITTED PURSUANT TO 21CFR803, IN COMPLIANCE WITH THE MEDICAL DEVICE REPORTING REQUIREMENT AND SHOULD NOT BE CONSIDERED TO BE AN ADMISSION THAT AN ALCON LABORATORIES, INC PRODUCT IS DEFECTIVE OR HAS CAUSED SERIOUS INJURY.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>2500LE ND: YAG LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER PHOTODISRUPTER</td>
</tr>
<tr>
<td>Device Type</td>
<td>2500LE</td>
</tr>
<tr>
<td>Catalog</td>
<td>2500LE</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### REPORTER INFORMATION:

| Name:          | (b) (6)                           |
| Address:       | (b) (b)                           |
| Health Professional: | Yes                           |
| EMAIL:         | (b) (6)                           |
| Phone:         | (b) (6)                           |
| International: |                                  |
| Fax:           |                                  |
| Occupation:    | 001 - PHYSICIAN                  |
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>23-Oct-1998</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Event Location (F12):</td>
<td>AMBULATORY SURGICAL FACILITY</td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Mfr 27-NOV-1998: REPORTER NOTED UNIT FIRED IN READY MODE. NO PT INJURY REPORTED.

Concomitant Medical Products:
NA

Mfr Name: ALCON LABORATORIES, INC.
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
27-NOV-1998: H-10: A COMPANY SERVICE REP CHECKED THE SYSTEM AND COULD NOT DUPLICATE REPORTED PROBLEM, BUT OBSERVED INTERMITTENT LOW ENERGY BURN. REPLACED "PCB" AND RIBBON CABLES. H-11: PARTIAL INFO IN SECTION F PROVIDED BY CUSTOMER'S INITIAL REPORT. CODES PROVIDED BY MFR. THIS REPORT WAS MAILED IN TO FDA ON: 11/19/98. DISCLAIMER: THIS INFORMATION IS SUBMITTED PURSUANT TO 21CFR803, IN COMPLIANCE WITH THE MEDICAL DEVICE REPORTING REQUIREMENT AND SHOULD NOT BE CONSIDERED TO BE AN ADMISSION THAT AN ALCON LABORATORIES, INC PRODUCT IS DEFECTIVE OR HAS CAUSED SERIOUS INJURY.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: 2500LE ND: YAG LASER
- **Device Type**: LASER PHOTODISRUPTER
- **Device Type**: 2500LE
- **Catalog**: 2500LE
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA

- **Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: [Redacted]
- **Address**: [Redacted]
- **Email**: [Redacted]
- **Phone**: [Redacted]
- **International**: [Redacted]
- **Fax**: [Redacted]
- **Occupation**: 001 - PHYSICIAN

Health Professional: Yes
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No:</th>
<th>Mfr Name:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Event Outcome (B2):</th>
<th>Date Mfr Rec'd (G4):</th>
<th>Reporter Occupation (E3):</th>
<th>Adverse Event (B1):</th>
<th>Event Location (F12):</th>
<th>Report Source (G3):</th>
</tr>
</thead>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
  Single Use (H5): N
  Device Usage (H8): R

Event Description (B5):
Mfr 01-JUL-1999: RPTR NOTED EYE PAIN DURING ACCIDENTAL EXPOSURE TO LASER LIGHT DURING FUNCTIONAL TEST. NO INTERVENTION REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON LABORATORIES, INC.
Address: 15800 ALTON PKWY.
           IRVINE, CA 92618
           UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
01-JUL-1999: H-10: CUSTOMER HAD NOT USED CORRECT FILTER WITH THIS INSTRUMENT. PARTIAL INFO IN SECTION F PROVIDED BY CUSTOMER'S INITIAL REPORT. CODES PROVIDED BY MFR. THIS REPORT WAS MAILED IN TO FDA ON: 06/23/1999.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 EYELITE
- **Catalog:** 532 EYELITE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)

- **Health Professional:** Yes

- **Occupation:** 001 - PHYSICIAN

EMAIL:

Phone: (*)

International:

Fax:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-1999-00202</th>
<th>Mfr Name: ALCON LABORATORIES</th>
<th>30-Jul-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 30-Jun-1999</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12): AMBULATORY SURGICAL FACILITY</td>
<td>Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Report Date (F8): 30-Jun-1999</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 30-Jun-1999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9): 0 YR 30 DAYS (1 MO)</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mfr 04-AUG-1999: RPTR NOTED LASER SPOT WAS TOO LARGE AND HAD TO GET CLOSE TO RETINA TO GET A SMALLER SPOT; BURNED HOLE IN RETINA. FINISHED PROCEDURE AS PLANNED; NO PERMANENT INJURY OR INTERVENTION REPORTED.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NI</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mfr Name: ALCON LABORATORIES, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Address: 15800 ALTON PKWY. IRVINE, CA 92618 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remedial Action (H7): OTHER</td>
<td>Correction/Removal No (H9): NA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 EYELITE
- **Catalog:** 532 EYELITE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

  Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-1999-00330</th>
<th>Mfr Name: ALCON LABORATORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>03-Nov-1999</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>03-Nov-1999</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>03-Nov-1999</td>
<td>Reporter Occupation (E3):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>03-Nov-1999</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td></td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Usage (H8): R</td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 14-DEC-1999: RPTR NOTED INTERMITTENT ERROR CODE MESSAGE WHEN TRYING TO FIRE MULTIPLE SHOTS. CASE CANCELLED. NO PT INJURY.

Concomitant Medical Products:
NI

Mfr Name: ALCON LABORATORIES, INC.
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVELOPMENT INFORMATION:

- **Brand:** 3000LE LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 3000LE
- **Catalog:** 3000LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2000-00031
Mfr Name: ALCON LABORATORIES
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
Single Use (H5): N
Device Usage (H8): U

Event Description (B5):
Mfr 24-FEB-2000: RPTR NOTED PROTECTION FILTER WAS NOT WELL POSITIONED, BUT THE SAFETY SYSTEM DID NOT FUNCTION. NO CLINICAL CONSEQUENCES BECAUSE THE NURSE NOTICED THE DEFECT BEFORE THE USE OF THE LASER.

Concomitant Medical Products:
NA

Mfr Name: ALCON LABORATORIES, INC.
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
24-FEB-2000: H-10: PRODUCT WAS NOT EVALUATED. CUSTOMER DID NOT SELECT CORRECT TERMINAL FOR USE. NO FILTER WAS REQUIRED WITH THE TERMINAL SELECTION MADE. DFU'S INSTRUCT OPERATOR TO SELECT AND CONFIRM THE RIGHT PORT. THIS REPORT WAS MAILED IN TO FDA ON: 2/16/00.
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 LASER
- **Catalog:** 532 LASER
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** UNK
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

- **EMAIL:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2000-00047</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
</tr>
</thead>
</table>

**Event Date (B3):** 17-Nov-1997  
**Report Date (B4):** 11-Feb-2000  
**Report Date (F8):** 11-Feb-2000  
**Date Mfr Rec’d (G4):** 11-Feb-2000  

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Event Location (F12):**  
**Report Source (G3):** FOREIGN, CONSUMER, HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Manufacture Date (H4):**  
**Expiration Date:**  
**Device Usage (H8):** R

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No  
**Remedial Action (H7):** OTHER  
**Correction/Removal No (H9):** NA  
**Additional Mfr Narrative (H10 & H11):**  

---

**Event Description (B5):**

Mfr 15-MAR-2000: REPORTER NOTED PT HAD LASER PROCEDURE OVER TWO YEARS AGO AND HAS FILED A COMPLAINT WITH HOSPITAL COMPLAINT COMMISSION. PT NOTED A GLARE AND RAINBOWS AND RELATES IT TO THE LASER PROCEDURE. DOCTOR NEVER SAW THE PT AFTER TREATMENT. NEITHER HOSPITAL NOR DOCTOR FEEL EVENTS WERE DUE TO A FAILURE OF THE LASER.

---

**Concomitant Medical Products:**

NI
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 3000LE LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 3000LE
- **Catalog:** 3000LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**EMAIL:** [REDACTED]
**Phone:** [REDACTED]
**International:**
**Fax:**

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2000-00049</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
</tr>
</thead>
</table>

**Event Date (B3):** 14-Feb-2000

**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y

**Report Date (B4):** 14-Feb-2000

**Event Outcome (B2):**

**Event Location (F12):**

**Date Mfr Rec'd (G4):** 14-Feb-2000

**Device Operator:** HEALTH PROFESSIONAL

**Report Source (G3):** HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):**

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** R

**Event Description (B5):**

Mfr 20-MAR-2000: REPORTER NOTED LASER JUMPS FROM 1.4MJ TO 8.3MJ/9.6MJ WHEN FIRED, AND DISPLAYED ERROR. THERE WAS NO INJURY TO PT OR USER, AND PT REPORTEDLY RECOVERING WELL.

**Concomitant Medical Products:**

NI

**Mfr Name:** ALCON LABORATORIES, INC.

**Address:** 15800 ALTON PKWY.

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: 2300 LASER
- **Device Type**: LASER PHOTODISRUPTOR
- **Device Type**: 2300LE
- **Catalog**: 2300LE
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA
- **Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: [redacted]
- **Address**: [redacted]
- **Health Professional**: Yes
- **Occupation**: 401 - BIOMEDICAL ENGINEER

**EMAIL**: [redacted]
**Phone**: [redacted]
**International**: [redacted]
**Fax**: [redacted]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2000-00145
Mfr Name: ALCON LABORATORIES

Event Date (B3): 26-May-2000
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 26-May-2000
Event Outcome (B2):

Event Location (F12):

Date Mfr Rec'd (G4): 26-May-2000
Reporter Occupation (E3): 002 - NURSE

Device Operator: HEALTH PROFESSIONAL

Mfr Name: ALCON LABORATORIES

Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H8): NA

Additional Mfr Narrative (H10 & H11):
28-JUN-2000: A CO SVC REP CHECKED THE SYSTEM AND ORDERED PARTS. RETURNED TO INSTALL DISPLAY INTERFACE PCB, HIGH REFLECTOR AND
STOP COLLAR ASSEMBLY. THIS REPORT WAS MAILED IN TO FDA ON: 06/23/2000.

Event Description (B5):

Mfr 28-JUN-2000: RPTR NOTED LASER WAS MISFIRING DURING IRIDECTOMY. POWER SET AT 6.2 RETURNED TO ZERO WHEN FIRED. ALSO NOTED BEAM
WAS JUMPING BACK AND FORTH. FIRED 20 SHOTS, COMPLETED CASE AS PLANNED AND NO PT/STAFF INJURY.

Concomitant Medical Products:
NA

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

Device Age (F9):

Expiration Date:

Manufacture Date (H4):

Single Use (H5): N

Device Usage (H8): R

Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Date Last Updated: 11/2/2010  9:17 AM
Recd: 502  Page: 1,007
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 2500 LE ND: YAG LASER
- **Device Type:** LASER PHOTODISRUPTER
- **Device Type:** 2500 LE
- **Catalog:** 2500 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>[b] (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>[b] (b)</td>
</tr>
</tbody>
</table>

- **Health Professional:** Yes

- **EMAIL:**
- **Phone:** [b] (b)
- **International:**
- **Fax:**

- **Occupation:** 002 - NURSE

Recd: 502 Page: 1,008 Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2028159-2000-00146

Event Date (B3): 25-May-2000
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 25-May-2000
Report Date (F8): 25-May-2000
Date Mfr Rec'd (G4): 25-May-2000
Event Location (F12): Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Event Outcome (B2): Event Report Type: MALFUNCTION
Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)
Device Age (F9): Manufacture Date (H4): N
Expiration Date:
Device Usage (H8): U

Event Description (B5):
Mfr 28-JUN-2000: RPTR NOTED PITTING OF INTRAOCULAR LENS DURING PROCEDURE. COULD NOT COMPLETE CASE AS PLANNED, AND CANCELLED SUBSEQUENT CASES.

Concomitant Medical Products:
NA

Mfr Name: ALCON LABORATORIES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 3000 LE ND: YAG LASER
- **Device Type:** LASER PHOTODISRUPTER
- **Device Type:** 3000 LE
- **Catalog:** 3000 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Health Professional:** Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>16-Jun-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>20-Jun-2000</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>20-Jun-2000</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2028159-2000-00172</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON LABORATORIES</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>401 - BIOMEDICAL ENGINEER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
</tbody>
</table>

Mfr June 19-2000: RPTR NOTED 20-25 CORNEAL BURNS AT END OF PROCEDURE. USED LUBRICATING EYE DROPS AND MEDICATION TO RELIEVE PAIN. CANCELLED CASE. PT PROGNOSIS IS REPORTED AS GOOD FOR VISUAL RECOVERY.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS ARGON/KRYPTON PHOTOCOAGULATOR
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** OPHTHALAS SP
- **Catalog:** OPHTHALAS SP
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 401 - BIOMEDICAL ENGINEER

- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-2000-00173</th>
<th>Mfr Name: ALCON LABORATORIES</th>
</tr>
</thead>
</table>

**Event Date (B3):** 22-Jun-2000  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Event Outcome (B2):**  
**Reporter Occupation (E3):** 002 - NURSE  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Product Code:** (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):** U

**Report Date (B4):** 22-Jun-2000  
**Event Date (B3):** 22-Jun-2000  
**Report Date (F8):**  
**Date Mfr Rec’d (G4):** 22-Jun-2000  
**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Event Description (B5):**
Mfr 27-JUL-2000: RPTR NOTED TRANSIENT CORNEAL SWELLING POST-TREATMENT THAT CLEARED QUICKLY AND PITTING LENS. NO INTERVENTION REPORTED.

**Concomitant Medical Products:**
NA

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** 2500 LE ND: YAG LASER
- **Device Type:** LASER PHOTODISRUPTER
- **Device Type:** 2500 LE
- **Catalog:** 2500 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

### REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Event Description (B5):</td>
<td>Event Description (B5):</td>
<td></td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**

NI

**Device Age (F9):**

Manufacture Date (H4):

Single Use (H5): N

Device Usage (H8): R

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- Brand: 2300 LE ND: YAG PHOTODISRUPTER
- Device Type: LASER PHOTODISRUPTER
- Device Type: 2300 LE
- Catalog: 2300 LE
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- Name: [Redacted]
- Address: [Redacted]
- Health Professional: Yes
- Occupation: 002 - NURSE

**EMAIL:** [Redacted]

**Phone:** [Redacted]

**International:** [Redacted]

**Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2000-00245</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
<th>Date Received</th>
<th>22-Sep-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Aug-2000</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>24-Aug-2000</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 17-OCT-2000: RPTR NOTED THE LASER PROBE TIP BROKE OFF IN PT'S EYE DURING PROCEDURE. RETRIEVED THE PIECE AND THERE WAS NO PT INJURY.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
17-OCT-2000: WAITING FOR EVAL RESULTS. PARTIAL INFO IN SECTION F PROVIDED BY CUSTOMER'S FORM 3500A. THIS REPORT MAILED IN TO FDA ON: 9/22/00.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER PROBE
- **Device Type:** LASER PROBE
- **Device Type:** NA
- **Catalog:** 8065010739
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Fax:**
- **Phone:**
- **International:**
- **Health Professional:** Yes
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>19-Oct-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>19-Oct-2000</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON LABORATORIES</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Oct-2000</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>19-Oct-2000</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2028159-2000-00310</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON LABORATORIES</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Nov-2000</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Nov-2000</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON LABORATORIES</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Nov-2000</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Nov-2000</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON LABORATORIES</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Nov-2000</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 29-NOV-2000: REPORTER NOTED INTERMITTENT PROBLEMS WITH LASER DURING PROCEDURE. WHEN STARTING TO LASER, FOUND THE ENERGY DELIVERED HAD JUMPED TO 12.5MJ. STOPPED PROCEDURE AND SENT PATIENT HOME. NO PT INJURY.

Concomitant Medical Products:
NA

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
29-NOV-2000: A COMPANY SERVICE REPRESENTATIVE CHECKED THE SYSTEM AND REPLACED THE Q SWITCH DRIVER TO RESOLVE CONDITION REPORTED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 2500 LE ND: YAG
- **Device Type:** LASER PHOTODISRUPTOR
- **Device Type:** 2500 LE
- **Catalog:** 2500 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes

- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**

- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2000-00311</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
</tr>
</thead>
</table>

**Event Date (B3):** 01-Oct-2000  
**Report Date (B4):** 19-Oct-2000  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 19-Oct-2000  
**Mfr Name:** ALCON LABORATORIES  
**Mfr 29-NOV-2000:** REPORTER NOTED INTERMITTENT PROBLEMS WITH LASER DURING PROCEDURE THE WEEK IN 2000. NO INJURY REPORTED.

**Product Code:** (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):** R  

**Event Description (B5):**
Mfr 29-NOV-2000: REPORTER NOTED INTERMITTENT PROBLEMS WITH LASER DURING PROCEDURE THE WEEK IN 2000. NO INJURY REPORTED.

**Concomitant Medical Products:**
NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PARKWAY  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
29-NOV-2000: A COMPANY SERVICE REPRESENTATIVE CHECKED THE SYSTEM AND REPLACED THE Q SWITCH DRIVER TO RESOLVE CONDITION REPORTED. QUESTIONNAIRE WAS SENT FOR ADDITIONAL PATIENT INFORMATION; NOT RECEIVED TO DATE.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** 2500 LE ND: YAG
- **Device Type:** LASER PHOTODISRUPTOR
- **Device Type:** 2500 LE
- **Catalog:** 2500 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Phone:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2001-00007</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
</tr>
</thead>
</table>

**Event Date (B3):** 07-Dec-2000  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Date Mfr Rec’d (G4):** 07-Dec-2000  
**Device Operator:** HEALTH PROFESSIONAL  
**Device Usage (H8):** R

**Adverse Event (B1):**  
**Problem (B1):** Y  
**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PARKWAY  
**UNITED STATES**

**Product Code:** (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

**Device Age (F9):**  
**Expiration Date:***  
**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

**Concomitant Medical Products:** NA

**Event Description (B5):**  
Mfr 12-JAN-2001: REPORTER NOTED UNIT CALIBRATED FINE AND THERE WERE NO ERROR MESSAGES, BUT FELT LASER WAS PITTING LENSES, REQUESTED FOCUS CHECK. NO PT INJURY.

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**  
12-JAN-2001: H-10: CUSTOMER HAS NOT SCHEDULED SERVICE AT THIS TIME. QUESTIONNAIRE HAS NOT BEEN RETURNED TO DATE. CODES PROVIDED BY MANUFACTURER.
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 2500 LE ND: YAG LASER
Device Type: LASER PHOTODISRUPTOR
Device Type: 2500 LE
Catalog: 2500 LE
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (b)
Address: (b) (b)

Health Professional: Yes

EMAIL: (b) (b)
Phone: (b) (b)
International: (b) (b)
Fax: (b) (b)

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2001-00008</th>
<th>Mfr Name:</th>
<th>ALCON LABORATORIES</th>
<th>Date Received: 05-Jan-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>07-Dec-2000</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>07-Dec-2000</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Dec-2000</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 12-JAN-2001: REPORTER NOTED UNIT CALIBRATED FINE AND THERE WERE NO ERROR MESSAGES, BUT FELT LASER WAS PITTING LENSES, REQUESTED FOCUS AND AIMING CHECK. NO PT INJURY, NO VISUAL ACUITY LOST.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
12-JAN-2001: H-10: CUSTOMER HAS NOT SCHEDULED SERVICE AT THIS TIME. QUESTIONNAIRE HAS NOT BEEN RETURNED TO DATE. CODES PROVIDED BY MFR.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** 2500 LE ND: YAG LASER
- **Device Type:** LASER PHOTODISRUPTOR
- **Device Type:** 2500 LE
- **Catalog:** 2500 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **Fax:** [Redacted]
- **International:** [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2002-00035  Mfr Name: ALCON LABORATORIES

Event Date (B3): 04-Jan-2002  Report Date (B4): 17-Jan-2002
Report Date (F8):  17-Jan-2002  Date Mfr Rec'd (G4): 17-Jan-2002

Event Report Type: MALFUNCTION  Event Outcome (B2):
Event Location (F12):  Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y

Date Received: 2028159-2002-00035  Mfr Name: ALCON LABORATORIES

Device Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4):
Expiry Date:
Device Usage (H8):

Event Description (B5):
Mfr 25-FEB-2002: REPORTER NOTED LASER TIP SEPARATED FROM PROBE WHILE IN PATIENT’S EYE, NEAR THE END OF THE PROCEDURE. TIP WAS REMOVED. NO INJURY, BUT FELT THIS COULD CAUSE INJURY IF IT RECURS.

Concomitant Medical Products:
NA

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
25-FEB-2002: H-10: WAITING FOR EVALUATION RESULTS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER PROBE
- **Device Type:** LASER PROBE
- **Device Type:** 8065010103
- **Catalog:** 8065010103
- **Serial:** (*confidential*)
- **Lot:** 1013807X
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 2028159-2002-00266
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 29-Aug-2002
Report Date (B4): 29-Aug-2002
Report Date (F8): 29-Aug-2002
Date Mfr Rec’d (G4): 29-Aug-2002

Event Report Type: MALFUNCTION
Event Location (F12): Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Outcome (B2):

Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE
Report Date (F8): 002 - NURSE

Event Description (B5):
Mfr 03-OCT-2002: REPORTER NOTED THEY ASSEMBLED AND TEST CALIBRATED THE LASER. LASER WAS ON STANDBY, DR STARTED TO TREAT AND NOTICED FILTER WAS OFF. THERE WAS NO ERROR MESSAGE RECEIVED THAT THE FILTER WAS NOT IN PLACE. ADJUSTED THE TOGGLE, TRIED AGAIN, THEN FILTER WAS IN PLACE. NO PT OR USER INJURY OCCURRED.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): OTHER
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
03-OCT-2002: H-10: A CO SERVICE REP CHECKED THE SYSTEM, REPLACED THE RELAY PCB AND RETURNED IT FOR FURTHER EVALUATION. WAITING FOR EVALUATION RESULTS.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPTHALAS 532 LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 EYELITE
- **Catalog:** 532 EYELITE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Recd: 513  Page: 1,030  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Mar-2003</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>10-Mar-2003</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>10-Mar-2003</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Rec'd (F8):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):          |                         |
Expiration Date:          |                         |
Device Usage (H8):        |                         |
Manufacture Date (H4):    |                         |
Single Use (H5):          |                         |
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):     | OTHER                  |
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11): 17-APR-2003:

Event Description (B5):

Concomitant Medical Products: NA
Device Available for Evaluation: R

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
          IRVINE, CA 92618
          UNITED STATES

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** LASER PROBE
- **Device Type:** LASER PROBE
- **Device Type:** 8065010203
- **Catalog:** 8065010203
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N/A

### REPORTER INFORMATION:

- **Health Professional:** Yes
- **Name:** (b) (b)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:** (b) (b)
- **Fax:** (b) (b)
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2003-00129
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 16-May-2003
Report Date (B4): 21-May-2003
Report Date (F8): 20-Jun-2003
Date Mfr Rec'd (G4): 21-May-2003

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Code: (OP)-LASER, OPHTHALMIC (HQF)

Event Report Type: MALFUNCTION
Event Outcome (B2): 001 - PHYSICIAN
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Device Age (F9):
Expiration Date:
Device Usage (H8):

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUN-2003: WAITING FOR EVALUATION RESULTS.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** OPHTHALAS 532 LASER
- **Catalog:** 8065-6786-01C
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** [ ] [ ]
- **Health Professional:** Yes

**EMAIL:**

**Phone:** (*)

**International:**

**Fax:**

**Occupation:** 001 - PHYSICIAN
03-DEC-2003: REPORTER NOTED LASER SHUT OFF DURING USE. SERVICE REQUEST MESSAGE APPEARED AND SYSTEM COULD NOT BE RESTARTED. CHANGED LASERS TO COMPLETE CASE. PT WAS UNDER ANESTHESIA DURING A FORTY-FIVE MINUTE DELAY. NO INJURY, BUT SURGEON FELT THIS COULD CAUSE A MAJOR PROBLEM IF IT RECURS. PT CONDITION REPORTED AS GUARDED.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPHTHALAS 532 EYELITE
Device Type: LASER PHOTOCOAGULATOR
Device Type: 532 EYELITE
Catalog: 532 EYELITE
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER
**Event Description (B5):**

Mfr 10-JUN-2004: REPORTER NOTED UNIT WAS TURNED ON IN LIO MODE; ATTACHED AN ENDOPROBE, AND WERE ABLE TO FIRE WITHOUT FILTER IN PLACE ON MICROSCOPE. DOCTOR AND ASSISTANT RECEIVED A BACK FLASH, BUT THERE WAS NO INJURY.

**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PKWY.

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):** OTHER

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

10-JUN-2004: PRODUCT WAS NOT AVAILABLE FOR EVALUATION. SCENARIO OCCURS WHEN SYSTEM IS TURNED OFF IN LIO MODE, AND THEN TURNED ON WITH THE INTENTION OF USING ENDOPROBE. PROMPTS REQUIRE USER TO CONFIRM MODE INTENDED. IF PROMPT IS SELECTED INCORRECTLY, YOU WON'T RECEIVE THE INSTRUCTION TO HAVE THE EXTERNAL FILTER IN PLACE.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>OPTHALAS 532 EYELITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER PHOTOCOAGULATOR</td>
</tr>
<tr>
<td>Device Type</td>
<td>532 EYELITE</td>
</tr>
<tr>
<td>Catalog</td>
<td>532 EYELITE</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

| Name:          | [b] (6)              |
| Address:       | [b] (6)              |
| Health Professional: | Yes                 |

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 
Occupation: 002 - NURSE
# MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2004-00066</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received:</th>
<th>17-Mar-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Feb-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Feb-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>19-Feb-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):** R

**Event Description (B5):**

Mfr 22-JUL-2004: REPORTER NOTED DOCTOR RECEIVED FLASHBACK DOING A TEST FIRE.

**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** OTHER
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):** 22-JUL-2004: A COMPANY SERVICE REP CHECKED THE SYSTEM AND FOUND IT MET PERFORMANCE SPECIFICATIONS. REVIEWED THE SOFTWARE WITH CUSTOMER. IT IS NECESSARY TO CONFIRM THE MODE REQUIRED DURING SET-UP.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand: OPHTHALAS 532 EYELITE
   Device Type: LASER PHOTOCOAGULATOR
   Device Type: 532 EYELITE
   Catalog: 532 EYELITE
   Serial: (*confidential*)
   Lot: NA
   Other ID: NA

   Reprocessed & Reused: N

REPORTER INFORMATION:

   Name: [b] (b)
   Address: [b] (b)
   EMAIL: [b] (b)
   Phone: [b] (b)
   International: 
   Fax: 
   Occupation: 002 - NURSE

   Health Professional: Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2004-00126</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Mar-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>18-Mar-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Mar-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td></td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Mar-2004</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Mar-2004</td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIO</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Mar-2004</td>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 08-MAR-2005: REPORTER NOTED BEAM WAS NOT POWERFUL ENOUGH; UNABLE TO COMPLETE CYCLODESTRUCTION PROCEDURE. MILD BURNS OF CONJUNCTIVA; NO TREATMENT NEEDED. SURGERY CANCELLED. REQUIRED TRABECULECTOMY TO TREAT PATIENT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON - IRVINE TECHNOLOGY CENTER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPHTHALAS 532 LASER
Device Type: LASER PHOTOCOAGULATOR
Device Type: OPHTHALAS 532 LASER
Catalog: 8065-6786-01
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)

Occupation: 001 - PHYSICIAN

Recd: 519  Page: 1,042  Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2004-00164</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Jun-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>23-Jun-2004</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>23-Jun-2004</td>
<td>Event Location (F12):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-JUN-2005: REPORTER NOTED CYCLODESTRUCTION PROCEDURE FAILED AS BEAM WAS NOT POWERFUL ENOUGH. INCIDENT RESULTED IN MILD BURNS OF CONJUCTIVA; NO TREATMENT REQUIRED. CANCELLED LASER PROCEDURE; CHANGED TO CRYOTHERAPY. NO SEQUELAE EXPECTED.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON-IVINE TECHNOLOGY CENTER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY. IRVINE, CA 92618 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 LASER
- **Device Type:** LASER PHOTOCOAGULATOR

Catalog: 8065-6786-01
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2004-00171</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received:</th>
<th>30-Jul-2004</th>
</tr>
</thead>
</table>

**Event Date (B3):** 30-Jun-2004  
**Report Date (B4):** 30-Jun-2004  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 30-Jun-2004

**Event Report Type:** MALFUNCTION

**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y

**Event Date (B3):** 30-Jun-2004

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):**

**Event Location (F12):**

**Device Operator:** HEALTH PROFESSIONAL

**Device Operator:** HEALTH PROFESSIONAL

**Adverse Event (B1):** Problem (B1): Y

**Event Location (F12):**

**Report Source (G3):** FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Report Source (G3):** FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Event Description (B5):**

Mfr 21-JUN-2005: REPORTER NOTED SEVERE FLASHBACK WHILE USING LASER INDIRECT OPHTHALMOSCOPE AT HIGH POWER. UNABLE TO CONTINUE WITH THE CASE, REGISTRAR TOOK OVER AND CLOSED CASE, WITHOUT FURTHER LASER TREATMENT OF THE PT. DR DID NOT REQUIRE ANY TREATMENT; VISION REMAINS NORMAL, WITH NO SEQUELAE.

**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**  
21-JUN-2005: A COMPANY SERVICE REP CHECKED THE SYSTEM AND FOUND IT TO MEET PERFORMANCE SPECIFICATIONS; RETURNED LIO. CUSTOMER USED SYSTEM LATER SAME DAY WITH ENDOPROBE, WITHOUT PROBLEM.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPTHALAS 532 EYELITE
Device Type: LASER PHOTOCOAGULATOR
Device Name: 532 EYELITE
Catalog: 532 EYELITE
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 001 - PHYSICIAN
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received:
2028159-2004-00191

Mfr Name: ALCON MANUFACTURING, LTD.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>15-Jul-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>15-Jul-2004</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>15-Jul-2004</td>
</tr>
</tbody>
</table>

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y

Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-PHOTOCOAGULATOR AND ACCESSORIES (HQB)
Device Age (F9): Manufacture Date (H4):
Expiry Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 17-AUG-2004: REPORTER NOTED LASER BECAME INOPERABLE DURING CASE; TREATMENT WITH LASER DISCONTINUED. COMPLETED CASE DOING A BUCKLE. PROGNOSIS REPORTED AS GOOD. CANCELLED REMAINING CASES FOR THE DAY.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-AUG-2004: A CO SERVICE REP CHECKED THE SYSTEM AND FOUND IT TO MEET PERFORMANCE SPECIFICATIONS.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OPHTHALAS 532 EYELITE
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 EYELITE
- **Catalog:** 532 EYELITE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** UNK - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 09-Nov-2004</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Mfr Rec'd (G4): 09-Nov-2004

Event Description (B5):

Mfr 20-DEC-2006: REPORTER NOTED DOCTOR FILTER WASN'T WORKING; COULD FIRE LASER WITHOUT EYE PROTECTION. NO INJURY TO USER.

Concomitant Medical Products:

NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CTR
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
20-DEC-2006: WAITING FOR EVALUATION RESULTS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** OPTHALAS 532 EYELITE
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 EYELITE
- **Catalog:** 532 EYELITE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** Fax:
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Event Outcome (B2):</th>
<th>Report Date (B4):</th>
<th>Event Location (F12):</th>
<th>Report Date (F8):</th>
<th>Event Location (F12):</th>
<th>Report Source (G3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>2028159-2005-00014</td>
<td>31-Jan-2005</td>
<td>MALFUNCTION</td>
<td>Y</td>
<td>31-Jan-2005</td>
<td>001 - PHYSICIAN</td>
<td>HEALTH PROFESSIONAL</td>
<td>001 - PHYSICIAN</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PARKWAY
**IRVINE, CA 92618**
**UNITED STATES**

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

17-MAR-2005: H-10: A COMPANY SERVICE REP CHECKED THE SYSTEM AND FOUND IT TO MEET PERFORMANCE SPECIFICATIONS. UNABLE TO DUPLICATE PERFORMANCE PROBLEM REPORTED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** EYELIRE LASER
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2005-00041</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received: 01-Apr-2005</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 01-Mar-2005</th>
<th>Event Description (B5):</th>
<th>Mfr 07-APR-2005: REPORTER NOTED REFLECTION OF LASER BEAM ON SLIT LAMP RESULTED IN ACCIDENTAL EYE IMPACT. POWER USED: 0.15W. BILATERAL DAZZLE WITH BLURRED VISION OCCURRED ONE TO TWO MINUTES AFTER START. OUTCOME REPORTED AS GOOD. FELT THERE WAS A LACK OF PROTECTION WITH FILTER.</th>
</tr>
</thead>
</table>

|------------------------------------------|-------------------------------|-------------------------------------|

<table>
<thead>
<tr>
<th>Device Operator: HEALTH PROFESSIONAL</th>
<th>Event Location (F12):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date Mfr Rec’d (G4): 04-Mar-2005</th>
<th>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date Last Updated: 11/2/2010 9:17 AM</th>
<th>Recd: 525</th>
</tr>
</thead>
</table>

**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:**

15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

07-APR-2005: A COMPANY SERVICE REP CHECKED THE SYSTEM AND FOUND IT TO MEET PERFORMANCE SPECIFICATIONS. RETURNED FILTER FOR FURTHER EVALUATION. UNABLE TO DUPLICATE REFLECTIONS AS DESCRIBED IN REPORTED FAILURE; FOUND DOCTOR PROTECTION FILTER TO MEET SPECIFICATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** OPHTALAS 532 EYELITE
- **Device Type:** LASER PHOTOCOAGULATOR
- **Device Type:** 532 EYELITE
- **Catalog:** 532 EYELITE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2005-00085
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 04-May-2005
Report Date (B4): 06-May-2005
Report Date (F8): 06-May-2005
Date Mfr Rec'd (G4): 06-May-2005
Event Report Type: MALFUNCTION
Event Outcome (B2): 001 - PHYSICIAN
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-PHOTOCOAGULATOR AND ACCESSORIES (HQB)
Device Age (F9):
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 29-JUN-2005: DURING SURGERY FOR RETINAL TEAR, FELT LASER DELIVERED BEAM AT A MUCH HIGHER POWER THAN INITIALLY SET; CLOSE TO 2 W INSTEAD OF 220/250 MW. PT HAD NON-SERIOUS CHOROIDAL HEMORRHAGE, WHICH RESOLVED ITSELF. INCIDENT DIDN'T RECUR AFTER SETTINGS WERE CHANGED TO A LOWER POWER 230 MW.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVING TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
29-JUN-2005: A CO SERVICE REP CHECKED THE SYSTEM AND FOUND IT TO MEET PERFORMANCE SPECIFICATIONS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** EYELIT LASER
- **Device Type:** LASERS
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NI
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-2005-00181</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>Date Mfr Rec'd (G4): 27-Sep-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 03-Jun-2004</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 03-Jun-2004</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 27-Sep-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 15800 ALTON PKWY. IRVINE, CA 92618 UNITED STATES</td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>Expiration Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single Use (H5): N</td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER</td>
<td>Remedial Action (H7): Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 15800 ALTON PKWY. IRVINE, CA 92618 UNITED STATES</td>
<td>Additional Mfr Narrative (H10 &amp; H11): 02-NOV-2005: AT THE TIME OF INITIAL COMPLAINT, A COMPANY REP CHECKED SYSTEM, REPLACED ENGINE TO RESOLVE PERFORMANCE PROBLEM REPORTED, AND RETURNED IT FOR FURTHER TESTING. FOUND LOW POWER BECAUSE INSUFFICIENT TRANSFER OF HEAT WITHIN LASER DIODE MELTED SOLDER, WHICH FLOWED OVER EMITTERS. DIODE SUPPLIER HAD BEEN CHANGED PRIOR THIS REPORTED COMPLAINT. THIS ENGINE WAS REPAIRED AND RETURNED TO STOCK. NO FURTHER EVENTS REPORTED WITH THIS S/N TO DATE.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: EYELITE LASER
- Device Type: LASER INSTRUMENT, SURGICAL, POWERED
- Device Type: EYELITE
- Catalog: 8065500001
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Health Professional: Yes
- EMAIL: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
- Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2005-00206

Event Date (B3): 20-Oct-2005
Report Date (B4): 20-Oct-2005
Report Date (F8): 20-Oct-2005
Date Mfr Rec'd (G4): 20-Oct-2005

Mfr Name: ALCON MANUFACTURING, LTD.

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Location (F12): 
Report Source (G3): HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): 
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): R

Manufacture Date (H4):

Single Use (H5): N

Event Description (B5):
Mfr 28-NOV-2005: REPORTER NOTED SYSTEM DISPLAYED AN ERROR MESSAGE AFTER CHANGING FROM 300MW TO 400MW DURING PROCEDURE.
SWITCHED TO A BACK-UP CRYO LASER THAT DID NOT WORK. PUT GAS BUBBLE IN PATIENT'S EYE TO COMPLETE PROCEDURE. STATED THERE WAS NO INJURY. PROGNOSIS REPORTED AS GOOD.

Concomitant Medical Products:
NA

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
28-NOV-2005: A COMPANY SERVICE REP PERFORMED CALIBRATION; REPLACED LIO CABLE FOR LOW POWER OUTPUT.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: Fax:

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2005-00231</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>15-Dec-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Nov-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Nov-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jan-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 27-DEC-2005: REPORTER NOTED SYSTEM SHUT DOWN AFTER ONLY 10% OF ANTICIPATED TREATMENT; DISPLAYED SERVICE MESSAGE. PROCEDURE WAS CANCELLED.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): Correction/Removal No (H9): Additional Mfr Narrative (H10 & H11):
27-DEC-2005: A COMPANY SERVICE REP REPLACED ENGINE AND RETURNED IT FOR FURTHER TESTING. WAITING FOR EVALUATION RESULTS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>2028159-2006-00123</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>0</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2028159-2006-00123</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>0</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2028159-2006-00123</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>0</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2028159-2006-00123</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>0</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2028159-2006-00123</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>0</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4):
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 28-APR-2006: UNIT JUST TURNED OFF; SERVICE REQUESTED SIGN CAME ON. UNABLE TO COMPLETE CASE AS PLANNED. OUTCOME REPORTED AS GOOD. PATIENT WILL LIKELY NEED ANOTHER SESSION OF LASER.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
28-APR-2006: A COMPANY SERVICE REP CHECKED SYSTEM, COMPLETED PM AND STP; SYSTEM FUNCTIONS PER SPECIFICATIONS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL,POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 28-Jul-2006

<table>
<thead>
<tr>
<th>MFR Report No: 2028159-2006-00226</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 01-Jun-2006</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4): 28-Jun-2006</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 28-Jun-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1): Y</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td></td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 24-AUG-2006: REPORTER NOTED ERROR MESSAGE, NEEDS SERVICE, OCCURRED DURING SET-UP. UNABLE TO PERFORM SCHEDULED CASES. NO INJURY REPORTED.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
24-AUG-2006: A COMPANY SERVICE REP CHECKED SYSTEM; REPAIRED DOCTOR FILTER CABLES DUE TO EXPOSED WIRES. COMPLETED SERVICE AND SYSTEM MET SPECS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
</table>


| Event Date (B3): | 18-Jul-2006 | Event Report Type: | MALFUNCTION | Adverse Event (B1): | Problem (B1): | Y |
| Report Date (B4): | 18-Jul-2006 | Event Outcome (B2): | | Event Location (F12): | | |
| Reporter Occupation (E3): | OTHER | Report Source (G3): | HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE |
| Device Operator: | HEALTH PROFESSIONAL |
| Date Mfr Rec’d (G4): | 18-Jul-2006 |

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):**

**Expiration Date:**

| Manufacture Date (H4): | Single Use (H5): | N | Single Use (H5): | N |

| Device Usage (H8): | R |

**Event Description (B5):**

Mfr 30-OCT-2006: REPORTER NOTED LASER SHUT DOWN AFTER 15 SHOTS; DISPLAYED A SERVICE REQUESTED MESSAGE. UNABLE TO COMPLETE PROCEDURE; CULMINATED AS SOON AS POSSIBLE. RESCHEDULED THREE OTHER CASES.

**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

30-OCT-2006: WAITING FOR EVALUATION RESULTS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: No Information

EMAIL: [redacted]
Phone: (NA)
International: [redacted]
Fax: [redacted]

Occupation: OTHER
## MAUDE EVENT REPORT (FOI)

### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2006-00256</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received:</th>
<th>18-Aug-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jul-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Jul-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>401 - BIOMEDICAL ENGINEER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>19-Jul-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):**

**Single Use (H5):** N

**Device Usage (H8):** R

**Event Description (B5):**

Mfr 30-OCT-2006: REPORTER NOTED LASER BROKE AFTER FIRING 3 SHOTS; HAD TO STOP CASE. SUBSEQUENT CASES WERE CANCELLED. THIS SAME PATIENT HAS BEEN RESCHEDULED THREE TIMES BECAUSE THIS LASER WAS NOT WORKING CORRECTLY.

**Concomitant Medical Products:**

- NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PKWY.

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

30-OCT-2006: RECEIVED ENGINE FOR EVALUATION. ENGINE SHOWED LOW POWER AND NO DB RANGE. THE KTP HAD NO DB TEMPERATURE RANGE FOR ITS OUTPUT. THE KTP WAS REPLACED, AND IT WAS REALIGNED. LASER ENGINE THEN PASSED ALL PERFORMANCE TESTS. ROOT CAUSE: WAS A NONCONFORMING KTP IN THE LASER ENGINE. THE KTP HAD NO DB RANGE.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>EYELITE LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL, POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>EYELITE</td>
</tr>
<tr>
<td>Catalog</td>
<td>8065500001</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Phone:</td>
</tr>
<tr>
<td></td>
<td>International:</td>
</tr>
<tr>
<td></td>
<td>Fax:</td>
</tr>
<tr>
<td>Health Professional:</td>
<td>Occupation:</td>
</tr>
<tr>
<td>Yes</td>
<td>401 - BIOMEDICAL ENGINEER</td>
</tr>
</tbody>
</table>

Repd: 533  Page: 1,070  Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Event Outcome (B2):</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25-Aug-2006</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
<td>Y</td>
</tr>
</tbody>
</table>

| Mfr Name: | ALCON MANUFACTURING, LTD. |

<table>
<thead>
<tr>
<th>Date Mfr Rec'd (G4):</th>
<th>Event Location (F12):</th>
</tr>
</thead>
<tbody>
<tr>
<td>28-Aug-2006</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

| Product Code: | (OP)-LASER, OPHTHALMIC (HQF) |

| Device Operator: | HEALTH PROFESSIONAL |

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr 20-JUN-2007: REPORTED NOTED LASER, IN LIO MODE, WILL CONTINUE TO FIRE AS FOOTPEDAL IS RELEASED. THERE WERE THREE CASES SCHEDULED, AND THEY WERE ABLE TO COMPLETE THEM. CHANGED TO ANOTHER MACHINE FOR NEXT DOCTOR. PT 1 OF 3: THERE WAS NO PT IMPACT, EXCEPT FOR A DELAY IN CASE.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>ALCON - IRVINE TECHNOLOGY CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY.</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Y</th>
</tr>
</thead>
</table>

| Device Evaluated by Manufacturer (H3): | No |

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Mfr Narrative (H10 &amp; H11):</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-JUN-2007: PRODUCT EVALUATION AND ROOT CAUSE ANALYSIS HAS NOT BEEN COMPLETED TO DATE.</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYE LITE LASER
- **Device Type:** LASER, INSTRUMENT, SURGICAL POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes

- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2006-00298</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>27-Sep-2006</th>
</tr>
</thead>
</table>

**Event Date (B3):** 25-Aug-2006  
**Event Report Type:** MALFUNCTION

**Event Outcome (B2):**

**Adverse Event (B1):**  
**Problem (B1):** Y

**Event Location (F12):**

**Report Source (G3):** HEALTH PROFESSIONAL

**Event Description (B5):**
Mfr 20-JUN-2007: REPORTED NOTED LASER, IN LIO MODE, WILL CONTINUE TO FIRE AS FOOTPEDAL IS RELEASED. THERE WERE THREE CASES SCHEDULED, AND THEY WERE ABLE TO COMPLETE THEM. CHANGED TO ANOTHER MACHINE FOR NEXT DOCTOR. PT 2 OF 3: THERE WAS NO PT IMPACT, EXCEPT FOR A DELAY IN CASE.

**Concomitant Medical Products:**
NA

**Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER**
**Address:** 15800 ALTON PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
20-JUN-2007: PRODUCT EVALUATION AND ROOT CAUSE ANALYSIS HAS NOT BEEN COMPLETED TO DATE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER, INSTRUMENT, SURGICAL POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

**EMAIL:** [redacted]
**Phone:** [redacted]
**International:** [redacted]
**Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2006-00299</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received: 27-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>25-Aug-2006</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Aug-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-JUN-2007: REPORTED NOTED LASER, IN LIO MODE, WILL CONTINUE TO FIRE AS FOOTPEDAL IS RELEASED. THERE WERE THREE CASES SCHEDULED, AND THEY WERE ABLE TO COMPLETE THEM. CHANGED TO ANOTHER MACHINE FOR NEXT DOCTOR. PT 3 OF 3: THERE WAS NO PT IMPACT, EXCEPT FOR A DELAY IN CASE.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON - IRVINE TECHNOLOGY CENTER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9): NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 20-JUN-2007: PRODUCT EVALUATION AND ROOT CAUSE ANALYSIS HAS NOT BEEN COMPLETED TO DATE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

**Brand:** EYELITE LASER  
**Device Type:** LASER, INSTRUMENT, SURGICAL POWERED  
**Device Type:** EYELITE  
**Catalog:** 8065500001  
**Serial:** (*confidential*)  
**Lot:** NA  
**Other ID:** NA  

Reprocessed & Reused: N

REPORTER INFORMATION:

**Name:** [Redacted]  
**Address:** [Redacted]  
**Email:** [Redacted]  
**Phone:** [Redacted]  
**International:** [Redacted]  
**Fax:** [Redacted]  

**Health Professional:** Yes  
**Occupation:** 002 - NURSE
**Event Description (B5):**

Mfr 04-MAY-2007: REPORTER NOTED SYSTEM SHUT DOWN IN MIDDLE OF CASE DISPLAYING ERROR "SERVICE REQUESTED" CODE. THEY CHANGED TO A DIFFERENT UNIT TO COMPLETE THE CASE. THE CASE WAS DELAYED FOR ABOUT ONE HOUR. THE PATIENT NOW HAS A CLOUDY CORNEA POST-OP. THE DOCTOR IS CONCERNED THAT IT WAS THE EXTENDED DELAY THAT CAUSED THE CLOUDING.

**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON-IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

04-MAY-2007: A COMPANY SERVICE REP CHECKED THE SYSTEM, FOUND LOW POWER, REPLACED LASER ENGINE AND RETURNED IT FOR FURTHER TESTING AND ROOT CAUSE ANALYSIS. COMPLETED SYSTEM CHECKOUT; UNIT MEETS SPECIFICATIONS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER, INSTRUMENT, SURGICAL POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Date (B3):** 01-Oct-2006  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y

**Report Date (B4):** 24-Oct-2006  
**Event Outcome (B2):**

**Date Mfr Rec'd (G4):** 24-Oct-2006  
**Device Operator:** HEALTH PROFESSIONAL

**Event Description (B5):**
Mfr 07-DEC-2006: A NURSE REPORTED THEY RECEIVED AN ERROR MESSAGE; ONE CASE WAS CANCELLED. THERE WAS NO PATIENT INJURY. NO ADDITIONAL INFORMATION IS EXPECTED.

**Concomitant Medical Products:**
NA

**Mfr Name:** ALCON MANUFACTURING, LTD.

**Product Code:** (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
07-DEC-2006: H-10: A COMPANY SERVICE REP CHECKED THE SYSTEM, FOUND THE SHUTTER MOTOR FREEZING WHILE FIRING, AND REPLACED THE ATTENUATER ASSEMBLY. THE SYSTEM WAS THEN TESTED TO SPECIFICATIONS. ALSO REPLACED A CABLE AS A PRECAUTION. PARTS WERE RETURNED FOR FURTHER INVESTIGATION. EVALUATION, INCLUDING A ROOT CAUSE ANALYSIS, IS IN PROGRESS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** 3000 LE ND: YAG LASER
- **Device Type:** LASER PHOTODISRUPTER
- **Device Type:** 3000 LE
- **Catalog:** 3000 LE
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Phone:** [redacted]
- **Fax:** [redacted]
- **International:** [redacted]
- **EMAIL:** [redacted]
- **Occupation:** 002 - NURSE

Health Professional: Yes
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2006-00463  Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 24-Oct-2006  Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y
Report Date (B4): 24-Oct-2006  Event Outcome (B2): 001 - PHYSICIAN  Event Location (F12):
Report Date (F8): 24-Oct-2006  Reporter Occupation (E3): HEALTH PROFESSIONAL
Date Mfr Rec'd (G4): 24-Oct-2006  Device Operator: HEALTH PROFESSIONAL

MFR Report No: 2028159-2006-00463  Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER

Event Description (B5):
Mfr 07-DEC-2006: A DOCTOR REPORTED AN ERROR MESSAGE OCCURRED. THERE WAS NO PATIENT INJURY; HOWEVER, APPROXIMATELY 5-7 CASES WERE CANCELLED AS A RESULT.

Concomitant Medical Products:
NA

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N  Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):  Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
07-DEC-2006: PRODUCT WILL NOT BE RETURNED FOR EVALUATION.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 2300 ND: YAG LASER
Device Type: LASER PHOTODISRUPTER
Device Type: YAG 2300
Catalog: YAG 2300
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]

Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 30-Oct-2006
Report Date (B4): 30-Oct-2006
Report Date (F8): 30-Oct-2006
Date Mfr Rec'd (G4): 30-Oct-2006

Event Description (B5):
Mfr 12-DEC-2006: A NURSE REPORTED THAT THE SYSTEM WILL NOT BOOT UP. THERE WAS NO PATIENT INJURY, BUT THREE CASES WERE CANCELLED. NO ADDITIONAL INFORMATION IS EXPECTED.

Concomitant Medical Products:
NA

Mfr Name: ALCON MANUFACTURING, LTD.

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:
Manufacture Date (H4): 01-Jan-2005
Single Use (H5): N
Device Usage (H8): R

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
12-DEC-2006: A COMPANY SERVICE REP CHECKED THE SYSTEM, RESEATED THE CABLES, AND THE SYSTEM TESTED TO SPECIFICATIONS. THERE WERE NO COMPONENTS REPLACED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)
Email: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Health Professional: Yes
Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 17-Nov-2006
Report Date (B4): 17-Nov-2006
Report Date (F8): 17-Nov-2006
Date Mfr Rec'd (G4): 17-Nov-2006

Event Description (B5):
Mfr 27-DEC-2006: A NURSE REPORTED THE DOCTOR WAS ABOUT 75% (ABOUT 60 SHOTS) INTO AN ARGON TRABECULARPLASTY PROCEDURE WHEN THE AIMING BEAM FADED. THE DOCTOR STOPPED THE PROCEDURE. THE DOCTOR THINKS THE PATIENT MAY NEED FURTHER SURGERY, HOWEVER HE WILL WAIT AND SEE HOW WELL THE RESPONSE IS FIRST. THE SYSTEM WAS USED ON TWO OR THREE OTHER PATIENTS WITH NO PROBLEMS.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
27-DEC-2006: A COMPANY SERVICE REP CHECKED THE SYSTEM AND REPLACED THE SHUTTER ASSEMBLY TO CORRECT THE PROBLEM. THE SYSTEM WAS THEN TESTED TO SPECIFICATIONS. THE RETURNED COMPONENT INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS, IS IN PROGRESS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

|----------------|---------------------|-----------|---------------------------|----------------------|-------------|

Event Date (B3): 01-Dec-2006
Report Date (B4): 05-Dec-2006
Report Date (F8):
Date Mfr Rec'd (G4): 05-Dec-2006

Event Report Type: MALFUNCTION
Event Outcome (B2): 
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)
Device Age (F9):
Expiration Date:
Device Usage (H8): R

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Event Description (B5): Mfr 17-JAN-2007: THE FACILITY REPORTED THE BULB WOULD NOT WORK, EVEN AFTER CHANGING TO A DIFFERENT BULB. FIVE CASES HAD BEEN CANCELLED, INCLUDING ONE PATIENT THAT HAD ALREADY BEEN PREPPED FOR SURGERY, WITH THE EYE OPEN.

Concomitant Medical Products:
NI

Mfr Name: ELLEX/ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Remedial Action (H7):
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>3000 LE ND: YAG LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER PHOTODISRUPTER</td>
</tr>
<tr>
<td>Device Type</td>
<td>3000 LE</td>
</tr>
<tr>
<td>Catalog</td>
<td>3000 LE</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

| Name            | (b) (6)               |
| Address         | (b) (b)               |

Health Professional: Yes

| EMAIL             | (b) (6)               |
| Phone International: | (b) (6)               |
| Fax              |                        |

Occupation: 002 - NURSE
Event Date (B3): 01-Jan-2007
Report Date (B4): 11-Jan-2007
Report Date (F8): 11-Jan-2007
Date Mfr Rec'd (G4): 11-Jan-2007
Date Mfr Rec'd (G4): 09-Feb-2007

Event Report Type: INJURY
Event Location (F12): AMBULATORY SURGICAL FACILITY
Report Source (G3): HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): 002 - NURSE

Mfr Name: ALCON MANUFACTURING, LTD.
Event Description (B5):
Mfr 30-MAR-2007: A NURSE REPORTS AN ERROR MESSAGE DURING SURGERY. THERE WAS NO PATIENT INJURY/IMPACT ASSOCIATED WITH THIS EVENT, HOWEVER, SEVERAL SUBSEQUENT CASES WERE CANCELLED.

Concomitant Medical Products:

NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
30-MAR-2007: WAITING FOR EVALUATION RESULTS.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: EYELITE LASER
- Device Type: LASER, INSTRUMENT, SURGICAL POWERED
- Catalog: 8065500001
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: [redacted]
- Address: [redacted]
- Health Professional: Yes
- Occupation: 002 - NURSE
- EMAIL: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2007-00089</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>09-Feb-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Jan-2007</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Jan-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>11-Jan-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td></td>
<td>Event Description (B5):</td>
<td>Mfr 30-MAR-2007: A SURGEON REPORTS A LASER FIRING ISSUE; THERE WERE NO PULSES AND NO ENERGY REPORTED. THERE WAS NO PATIENT INJURY/IMPACT ASSOCIATED WITH THIS EVENT, HOWEVER 5-6 CASES WERE CANCELLED.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON - IRVINE TECHNOLOGY CENTER</td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>30-MAR-2007: WAITING FOR EVALUATION RESULTS.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY.</td>
<td></td>
<td></td>
<td>IRVINE, CA 92618</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>30-MAR-2007: WAITING FOR EVALUATION RESULTS.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 3000 LE LASER
Device Type: LASER, INSTRUMENT, SURGICAL POWERED
Device Type: 3000LE
Catalog: 3000LE
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International: 
Fax: 

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2007-00102</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>16-Feb-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jan-2007</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Jan-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 11-APR-2007: REPORTER NOTED HARDWARE ERROR CODE PRIOR TO SURGERY. AS RESULT, 2 CASES WERE CANCELLED. NO INJURY REPORTED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON - IRVINE TECHNOLOGY CTR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY. IRVIN, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>11-APR-2007: INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER

Device Type: LASER INSTRUMENT, SURGICAL, POWERED

Device Type: EYELITE

Catalog: 8065500001

Serial: (*confidential*)

Lot: NA

Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [ redacted ]

Address: [ redacted ]

Health Professional: Unknown

EMAIL: [ redacted ]

Phone: [ redacted ]

International: [ redacted ]

Fax:

Occupation: UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received


Event Date (B3): 01-Jan-2007
Report Date (B4): 24-Jan-2007
Report Date (F8):
Date Mfr Rec'd (G4): 24-Jan-2007

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL,
COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 14-MAR-2007: THE FACILITY REPORTED THE DOCTOR DID NOT GET ENOUGH POWER FROM THE LASER WHEN THE CASE STARTED; THE CASE WAS CANCELLED. THERE WAS NO PT INJURY. NO ADD'L INFO IS EXPECTED.

Concomitant Medical Products:
NA

Mfr Name: ALCON-IRVINE TECHNOLOGY CTR
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
14-MAR-2007: A COMPANY SERVICE REP CHECKED THE SYSTEM AND FOUND THE ROOT CAUSE WAS LOW POWER FROM THE SLIT OPTIC FIBER DUE TO MISALIGNED LASER OPTICS. THE REP REALIGNED THE LASER OPTICS, PERFORMED CALIBRATION AND PERFORMED ALL SYSTEM CHECKS; SYSTEM MET SPECIFICATIONS. NO PARTS ARE RETURNING FOR EVALUATION, NO FURTHER ACTION REQUIRED.

Recd: 546 Page: 1,095 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER, INSTRUMENT, SURGICAL POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** Fax:
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2007-00165
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 20-Feb-2007
Report Date (B4): 20-Feb-2007
Report Date (F8):
Date Mfr Rec'd (G4): 20-Feb-2007

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8):
Event Location (F12):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1):
Problem (B1): Y

Mfr Report No:
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
06-JUN-2007: A COMPANY SERVICE REPRESENTATIVE CHECKED THE SYSTEM, REPLACED THE LASER ENGINE, CALIBRATED THE SYSTEM, AND TESTED THE SYSTEM TO SPECIFICATIONS. THE LASER ENGINE HAS BEEN RETURNED FOR FURTHER EVALUATION. THE INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: EYELITE LASER
- **Device Type**: LASER, INSTRUMENT, SURGICAL POWERED
- **Device Type**: EYELITE
- **Catalog**: 8065500001
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA
- **Reprocessed & Reused**: N

REPORTER INFORMATION:

- **Name**:
- **Address**:
- **Email**:
- **Phone**:
- **International**:
- **Fax**:
- **Health Professional**: Yes
- **Occupation**: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received 2028159-2007-00265
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 25-Apr-2007
Report Date (B4): 30-Apr-2007
Report Date (F8): 01-May-2007
Date Mfr Rec'd (G4): 31-May-2007

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jan-2002
Expiration Date:
Device Usage (H8):

Event Description (B5):
Mfr 11-JUN-2007: THE FACILITY REPORTED THAT THE LIO STOPPED WORKING DURING A CASE. CASES WERE CANCELLED. ADDITIONAL INFORMATION RECEIVED FROM THE FACILITY STATED THE LIO HEADSET HAS AIMING BEAM AND FIRES, BUT THERE IS NO OUTPUT RECORDED ON THE LASER METER. THE DOCTOR CONTACTED THE BIOMED DEPARTMENT, THEN SWITCHED TO A CRYO UNIT. THEY WERE NOT ABLE TO COMPLETE THE PROCEDURE AS PLANNED; THE PATIENT NEEDS TO RESCHEDULE THE CASE. TWO SUBSEQUENT CASES WERE CANCELLED.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *(b) (6)*
- **Address:** *(b) (6)*
- **Health Professional:** Yes
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:**
- **Fax:**
- **Occupation:** 002 - NURSE

Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received


Event Date (B3): 01-Jan-2007 Event Report Type: MALFUNCTION Date Mfr Rec'd (G4): 01-May-2007


Report Date (F8): Reporter Occupation (E3): Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Date Rec'd: 31-May-2007

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jan-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: 
Address: 
Health Professional: Yes

EMAIL: 
Phone: 
International: 
Fax: 
Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2007-00286</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received:</th>
<th>14-Jun-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>15-May-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>15-May-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ALCON- IRVINE TECHNOLOGY CENTER</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY. \ IRVINE, CA 92618 \ UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated for Evaluation:</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedy Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]

Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
Recd: 550
Page: 1,104
Date Last Updated: 11/2/2010 9:17 AM
Recd: 550
Page: 1,104
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 2028159-2007-00304
Mfr Name: ALCON MANUFACTURING, LTD.
Report Date (F8): 22-May-2007
Date Mfr Rec'd (G4): 22-May-2007

Event Date (B3): 22-May-2007
Event Report Type: MALFUNCTION
Event Outcome (B2):

Adverse Event (B1):
Problem (B1): Y

Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 10-May-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name:
Address:

Health Professional: Yes

EMAIL: (b)(6)
Phone: (b)(6)
International:
Fax:

Occupation: 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM
## MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Report Type:** MALFUNCTION  
**Event Date (B3):** 26-Jun-2007  
**Report Date (B4):** 27-Jun-2007  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 28-Jun-2007  
**Mfr Name:** ALCON MANUFACTURING, LTD.  
**MFR Report No:** 2028159-2007-00362  
**Report Date (B4):** 27-Jun-2007  
**Event Location (F12):**  
**Event Outcome (B2):**  
**Adverse Event (B1):** Problem (B1): Y  
**Event Description (B5):**  

**Mfr Description:** THE CUSTOMER REPORTED THAT THERE WAS NO POWER TO THE LASER INDIRECT OPHTHALMOSCOPE (LIO) DURING A PROCEDURE. THE PATIENT HAD DIABETIC RETINOPATHY AND THE EYE WAS FULL OF BLOOD. THE DOCTOR WAS NOT ABLE TO SEE WELL ENOUGH TO PROCEED AND FINISH THE CASE. THE PATIENT WAS BLOCKED AND INTUBATED. THE PROCEDURE WILL BE RESCHEDULED AFTER THE SYSTEM HAS BEEN CHECKED. ONE CASE WAS CANCELLED.

**Concomitant Medical Products:**  
**NI**

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PARKWAY  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  
**Remedial Action (H7):**  
**Correction/Removal No (H9):** NA  
**Additional Mfr Narrative (H10 & H11):**  

15-AUG-2007: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND CONFIRMED THE PROBLEM OF NO POWER WITH THE LIO. THE CABLE FIBER WAS REPLACED DUE TO HAVING A KINK ABOUT 10 INCHES AWAY FROM THE CONNECTOR. INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2007-00373
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 27-Jun-2007
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Event Date (B4): 27-Jun-2007
Event Outcome (B2):

Report Date (F8):
Date Mfr Rec'd (G4): 27-Jun-2007

MFR Report No: 2028159-2007-00373
Mfr Name: ALCON MANUFACTURING, LTD.
26-Jul-2007

Event Description (B5):
Mfr 15-AUG-2007: THE NURSE REPORTED THAT DURING THE CASE, AFTER 4 TO 5 SHOTS, A SERVICE REQUEST ERROR MESSAGE APPEARED. THEY WERE UNABLE TO CLEAR THE ERROR MESSAGE, AND CASE WAS STOPPED. THE DOCTOR HAD WANTED TO DO MORE THAN A FEW SHOTS, BUT SHE WAS UNSURE IF THE PATIENT WOULD NEED TO BE RESCHEDULED. ADD'L INFO HAS BEEN REQUESTED.

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
15-AUG-2007: INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: EYELITE LASER
- Device Type: LASER INSTRUMENT, SURGICAL, POWERED
- Device Type: EYELITE
- Catalog: 8065500001
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA
- Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: [redacted]
- Address: [redacted]
- Health Professional: Yes
- Occupation: 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2007-00407</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>Date Received: 13-Sep-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Aug-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>14-Aug-2007</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>14-Aug-2007</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

| Product Code: | (OP)-LASER, OPHTHALMIC (HQF) |
| Device Age (F9): | Manufacture Date (H4): 11-Aug-2006 |
| Expiration Date: | Single Use (H5): N |
| | Device Usage (H8): R |

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
09-OCT-2007: INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** OTHER
Event Date (B3): 14-Sep-2007
Event Report Type: MALFUNCTION
Report Date (B4): 14-Sep-2007
Report Date (F8): 14-Sep-2007
Date Mfr Rec'd (G4): 14-Sep-2007

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
28-NOV-2007: INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM
Page: 1,114
Recd: 555
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2007-00511
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 30-Oct-2007
Report Date (B4): 30-Oct-2007
Report Date (F8): 30-Oct-2007
Date Mfr Rec'd (G4): 30-Oct-2007
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y

Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
12-DEC-2007: A COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND OPTIMIZED THE KTP TEMPERATURE. HE ALSO DETERMINED THAT THE LIO FIBER HAD LOW OUTPUT. INVESTIGATION ROOT CAUSE ANALYSIS IS IN PROGRESS.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYE LIT LASER
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: EYE LITE LASER
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)
Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: Fax:

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.


Event Date (B3): 15-Oct-2007  Event Report Type: MALFUNCTION
Report Date (F8): 19-Nov-2007  Reporter Occupation (E3): 002 - NURSE
Date Mfr Rec'd (G4): 19-Nov-2007  Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

29-FEB-2008: THE CUSTOMER SERVICE REP EXAMINED THE SYSTEM AND FOUND UNSTABLE POWER. THE LASER ENGINE WAS REPLACED AND SENT IN HOUSE FOR EVALUATION. INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. THIS REPORT MAILED IN TO FDA ON: 12/19/2007.

Concomitant Medical Products:

NI

Event Description (B5):


Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYE LITE LASER
Device Type: LASER TREATMENT, SURGICAL, POWERED
Device Type: EYELITE
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received


Event Date (B3): 29-Nov-2007  Report Date (B4): 30-Nov-2007  Report Date (F8):

Date Mfr Rec’d (G4): 30-Nov-2007  Mfr 29-FEB-2008: DURING A PROCEDURE, THE SURGEON REPORTED THAT HE SAW "GREEN SPOT" AND "VISUAL DISTURBANCES" AFTER USING THE LASER. IT WAS THE SURGEON AND NOT THE PT, WHO REPORTED THESE SIDE EFFECTS. THE SURGEON PLANS TO HAVE A COLLEAGUE CHECK HIS VISION. ADDITIONAL INFO HAS BEEN REQUESTED.

Event Report Type: MALFUNCTION  Adverse Event (B1): Problem (B1): Y

Event Outcome (B2):  Reporter Occupation (E3): OTHER  Event Location (F12):

Report Date (F8):

Report Source (G3): HEALTH PROFESSIONAL, FOREIGN, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL

Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9):  Manufacture Date (H4):

Expiration Date: Single Use (H5): N  Device Usage (H8):

Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

NI

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER

Address: 15800 ALTON PKWY.

IRVINE, CA 92618

UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):

29-FEB-2008: INVESTIGATION, INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. THIS REPORT MAILED IN TO FDA ON: 12/19/2007.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>EYELITE LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL, POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>EYELITE</td>
</tr>
<tr>
<td>Catalog</td>
<td>806550001</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>[b] [b]</td>
</tr>
<tr>
<td>Address:</td>
<td>[b] [b]</td>
</tr>
</tbody>
</table>

**Health Professional:** Yes

**EMAIL:**

**Phone:**

**International:** NI - -

**Fax:**

**Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2008-00056</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>07-Feb-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Jan-2008</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Jan-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>11-Jan-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:

Concomitant Medical Products: NI

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): NA

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
18-APR-2008: THE CUSTOMER SERVICE REP CHECKED THE SYSTEM AND COULD NOT DUPLICATE THE ERROR CODE. THE FOOTSWITCH WAS REPLACED FOR DIAGNOSTIC PURPOSES. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE.

**DEVICE INFORMATION:**

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED.
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [b] (6)
- **Address:** [b] (6)
- **EMAIL:**
- **Phone:**
- **International:** [b] (6)
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-2008-00064</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>Event Date (B3): 17-Jan-2008</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 18-Jan-2008</td>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9): Manufacture Date (H4): 01-Sep-2005</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Expiration Date: Single Use (H5): N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products: NI

| Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER |
| Address: 15800 ALTON PKWY. |
| IRVINE, CA 92618 |
| UNITED STATES |

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): NA

Correction/Removal No (H9): NA

MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b)(6)
- **Address:** (b)(6)
- **Health Professional:** Yes
- **Email:** (b)(6)
- **Phone:** (b)(6)
- **International:** Fax:

**Occupation:** 001 - PHYSICIAN

Recd: 560  Page: 1,124  Date Last Updated: 11/2/2010  9:17 AM
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-2008-00120</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 28-Feb-2008</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 28-Feb-2008</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 28-Feb-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

#### Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

- **Device Age (F9):** Manufacture Date (H4): 06-Feb-2007
- **Expiration Date:**
- **Device Usage (H8):**

#### Event Description (B5):

Mfr 27-MAY-2008: THE CUSTOMER REPORTED THAT DURING THE LASER TREATMENT THE SYSTEM SHUT DOWN. THE CUSTOMER TURNED THE MACHINE OFF, UNPLUGGED IT, WAITED, RE-PLUGGED THE MACHINE AND TURNED IT BACK ON. AN ERROR MESSAGE DISPLAYED. THEY HAD NO BACKUP MACHINE AT THE TIME. THE SURGEON ESTIMATED THAT HE PERFORMED ONLY 25% OF THIS PT'S TREATMENT. THE FOLLOWING CASE WAS RESCHEDULED. MULTIPLE ATTEMPTS MADE FOR ADDITIONAL INFO, WITH NO FURTHER INFO RECEIVED.

#### Concomitant Medical Products:

- **NI**

#### Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER

- **Address:** 15800 ALTON PKWY.
  IRVINE, CA 92618
  UNITED STATES

#### Device Available for Evaluation: Y

#### Device Evaluated by Manufacturer (H3): Yes

#### Remedial Action (H7):

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **International:**
- **Fax:**
- **EMAIL:**
- **Phone:** (b) (b)
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2008-00132</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>09-Apr-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>14-Mar-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>14-Mar-2008</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):** 10-Jun-2004

**Expiration Date:**

**Single Use (H5):** N

**Device Usage (H8):** R

**Event Description (B5):**

Mfr 11-JUN-2008: THE CUSTOMER REPORTED THE LASER CABLE FLIPS DOWN ON THE FIBER OPTICS. THE SURGEON ABORTED THE PROCEDURE. ATTEMPTS WERE MADE FOR MORE INFO ON THE EVENT AND PT STATUS WITH NO RESPONSE.

**Concomitant Medical Products:**

NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PKWY.

IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)

Health Professional: Yes

- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** Fax:

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2008-00141</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>21-Apr-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>22-Mar-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>22-Mar-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): | Manufacture Date (H4): | 02-Sep-2003 |
Expiration Date: | Single Use (H5): | N |
Device Usage (H8): | R |

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: EYELITE LASER
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: EYELITE LASER
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)
Email: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Occupation: 002 - NURSE

Health Professional: Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2008-00263  Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 12-Jun-2008  Event Report Type: MALFUNCTION
Report Date (B4): 12-Jun-2008
Report Date (F8): 12-Jun-2008
Date Mfr Rec'd (G4): 12-Jun-2008

Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): Event Location (F12):
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Report Date (F8): OTHER
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): Single Use (H5): N
Expiry Date: Device Usage (H8): R

Event Description (B5):
Mfr 23-SEP-2008: THE CUSTOMER REPORTED THE SURGEON HAD A HARD TIME GETTING THE PROBE THROUGH THE CANNULA. THE SURGEON WAS ABLE TO COMPLETE THE CASE WITH NO PATIENT INJURY.

Concomitant Medical Products:

NI

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
23-SEP-2008: THE PROBE HAS BEEN RECEIVED FOR EVALUATION. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CRF 803.56 WHEN ADDITIONAL REPORTABLE INFORMATION BECOMES AVAILABLE.

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA, 92618
UNITED STATES

Recd: 564  Page: 1,131  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EYELITE LASER
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** EYELITE
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>26-Jun-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>26-Jun-2008</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>26-Jun-2008</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Jun-2008</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2028159-2008-00272</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Jul-2007</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NI</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
</tr>
</tbody>
</table>

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** OPTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** (b) (b)
- **Address:** (b) (b)
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2008-00297</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>21-Aug-2008</th>
</tr>
</thead>
</table>

**Event Date (B3):** 07-Jul-2008  
**Report Date (B4):** 22-Jul-2008  
**Report Date (F8):** 08-Jul-2008  
**Date Mfr Rec'd (G4):** 22-Jul-2008

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Reporter Occupation (E3):** 500 - RISK MANAGER  
**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:** Single Use (H5): N  
**Device Usage (H8):** R

**Event Description (B5):**
Mfr 01-DEC-2008: A MEDWATCH (SEE ATTACHED) FORM WAS REC'D FROM THE CUSTOMER REPORTING THAT DURING A LASER PROCEDURE, THERE WAS NO AIMING BEAM NOTED. THE CUSTOMER STATED THE FIBER WAS DISLODGED FROM THE SHEATH. NO PT INJURY WAS REPORTED.

**Concomitant Medical Products:**
NA

**Mfr Name:** ALCON- IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
01-DEC-2008: THE LASER PROBE WAS REC'D FOR IN HOUSE TESTING. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY WHEN ADD'L REPORTABLE INFO BECOMES AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

| Brand: | OPTHALAS 523 EYELITE LASER SYSTEM |
| Device Type: | LASER INSTRUMENT, SURGICAL, POWERED |
| Device Type: | 8065500001 |
| Catalog: | 8065500001 |
| Serial: | (*confidential*) |
| Lot: | NA |
| Other ID: | NA |

Reprocessed & Reused: N

**REPORTER INFORMATION:**

| Name: | [b](b) |
| Address: | [b](b) |

Health Professional: Yes

| EMAIL: | [b](b) |
| Phone: | [b](b) |
| International: | |
| Fax: | |

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2008-00302</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received:</th>
<th>21-Aug-2008</th>
</tr>
</thead>
</table>

Event Date (B3): 03-Jul-2008
Report Date (B4): 03-Jul-2008
Report Date (F8): 03-Jul-2008
Date Mfr Rec’d (G4): 07-Jul-2008

Event Report Type: MALFUNCTION
Event Outcome (B2): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3): COMPANY REPRESENTATIVE, HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Feb-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 03-NOV-2008: THE CUSTOMER INITIALLY REPORTED A SYSTEM MESSAGE DISPLAYED, THE SYSTEM WOULD NOT RESPOND AND ONE PROCEDURE HAD TO BE DELAYED. ADDITIONAL INFORMATION RECEIVED IN 2008, STATED THAT THE SURGEON SWITCHED TO CRYOPEXY TO COMPLETE THE CASE. THERE WAS NO PATIENT INJURY REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Recd: 567  Page: 1,137  Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
  - (b) (b)
  - (b) (b)
- **Email:**
- **Phone:**
  - (b) (b)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>15-Aug-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4)</td>
<td>18-Aug-2008</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>15-Aug-2008</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Aug-2008</td>
</tr>
<tr>
<td>Mfr 06-JAN-2009: THE NURSE REPORTED THAT THE SURGEON NOTICED THE ENDOLASER PROBE STARTED TO SMOKE WITHIN THE EYE. THE SURGEON WOULD LIKE TO RETURN THE PROBE FOR TESTING. THERE WAS NO PATIENT INJURY REPORTED.</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ALCON MANUFACTURING, LTD.</td>
<td></td>
</tr>
<tr>
<td>MFR Report No: 2028159-2008-00341</td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 17-Sep-2008</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4): 01-Dec-2003</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

NI

Mfr Name: ALCON - IRVINE TECH CTR
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
06-JAN-2009: THE COMPANY SERVICE REP EXAMINED THE SYSTEM, AND WAS NOT ABLE TO REPLICATE THE COMPLAINT. THE SYSTEM WAS TESTED, AND MET ALL PRODUCT SPECIFICATIONS. MULTIPLE ATTEMPTS WERE MADE FOR SAMPLE RETURN WITH NO RESPONSE TO DATE. THE ROOT CAUSE OF THE PATIENT EVENT CANNOT BE DETERMINED IN THIS INVESTIGATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPHTHALAS 532 EYELITE LASER SYSTEM
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: 8065500001
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (b)
Address: (b) (b)
Health Professional: Yes
EMAIL: (b) (b)
Phone: (b) (b)
International: Fax:
Occupation: 002 - NURSE

(b) (6)
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2008-00362
Mfr Name: ALCON MANUFACTURING, LTD.
03-Oct-2008

Event Date (B3): 04-Sep-2008
Report Date (B4): 04-Sep-2008
Report Date (F8):
Date Mfr Rec'd (G4): 04-Sep-2008

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y

Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:
Device Usage (H8): R

Manufacture Date (H4): 01-Jun-2004
Single Use (H5): N

Event Description (B5):

Concomitant Medical Products:
Ni

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
09-OCT-2008: THE CO SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND CONFIRMED THE COMPLAINT. THE BACKpanel BOARD AND LASER ENGINE WERE REPLACED TO ADDRESS THE ISSUE. THE SYSTEM WAS TESTED AND MET ALL PRODUCT SPECIFICATIONS. THE BACKpanel BOARD AND LASER ENGINE WERE SENT FOR IN HOUSE TESTING. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-2008-00363</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>03-Oct-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Sep-2008</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>04-Sep-2008</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Sep-2008</td>
<td>Reporter Occupation (E3): UNK - UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>04-Sep-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4): 01-Mar-2008</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 02-FEB-2009: THE CUSTOMER REPORTED THE SYSTEM DISPLAYED A SYSTEM MESSAGE. THE CUSTOMER COULD NOT COMPLETE THE LASER TREATMENT AFTER SEVERAL SHOTS. THE SURGEON CLOSED THE INCISION AND COMPLETED SURGERY ON THE FOLLOWING DAY. MULTIPLE ATTEMPTS WERE MADE FOR MORE INFORMATION ON THE EVENT AND PATIENT STATUS WITH NO RESPONSE TO DATE.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
         IRVINE, CA 92618
         UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
02-FEB-2009: INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED, WHEN ADDITIONAL INFORMATION BECOMES AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>OPTHALAS 532 EYELITE LASER SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>8065500001</td>
</tr>
<tr>
<td>Catalog</td>
<td>8065500001</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>[redacted]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[redacted]</td>
</tr>
<tr>
<td>Health</td>
<td>Yes</td>
</tr>
<tr>
<td>Professional</td>
<td>Yes</td>
</tr>
</tbody>
</table>

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Mfr Name:</th>
<th>Date Mfr Rec'd (G4):</th>
</tr>
</thead>
<tbody>
<tr>
<td>2028159-2008-00368</td>
<td>ALCON MANUFACTURING, LTD.</td>
<td>08-Sep-2008</td>
</tr>
</tbody>
</table>

Event Date (B3): 01-Jan-2008
Report Date (B4): 09-Sep-2008
Report Date (F8): 08-Sep-2008

Event Report Type: MALFUNCTION
Event Outcome (B2): Event Location (F12):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-May-2008
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 12-FEB-2009: THE FACILITY BIOMEDICAL TECHNICIAN STATED THE SYSTEM FROZE DURING A CASE LAST WEEK. HE WAS UNSURE OF THE EXACT DATE; HOWEVER, IT WAS DURING AN EMERGENCY CASE AND THEY WERE UNABLE TO BOOT UP THE SYSTEM. THE CASE WAS UNABLE TO BE COMPLETED WITH THE SYSTEM AND THE FACILITY DOES NOT HAVE A BACK UP. MULTIPLE ATTEMPTS WERE MADE FOR MORE INFORMATION ON THE EVENT AND PATIENT STATUS WITH NO RESPONSE TO DATE.

Concomitant Medical Products: NI

Mfr Name: ALCON - IRVIN TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
12-FEB-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM, AND REPLACED THE LASER ENGINE AND BACK PANEL. THE SYSTEM WAS THEN TESTED, AND MET ALL PRODUCT SPECIFICATIONS. THE LASER ENGINE AND BACK PANEL WERE SENT FOR IN HOUSE TESTING. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED, WHEN ADDITIONAL INFORMATION BECOMES AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>OPTHALAS 532 EYELITE LASER SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>8065500001</td>
</tr>
<tr>
<td>Catalog</td>
<td>8065500001</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

Health Professional: Yes

| EMAIL: | (b) (6) |
| Phone: | (b) (6) |
| International: | |
| Fax: | |

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 24-Sep-2008
Report Date (B4): 24-Sep-2008
Date Mfr Rec'd (G4): 01-Oct-2008

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y
Problem (B1): Y
Event Location (F12): HEALTH PROFESSIONAL
Report Source (G3): COMPANY REPRESENTATIVE

Event Description (B5):

Concomitant Medical Products:
NI

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): 
Correction/Removal No (H9): NA

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Apr-2007
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Mfr Name: ALCON MANUFACTURING, LTD.
MFR Report No: 2028159-2008-00392

Date Last Updated: 11/2/2010 9:17 AM
Recd: 572 Page: 1,147
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MFR Report No:** 2028159-2008-00397  
**Mfr Name:** ALCON MANUFACTURING, LTD.  
**Date Received:** 31-Oct-2008

**Event Date (B3):** 02-Oct-2008  
**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y

**Event Outcome (B2):**

**Event Location (F12):**

**Report Source (G3):** HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):** Manufacture Date (H4): 01-Sep-2008

**Expiration Date:**

**Device Usage (H8):** R

**Event Description (B5):**


**Concomitant Medical Products:**

NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
17-MAR-2009: THERE WERE NO SAMPLES RETURNED FOR EVALUATION. THERE WAS NO ADDITIONAL INFORMATION RELATED TO THIS COMPLAINT PROVIDED AND THE SYSTEM WAS FOUND TO MEET SPECIFICATIONS WHEN EXECUTING THE SERVICE TEST PROCEDURE. THE LASER FIRING TONE ON THE LASER SYSTEM IS NOT DESIGNED TO CORRELATE TO THE RATE AT WHICH THE LASER IS FIRING. THE FACILITY CONTINUED TO USE THE SYSTEM WITH NO PROBLEMS REPORTED. A REVIEW OF COMPLAINTS FOR THE LAST 24 MONTHS REVEALED NO ADDITIONAL COMPLAINTS RELATED TO THE REPORTED EVENT. A REVIEW OF SERVICE REQUESTS FOR THE LAST 24 MONTHS REVEALED NO ADDITIONAL SERVICE REQUESTS RELATED TO THE REPORTED EVENT. A QUESTIONNAIRE WAS SENT TO THE REPORTER ON 10/14/2008, AND FOLLOWED UP ON 10/16/2008 AND 10/24/2008. NO RESPONSE TO THE QUESTIONNAIRE WAS RECEIVED. THIS REPORT WAS MAILED TO FDA ON: 10/31/2008.

DEVICE INFORMATION:

Brand: PUREPOINT
Device Type: LASER, OPHTHALMIC
Device Type: PUREPOINT
Catalog: 8065750597
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health Professional: Yes

EMAIL:
Phone: [b] (6)
International:
Fax:

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2008-00403</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>05-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Oct-2008</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>06-Oct-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Apr-2008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: PUREPOINT
Device Type: LASER, OPHTHALMIC
Device Type: PUREPOINT
Catalog: 8065750597
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)
Health Professional: Yes

EMAIL: 
Phone: (b) (6)
International: 
Fax: 

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>21-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>2028159-2008-00432</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 29-Oct-2008  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Report Date (B4):** 29-Oct-2008  
**Event Location (F12):**  
**Date Mfr Rec'd (G4):** 29-Oct-2008  
**Mfr Report No:**  
**Report Date (F8):** 29-Oct-2008  
**Event Source (G3):**  
**Adverse Event (B1):** Y  
**Problem (B1):** Y  

**Event Description (B5):**
Mfr 28-NOV-2008: THE NURSE REPORTED RECEIVING A SYSTEM MESSAGE WHILE ATTEMPTING TO LASER. THE SURGEON HAD TO SWITCH TO CRYOPEXY TO FINISH THE CASE. THIS EXTENDED THE CASE BY TWO HOURS. THE PATIENT DID HAVE THE LASER PROCEDURE COMPLETED IN THE SURGEON'S OFFICE. THE PATIENT IS DOING WELL.

**Concomitant Medical Products:**
NI

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**  
**Manufacture Date (H4):** 01-Jan-2004  
**Expiration Date:**  
**Single Use (H5):** N  
**Device Usage (H8):** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 352 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occuption:** 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM

Recd: 575  Page: 1,154
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2008-00455

Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 17-Nov-2008
Report Date (B4): 17-Nov-2008
Report Date (F8):
Date Mfr Rec'd (G4): 17-Nov-2008

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

MFR Report No: 2028159-2008-00455

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:

Manufacture Date (H4): 01-Nov-2006
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 02-JUN-2009: THE NURSE REPORTED THE SYSTEM SHUT OFF AUTOMATICALLY AND DISPLAYED A SYSTEM MESSAGE FORTY-FIVE MINUTES INTO THE CASE. THE SURGERY WAS COMPLETED, BUT THE LASER PORTION WAS NOT COMPLETED. MULTIPLE ATTEMPTS WERE MADE FOR PATIENT STATUS WITH NO RESPONSE TO DATE.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CTR
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
02-JUN-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND REPLACED THE POWER POTENTIOMETER ASSEMBLY. THE POWER POTENTIOMETER ASSEMBLY WAS SENT IN HOUSE FOR TESTING. THE SYSTEM WAS THEN TESTED AND MET ALL PRODUCT SPECIFICATIONS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED WHEN ADDITIONAL INFORMATION BECOMES AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>OPHTHALAS 532 EYELITE LASER SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL, POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>8065500001</td>
</tr>
<tr>
<td>Catalog</td>
<td>8065500001</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

| Name:            | (b) (b)                             |
| Address:         | (b) (b)                             |

Health Professional: Yes

| EMAIL:           | (b) (b)                             |
| Phone:           | (b) (b)                             |
| International:   |                                    |
| Fax:             |                                     |

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2028159-2008-00467
Mfr Name: ALCON MANUFACTURING, LTD.
Event Date (B3): 20-Nov-2008
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): Event Location (F12): Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL
Report Date (B4): 20-Nov-2008
Report Date (F8): OTHER
Date Mfr Rec'd (G4): 20-Nov-2008
Report Date (F8): OTHER
Date Recd (G4): 19-Dec-2008
MFR Report No: 2028159-2008-00467
Mfr Name: ALCON MANUFACTURING, LTD.
Date Received: 19-Dec-2008

Event Description (B5):
Mfr 08-MAY-2009: THE SURGEON REPORTED THAT A BURNING ODOR AND SMOKE CAME FROM THE SYSTEM DURING THE PROCEDURE. THERE WAS NO PT INJURY REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
08-MAY-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND REPLACED THE LASER ENGINE. THE LASER ENGINE HAS BEEN SENT FOR IN HOUSE TESTING. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE.

Date Last Updated: 11/2/2010 9:17 AM
Recd: 577 Page: 1,157
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Email:**
- **Phone:**
- **International:** (b) (6)
- **Fax:**

Health Professional: Yes

Occupation: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>Date Received: 07-Jan-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Dec-2008</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Dec-2008</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-Dec-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td></td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
<td>Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-May-1998
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: ALCON MANUFACTURING, LTD.
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2009-00022
Mfr Name: ALCON MANUFACTURING, LTD.
16-Jan-2009

Event Date (B3): 18-Dec-2008
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y
Report Date (B4): 18-Dec-2008
Event Outcome (B2):
Event Location (F12): Healthcare Professional, COMPANY REPRESENTATIVE
Date Mfr Rec'd (G4): 18-Dec-2008
Device Operator: HEALTH PROFESSIONAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2007
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type**: LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type**: 8065500001
- **Catalog**: 8065500001
- **Serial**: (confidential)
- **Lot**: NA
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: [REDACTED]
- **Address**: [REDACTED]
- **Health Professional**: Yes
- **EMAIL**: [REDACTED]
- **Phone**: [REDACTED]
- **International**: [REDACTED]
- **Fax**: [REDACTED]
- **Occupation**: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY
Date Received
02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

Date Received
2028159-2009-00030
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 05-Jan-2009
Report Date (B4): 05-Jan-2009
Report Date (F8):
Date Mfr Rec’d (G4): 05-Jan-2009

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL,
COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jun-2006
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 08-JUN-2009: THE SURGEON REPORTED HE WAS ONLY ABLE TO FIRE 14 SHOTS BEFORE THE SYSTEM SHUT DOWN WITH A SYSTEM MESSAGE ON
DISPLAY. THE PATIENT TREATMENT WAS DISCONTINUED AND RESCHEDULED. NO PATIENT HARM WAS REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
08-JUN-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND COULD NOT DUPLICATED THE SYSTEM MESSAGE. THE SYSTEM
WAS RECALIBRATED AND TEMPERATURE ADJUSTMENT PERFORMED. THE SYSTEM WAS THEN TESTED AND MET ALL PRODUCT SPECIFICATIONS.
THIS REPORT WAS MAILED TO FDA ON: 01/23/2009.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPTHALAS 532 EYELITE LASER SYSTEM
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: 8065500001
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name:
Address:
Health Professional: Yes

EMAIL:
Phone:
International:
Fax:
Occupation: OTHER

Date Last Updated: 11/2/2010 9:17 AM
Recd: 580 Page: 1,164
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>09-Jan-2009</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>13-Jan-2009</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>13-Jan-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2028159-2009-00042</td>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 18-FEB-2009: THE SURGEON REPORTED THE LASER FIRED WITHOUT THE DRS FILTER BEING IN PLACE. THE SURGEON STATED THAT HE VIEWED THE LASER PULSE. THE NURSE STATED THE SURGEON WAS PERFORMING A CASE AND WAS UNABLE TO CONTINUE, AS HE STATED HE HAD FULL VIEW OF THE LASER PULSE AND EXPERIENCED BLURRED VISION. THE ATTENDING SURGEON COMPLETED THE CASE WITH NO IMPACT TO THE PATIENT. THE SURGEON WAS UNABLE TO COME TO WORK THE NEXT DAY AS HIS VISION WAS BLURRED. MULTIPLE ATTEMPTS WERE MADE FOR SURGEON STATUS WITH NO RESPONSE TO DATE.

**Concomitant Medical Products:**
- NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes
**Remedial Action (H7):**
**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Health Professional:** Yes
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 002 - NURSE

(b) (6)

(b) (6)

(b) (6)

(b) (6)
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2028159-2009-00063</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
<th>Event Date (B3): 03-Feb-2009</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td>Date Mfr Rec'd (G4): 22-Feb-2009</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Dec-2004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

**Concomitant Medical Products:**
NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**
**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
02-JUL-2009: THE COMPANY SERVICE REP EXAMINED THE SYSTEM AND DETERMINED THE LASER ENGINE NEEDS TO BE REPLACED. THE LASER ENGINE IS ON BACK ORDER. THE SYSTEM IS NOT IN USE AT THIS TIME, PENDING REPLACEMENT OF THE LASER ENGINE. THE COMPANY SALES REP PROVIDED A LOANER SYSTEM TO THE FACILITY. THERE WAS NO SAMPLE RETURNED FOR EVAL AS YET AND NOT ADDITIONAL INFO PROVIDED RELATED TO THE REPORTED EVENT. THE ROOT CAUSE CANNOT BE DETERMINED AT THIS TIME. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE. THIS REPORT WAS MAILED TO FDA ON: 03/03/2009.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes

EMAIL: (b) (b)

Phone: (b) (b)

International: (b) (b)

Fax: (b) (b)

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>11-Dec-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>12-Dec-2008</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Mar-2009</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2028159-2009-00118</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Mar-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>12-Dec-2008</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>11-Dec-2008</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 17-AUG-2009: THE SURGEON REPORTED THAT WHILE USING THE MICROSCOPE THE FIXATION SCREW ON THE LASER SAFETY FILTER LOOSENED. 
THE EYEPIECE OF THE MICROSCOPE FELL ON THE PATIENT'S FOREHEAD. THE FOREHEAD SWELLED. NO ADDITIONAL TREATMENT WAS REQUIRED. 
NO PATIENT INJURY WAS REPORTED.

**Concomitant Medical Products:**

None

**Device Available for Evaluation:**

N

**Device Evaluated by Manufacturer (H3):**

No

**Remedial Action (H7):**

Correction/Removal No (H9): NA

**Additional Mfr Narrative (H10 & H11):**

17-AUG-2009: THE CUSTOMER STATED THE SAFETY FILTER IS CHECKED BEFORE USING IT TO MAKE SURE IT IS SECURELY FASTENED. THE SAFETY FILTER IS SECURED AT 2 POINTS. THERE WAS NO SAMPLE RETURNED FOR EVALUATION. THERE IS INSUFFICIENT INFORMATION TO CONFIRM OR REPlicate THE REPORTED EVENT AND THEREFORE THE ROOT CAUSE CANNOT BE DETERMINED AT THIS TIME.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 02-Nov-2010

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00179</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>ALCON MANUFACTURING, LTD.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>04-May-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>04-May-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>04-May-2009</td>
</tr>
</tbody>
</table>

Date Mfr Rec’d (G4): 04-May-2009

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Location (F12):
Event Description (B5):
Mfr 08-OCT-2009: THE SURGEON REPORTED THE SYSTEM WAS TURNED ON AND A BLANK SCREEN DISPLAYED. THE SURGEON WAS NOT ABLE TO USE THE LASER BUT WAS ABLE TO COMPLETE THE CASE. ADDITIONAL INFO FROM THE SURGEON STATED, HE WAS ABLE TO COMPLETE THE CASE WITH NO ADDITIONAL SURGERY REQUIRED. THE PT IS DOING WELL.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CTR
Address: 15800 ALTON PKWY.
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
08-OCT-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND REPLACED THE CORE MODULE. THE CORE MODULE HAS BEEN SENT FOR IN-HOUSE TESTING. THE SYSTEM WAS THEN TESTED AND MET ALL PRODUCT SPECIFICATIONS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE. (B) (4)
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: PUREPOINT
Device Type: LASER, OPHTHALMIC
Device Type: PUREPOINT
Catalog: 8065750597
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2028159-2009-00206
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 18-May-2009
Report Date (B4): 18-May-2009
Report Date (F8): 18-May-2009
Date Mfr Rec’d (G4): 18-May-2009

Event Report Type: MALFUNCTION
Event Outcome (B2): 002 - NURSE
Report Date (F8): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Mar-2008
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 29-SEP-2009: THE NURSE REPORTED THE SURGEON STATED THAT ON THE LAST CASE HE OBSERVED A GREEN LIGHT WHILE USING THE LIO HEADSET. THE SURGERY WAS COMPLETED, AND THERE WAS NO HARM TO THE PATIENT OR TO THE SURGEON. ADDITIONAL INFORMATION RECEIVED STATED THE SURGEON WAS PERFORMING A PAN RETINAL PHOTOCOAGULATION AND A RETINOPEXY FOR A RETINAL DETACHMENT. NO PATIENT OR SURGEON HARM WAS REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2009-00233

Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 03-Jun-2009
Report Date (B4): 03-Jun-2009
Report Date (F8):
Date Mfr Rec'd (G4): 03-Jun-2009

Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Event Location (F12):
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2007
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 02-OCT-2009: THE NURSE REPORTED THAT DURING THE CASE, THE SURGEON WAS ABLE TO FIRE 80 SHOTS AND THEN A SYSTEM MESSAGE DISPLAYED, WHICH COULD NOT BE CLEARED. ADDITIONAL INFORMATION RECEIVED FROM THE SURGEON STATED HE HAD COMPLETED ABOUT 98% OF THE LASER TREATMENT. THE PATIENT IS DOING VERY WELL WITH THE CURRENT TREATMENT. NO PATIENT INJURY WAS REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
02-OCT-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND CONFIRMED THE PROBLEM REPORTED. THE LASER ENGINE WAS REPLACED AND SENT FOR IN-HOUSE TESTING. THE SYSTEM WAS THE TESTED AND MET ALL PRODUCT SPECIFICATIONS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFORMATION BECOMES AVAILABLE. (B) (4)
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Health Professional:** Yes
- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00247</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>10-Jul-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>12-Jun-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Jun-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Nov-2008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER
**Address:** 15800 ALTON PARKWAY
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA
**Additional Mfr Narrative (H10 & H11):**

15-OCT-2009: THE COMPANY SERVICE REP EXAMINED THE SYSTEM AND CONFIRMED THE COMPLAINT. THE SHUTTER MECHANISM WAS REPLACED. THE SYSTEM WAS THEN TESTED AND MET ALL PRODUCT SPECIFICATIONS. THE SAMPLE HAS BEEN RECEIVED AND IN-HOUSE TESTING IS IN PROGRESS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFORMATION BECOMES AVAILABLE. (B) (4)
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: PUREPOINT
Device Type: LASER, OPHTHALMIC
Catalog: 8065750597
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Occupation: 002 - NURSE
# MAUDE EVENT REPORT (FOI)

## SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Date Received

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Jun-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>18-Jun-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Jun-2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Event Description (B5):

Mfr 02-NOV-2009: THE NURSE REPORTED A SYSTEM MESSAGE DISPLAYED DURING THE FIRST CASE THAT COULD NOT BE CLEARED. THE FIRST CASE WAS PREPPED, THE SECOND CASE WAS NOT PREPPED. BOTH CASES WERE CANCELED. NO PT INJURY WAS REPORTED.

### Concomitant Medical Products:

NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER

Address: 15800 ALTON PKWY.

IRVINE, CA 92618

UNITED STATES

### Device Available for Evaluation: Y

### Device Evaluated by Manufacturer (H3): Yes

### Remedial Action (H7):

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):

02-NOV-2009: THE COMPANY SERVICE REP EXAMINED THE SYSTEM AND CONFIRMED THE SYSTEM MESSAGE REPORTED. THE POWER POTentiOMETER WAS REPLACED AND SENT FOR IN-HOUSE TESTING. THE SYSTEM WAS THEN TESTED AND MET ALL PRODUCT SPECS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE. (B) (4). (B) (4). (B) (4).
DEVICE INFORMATION:

- **Brand:** OPTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)  
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: Date Last Updated: 11/2/2010 9:17 AM

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00269</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 22-Jun-2009  
**Report Date (B4):** 22-Jun-2009  
**Report Date (F8):** 22-Jun-2009  
**Date Mfr Rec'd (G4):** 22-Jun-2009

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER  
**Device Operator:** HEALTH PROFESSIONAL  
**Report Source (G3):** HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):** 01-Apr-2005  
**Expiration Date:** N  
**Device Usage (H8):** R

**Event Description (B5):**

Mfr 07-OCT-2009: THE SURGEON REPORTED THAT DURING SET UP FOR SURGERY THE SYSTEM SHUT DOWN. THE STAFF RECONNECTED THE POWER CABLE, BUT THE SYSTEM WOULD NOT REBOOT. THE CASE WAS DELAYED FOR 2.5 HRS UNTIL A REPLACEMENT SYSTEM WAS OBTAINED. THE SURGERY WAS COMPLETED AS PLANNED. NO PATIENT INJURY WAS REPORTED.

**Concomitant Medical Products:**

NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER  
**Address:** 15800 ALTON PKWY.  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

07-OCT-2009: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND REPLACED THE POWER SUPPLY. THE POWER SUPPLY WAS SENT FOR IN-HOUSE TESTING. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY WHEN ADDITIONAL REPORTABLE INFORMATION BECOMES AVAILABLE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type**: LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type**: 80655000001
- **Catalog**: 80655000001
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: (b) (6)
- **Address**: (b) (6)
- **EMAIL**: (b) (6)
- **Phone**: (b) (6)
- **International**: (b) (6)
- **Fax**: (b) (6)
- **Health Professional**: Yes
- **Occupation**: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00285</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received:</th>
<th>31-Jul-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Jul-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Jul-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>02-Jul-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Dec-2004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>ALCON - IRVINE TECHNOLOGY CENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>15800 ALTON PKWY.</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |

**Remedial Action (H7):**

| Correction/Removal No (H9): | NA |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>OPHTHALAS 532 EYELITE LASER SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL, POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>8065500001</td>
</tr>
<tr>
<td>Catalog</td>
<td>8065500001</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>NA</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

| Name | (b) (6) |
| Address | (b) (6) |
| EMAIL | (b) (6) |
| Phone | (b) (6) |
| International | (b) (6) |
| Fax | |

Health Professional: Yes

Occupation: OTHER
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 2028159-2009-00294
Mfr Name: ALCON MANUFACTURING, LTD.
Date Received: 06-Aug-2009

Event Date (B3): 07-Jul-2009
Report Date (B4): 07-Jul-2009
Report Date (F8):
Date Mfr Rec'd (G4): 07-Jul-2009

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): Report Source (G3):

Date Mfr Rec'd (G4): 07-Jul-2009

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Manufacture Date (H4):
Single Use (H5): N

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA

Event Description (B5):
Mfr 16-OCT-2009: THE AFFILIATE REPORTED THAT A SYSTEM MESSAGE DISPLAYED DURING SURGERY. THE AUTOMATIC SHOTS OF THE LASER STOPPED, AND IT WAS NECESSARY TO SHOOT THEM MANUALLY USING THE FOOTSWITCH. NO PT HARM OR SIGNIFICANT PROCEDURAL DELAY WAS REPORTED. TWO OTHER CASES WERE CANCELLED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Additional Mfr Narrative (H10 & H11):
16-OCT-2009: NO SAMPLES HAVE BEEN RETURNED FOR INVESTIGATION. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROCESS. A SUPPLEMENTAL MDR WILL BE FILED WHEN ADDITIONAL REPORTABLE INFO BECOMES AVAILABLE. (ERROR MESSAGE GIVEN). THIS REPORT WAS MAILED TO FDA ON: 08/06/2009.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPTHALAS 532 EYELITE LASER SYSTEM
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: 8065500001
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (5)
Fax: (b) (6)

Health Professional: No

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00299</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
<th>Date Received</th>
<th>07-Aug-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Jul-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>09-Jul-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>09-Jul-2009</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>09-Jul-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 09-NOV-2009: THE CUSTOMER REPORTED THAT DURING SURGERY, THE LASER WOULD NOT CONTINUE TO FIRE. THEY ATTEMPTED TO REBOOT THE SYSTEM 5 TIMES. THE CASE WAS COMPLETED AS PLANNED WITH A 30 MINUTE DELAY IN THE PROCEDURE. ADD'L INFO HAS BEEN REQUESTED, WITH NO RESPONSE TO DATE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 15800 ALTON PKWY.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *(b) (6)*
- **Address:** *(b) (b)*
- **EMAIL:** *(b) (b)*
- **Phone:** *(b) (6)*
- **International:** *(b) (b)*
- **Fax:** *(b) (b)*
- **Health Professional:** Yes
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2028159-2009-00304
Mfr Name: ALCON MANUFACTURING, LTD. 07-Aug-2009
Event Date (B3): 01-Jul-2009
Report Date (B4): 10-Jul-2009
Report Date (F8):
Date Mfr Rec'd (G4): 10-Jul-2009
MFR Report No: 2028159-2009-00304
Mfr Name: ALCON MANUFACTURING, LTD.

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Date Mfr Rec'd (G4): 07-Aug-2009
Mfr Name: ALCON MANUFACTURING, LTD.

Event Description (B5):
Mfr 14-AUG-2009: DURING FOLLOW-UP ON ANOTHER COMPLAINT, THE REPORTER STATED THAT THERE HAD BEEN TWO ABORTED CASES DUE TO THE SYSTEM SHUTTING DOWN AND NOT BEING ABLE TO REBOOT. ONE OR BOTH PATIENTS HAD SUBSEQUENT TREATMENT AT ANOTHER FACILITY. ADDITIONAL FOLLOW-UP WITH THE SURGEON PROVIDED LIMITED INFORMATION ON ONLY ONE PATIENT. HE COULD NOT REMEMBER WHICH PATIENT IT WAS. THE SURGERY WAS PROBABLY TREATMENT FOR A RETINAL DETACHMENT. HE REPORTED THAT THE PATIENT OUTCOME WAS GOOD.

Concomitant Medical Products:
BSS PLUS

Mfr Name: ALCON-IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): OTHER
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPHTHALAS 532 EYELITE LASER SYSTEM
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: 8065500001
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] [b]
Address: [b] [b]

EMAIL: [b]
Phone: [b] [b]
International: [b]
Fax: [b]

Health Professional: Yes

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00385</th>
<th>Mfr Name:</th>
<th>ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Aug-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>18-Aug-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Aug-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>17-Aug-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>17-Aug-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 02-NOV-2009: THE NURSE REPORTED THAT THE LASER INDIRECT OPHTHALMOSCOPE (LIO) WAS NOT WORKING. NO ILLUMINATION WAS NOTED. THERE WAS A 10 MINUTE DELAY IN THE PROCEDURE. THE SURGEON COMPLETED THE LASER WITH AN ENDOLASER PROBE. NO PT INJURY WAS REPORTED.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- **Brand:** PUREPOINT
- **Device Type:** LASER, OPHTHALMIC
- **Device Type:** PUREPOINT
- **Catalog:** 8065750597
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:** [Redacted]
**Fax:** [Redacted]

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

Event Date (B3): 25-Aug-2009
Report Date (B4): 25-Aug-2009
Date Mfr Rec’d (G4): 25-Aug-2009
Date Mfr Rec’d (G4): 25-Aug-2009

MFR Report No: 2028159-2009-00394
Mfr Name: ALCON MANUFACTURING, LTD.

Event Report Type: MALFUNCTION
Event Outcome (B2):

Adverse Event (B1):
Problem (B1): Y

Event Location (F12):
Report Source (G3):

Report Date (F8):

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):

Device Usage (H8): R
Single Use (H5): N

Device Code: (OP)-LASER, OPHTHALMIC (HQF)

Manufacture Date (H4): 01-Jul-2005
Expiration Date:

Device Age (F9):

Report Date (B4):

Report Date (F8):

Date Mfr Rec’d (G4):
25-Aug-2009
25-Aug-2009
Date Mfr Rec’d (G4):
25-Aug-2009
25-Aug-2009

Date Last Updated: 11/2/2010  9:17 AM
Recd: 595  Page: 1,193
Date Last Updated: 11/2/2010  9:17 AM
Recd: 595  Page: 1,193
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPHTHALAS 532 EYELITE LASER SYSTEM
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: 8065500001
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Health Professional: Yes

EMAIL: (b) (b)
Phone: (b) (b)
International: Fax:

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 2028159-2009-00441

Mfr Name: ALCON MANUFACTURING, LTD.

Event Report Type: MALFUNCTION

Adverse Event (B1): Problem (B1): Y

Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Date Mfr Rec'd (G4): 17-Sep-2009

Device Operator: HEALTH PROFESSIONAL

Event Date (B3): 16-Sep-2009

Report Date (B4): 17-Sep-2009

Date Event (B5): 16-Sep-2009

Report Date (F8): 17-Sep-2009

Date Mfr Rec'd (G4): 16-Oct-2009

Mfr Name: ALCON MANUFACTURING, LTD.

Event Description (B5):
Mfr 08-JAN-2010: THE NURSE REPORTED A SYSTEM MESSAGE DISPLAYED DURING SURGERY. THE SURGEON WAS NOT ABLE TO FINISH THE LASER PORTION OF THE SURGERY. THE NURSE STATED THE PATIENT WILL NOT BE RESCHEDULED FOR ADDITIONAL SURGERY AT THIS TIME. ONE CASE WAS CANCELLED. NO PATIENT INJURY WAS REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
08-JAN-2010: THE COMPANY SERVICE REPRESENTATIVE EXAMINED THE SYSTEM AND THE LASER ENGINE WAS REPLACED. THE LASER ENGINE WILL BE SENT FOR IN-HOUSE TESTING. THE SYSTEM WAS THEN TESTED AND MET ALL PRODUCT SPECIFICATIONS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDING WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFORMATION BECOMES AVAILABLE. (B) (4). (B) (4). (B) (4).
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OPHTHALAS 532 EYELITE LASER SYSTEM
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: 8065500001
Catalog: 8065500001
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2028159-2009-00525</th>
<th>Mfr Name: ALCON MANUFACTURING, LTD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Nov-2009</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Nov-2009</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Nov-2009</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, FOREIGN, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>01-Feb-2001</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
</tbody>
</table>
| Event Description (B5): | Mfr 05-MAR-2010:  | THE SURGEON REPORTED A SYSTEM MESSAGE DISPLAYED. THE CUSTOMER ATTEMPTED TO REBOOT THE SYSTEM SEVERAL TIMES WITH THE SYSTEM MESSAGE CONTINUING TO DISPLAY. THE COMPANY SERVICE REPRESENTATIVE BROUGHT A LOANER SYSTEM AND THE CASE WAS COMPLETED AS PLANNED. THE CASE WAS DELAYED AN HOUR WHILE WAITING FOR THE LOANER SYSTEM. THE ANESTHESIA TIME WAS EXTENDED. NO PATIENT INJURY WAS REPORTED.
| Concomitant Medical Products: | NI | |
| Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER | |
| Address: 15800 ALTON PARKWAY | |
| IRVINE, CA 92618 | |
| UNITED STATES | |
| Device Available for Evaluation: Y | |
| Device Evaluated by Manufacturer (H3): No | |
| Remedial Action (H7): | | |
| Correction/Removal No (H9): | NA | |
| Additional Mfr Narrative (H10 & H11): | 05-MAR-2010: THE SYSTEM HAS BEEN RETURNED AND IN-HOUSE TESTING IS IN PROGRESS. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADDITIONAL REPORTABLE INFORMATION BECOMES AVAILABLE. (B) (4). (B) (4) |
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPHTHALAS 532 EYELITE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [d] (b)
- **Email:**
- **Phone:**
- **International:** UNK - -
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

| MFR Report No: | 2028159-2009-00546 | Event Date (B3): | 01-Dec-2009 |
| Mfr Name: | ALCON MANUFACTURING, LTD. | Event Report Type: | MALFUNCTION |
| Reporter Occupation (E3): | OTHER | Event Location (F12): | FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE |
| Reporter Name: | ALCON - IRVINE TECHNOLOGY CENTER | Event Outcome (B2): | OTHER |
| Address: | 15800 ALTON PKWY. IRVINE, CA 92618 UNITED STATES |
| Date Mfr Rec'd (G4): | 02-Dec-2009 | Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Manufacture Date (H4): | 01-Dec-2005 | Device Operator: | HEALTH PROFESSIONAL |
| Single Use (H5): | N | Expiration Date: |
| Device Usage (H8): | R |

**Event Description (B5):**
Mfr 08-MAR-2010: THE NURSE REPORTED THE SYSTEM STOPPED WORKING DURING SURGERY. THE SURGEON COMPLETED THE SURGERY WITH A CRYOPEXY PROBE. THERE WAS A 15 MINUTE DELAY. THE PT WAS UNDER GENERAL ANESTHESIA, WHICH WAS PROLONGED.

**Concomitant Medical Products:**
NI

**Mfr Name:** ALCON - IRVINE TECHNOLOGY CENTER

**Address:** 15800 ALTON PKWY. IRVINE, CA 92618 UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
08-MAR-2010: ADD'L INFO HAS BEEN REQUESTED. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADD'L REPORTABLE INFO BECOMES AVAILABLE. (B) (4). (B) (4). (B) (4).
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OPTHALAS 532 EYELYTE LASER SYSTEM
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 8065500001
- **Catalog:** 8065500001
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [b] (6)
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:** [b] (6)
- **Fax:**
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2028159-2009-00549
Mfr Name: ALCON MANUFACTURING, LTD.

Event Date (B3): 27-Nov-2009
Event Report Type: MALFUNCTION

Report Date (B4): 27-Nov-2009
Event Outcome (B2): OTHER

Date Mfr Rec'd (G4): 27-Nov-2009
Reporter Occupation (E3): HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y

Event Location (F12): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL

Device Age (F9): Manufacture Date (H4): 01-Sep-2001
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 08-MAR-2010: THE SURGEON REPORTED A SYSTEM MESSAGE DISPLAYED DURING THE PROCEDURE. THE PT HAD A PRE-EXISTING OCULAR CONDITION OF A SMALL TEAR IN THE RETINA, FOR WHICH PRIORITY TREATMENT WAS REQUIRED. THE SYSTEM WAS SWITCHED OUT AND THE CASE WAS COMPLETED AS PLANNED. ADD'L INFO FROM THE SURGEON STATED THE PT HAD A SMALL RETINAL TEAR, WHICH WAS NOT CAUSED BY AN ALCON PRODUCT. HOWEVER, IF THE RETINAL TEAR COULD NOT HAVE BEEN LASERED THAT DAY, A RETINAL TEAR COULD HAVE OCCURRED. NO PT INJURY WAS REPORTED.

Concomitant Medical Products:
NI

Mfr Name: ALCON - IRVINE TECHNOLOGY CENTER
Address: 15800 ALTON PKWY.
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7): NA
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11): 08-MAR-2010: ADD'L INFO HAS BEEN REQUESTED. INVESTIGATION INCLUDING ROOT CAUSE ANALYSIS IS IN PROGRESS. A SUPPLEMENTAL MDR WILL BE FILED AS NECESSARY IN ACCORDANCE WITH 21 CFR 803.56 WHEN ADD'L REPORTABLE INFO BECOMES AVAILABLE. (B) (4). (B) (4). (B) (4).
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

| Brand: | OPHTHALAS 532 EYELYTE LASER SYSTEMS |
| Device Type: | LASER INSTRUMENT, SURGICAL, POWERED |
| Device Type: | 8065500001 |
| Catalog: | 8065500001 |
| Serial: | (*confidential*) |
| Lot: | NA |
| Other ID: | NA |

Reprocessed & Reused: N

REPORTER INFORMATION:

| Name: | [b] (6) |
| Address: | [b] (6) |

Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2030430-2008-00001</th>
<th>Mfr Name: AMS INNOVATIVE CENTER-PHOENIX</th>
<th>Date Mfr Rec'd (G4): 25-Jan-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 27-Dec-2007</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): N</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 07-Jan-2008</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): * - INVALID DATA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 25-Jan-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Dec-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): Mfr 12-MAR-2008: WHILE USING HOLMIUM LASER TO LASER A RIGHT URETERAL CALCULUS, LASER FIBER BROKE AND BURNED THE UROLOGIST'S TIP OF MIDDLE FINGER OF LEFT HAND. FIBER WAS BENT AND BROKEN APPROX. 35&quot; FROM THE TIP. BROKEN AREA WAS NOT INSIDE THE PT. HOLMIUM LASER SETTINGS WERE: ENERGY 0.8, RATE 16, POWER 12.8. DID THIS EVENT INVOLVE AN ELECTROPHYSIOLOGY PROCEDURE OR AN ATTEMPTED ELECTROPHYSIOLOGY PROCEDURE? NO.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>BOSTON SCIENTIFIC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: ONE BOSTON SCIENTIFIC PLACE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NATICK, MA 01760</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 12-MAR-2008: THE FIBER IS BROKEN AT THE END OF THE STRAIN RELIEF HEAT SHRINK WITH NO MELTING OR BURNING OF THE JACKET. THERE ARE ALSO TWO DENTS ON OPPOSITE SIDES OF THE BLUE SHRINK TUBE. THIS BREAK APPEARS TO BE DUE TO KINKING THE FIBER OR BEING DROPPED ON THE CONNECTOR END WHICH FRACTURED THE GLASS FERRULE.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INNOVAQUARTZ ACCUFLEX
- **Device Type:** LASER FIBER
- **Device Type:** 840802
- **Catalog:** 840802
- **Serial:** (*confidential*)
- **Lot:** TRF3486S
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:** (b) (b)
- **Phone:** (*)
- **International:** (b) (b)
- **Fax:** (b) (b)

Health Professional: No Information

Occupation: * - INVALID DATA
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2030430-2009-00003</th>
<th>Mfr Name:</th>
<th>AMS INNOVATIVE CENTER-PHOENIX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>29-Dec-2006</td>
<td>Event Report Type:</td>
<td>DEATH</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>14-Oct-2009</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Reptd (G7):</td>
<td></td>
<td>Report Source (G3):</td>
<td>DISTRIBUTOR</td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 28-OCT-2009: DISTRIBUTOR FORWARDED NOTICE OF A LEGAL COMPLAINT FILED AGAINST THEM INVOLVING AN ACCUFLEX FIBER. THE DISTRIBUTOR'S INTERNAL INVESTIGATION LEADS THEM TO BELIEVE THAT THIS WAS A PROCEDURE IN WHICH A 1000UM ACCUFLEX FIBER WAS USED WITH A LASER TO REMOVE MUCUS FROM LUNG TRANSPLANT PATIENTS. DURING THE PROCEDURE, THE LASER FIRED INTO THE BRONCHOSCOPE, CAUSING THE BRONCHOSCOPE TO BURN AND THE PT TO HAVE A MILD THERMAL BURNS ALONG THE TRACK OF THE BRONCHOSCOPE. THE COMPLAINT FURTHER ALLEGES THAT THIS EVENT PLAYED A ROLE IN THE PT'S DEATH 4 MONTHS LATER.

Concomitant Medical Products:

Device Available for Evaluation:
Device not Returned to Manufacturer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
28-OCT-2009: COMPLAINT FROM USER WAS NOT REPORTED TO AMS OR OUR DISTRIBUTOR FOR THIS DEVICE. DEVICE HAS NOT BEEN RETURNED FOR EVAL, AND AMS HAS NOT BEEN ABLE TO CONFIRM THE FIBER USED IS OUR ACCUFLEX DEVICE. DISTRIBUTOR BELIEVES IT MUST BE THIS DEVICE, AS THEY BELIEVE IT IS THE ONLY ONE THEY SELL THAT IS COMPATIBLE WITH THE MODEL OF LASER USED IN THE PROCEDURE.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: ACCUFLEX
- Device Type: LASER FIBER
- Device Type: UNK
- Catalog: UNK
- Serial: (*confidential*)
- Lot: UNK
- Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: 
- Address: 
- EMAIL: 
- Phone: 
- International: 
- Fax: 

- Health Professional: No Answer
- Occupation: OTHER

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2002-00001</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>11-Oct-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Sep-2002</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Sep-2002</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>12-Sep-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Jun-2002

Expiration Date: 30-Jun-2002

Single Use (H5): Y

Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>INTRALASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>3 MORGAN</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

22-OCT-2002:

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS DISPOSABLE PT INTERFACE
- **Device Type:** LASER KERATOME
- **Device Type:** PI-02
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** 06070201
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

The output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2002-00002</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Sep-2002</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Sep-2002</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>19-Sep-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td>Report Date (F8):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Event Location (F12):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td>Address:</td>
<td>3 MORGAN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IRVINE, CA 92618</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

Remedial Action (H7):
Correction/Removal No (H9):
24-OCT-2002: INTRALASE SENT OUT A SERVICE ENGINEER TO INVESTIGATE AND REPAIR THE LASER. DURING THE INVESTIGATION, IT WAS DISCOVERED THAT THE GANTRY SKINS WERE RUBBING AND CATCHING ON A POST THAT HOLDS THE SCREW FOR THE GANTRY X-AXIS. THE DEVICE WAS REPAIRED AND NO FURTHER PROBLEMS WERE REPORTED.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: (b) (6)

Health Professional: Yes

EMAIL: 
Phone: (b) (6)
International: 
Fax: 

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 05-Nov-2002
MFR Report No: 2032002-2002-00019
Mfr Name: INTRA LASE CORP.

Event Date (B3): 27-Jul-2002
Report Date (B4): 02-Aug-2002
Report Date (F8): 02-Aug-2002
Date Mfr Rec'd (G4): 02-Aug-2002

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F4): 02-Aug-2002
Event Location (F12): Reporter Occupation (E3): HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Report Date (F8): 02-Aug-2002
Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Apr-2002
Expiration Date:
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
07-NOV-2002: DEVICE EVAL NOT WARRANTED. UNLIKELY THAT THE DEVICE CONTRIBUTED TO THE EVENT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 2002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2002-00020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Sep-2002</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>29-Oct-2002</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>29-Oct-2002</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>29-Oct-2002</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

**Remedial Action (H7):**

Device not Returned to Manufacturer

**Additional Mfr Narrative (H10 & H11):**

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS DISPOSABLE PATIENT INTERFACE
- **Device Type:** LASER KERATOME
- **Device Type:** PI-20
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:**

- **Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 11-Nov-2002

MFR Report No: 2032002-2002-00021
Mfr Name: INTRA LASE CORP.

Event Date (B3): 03-Aug-2002
Report Date (B4): 05-Aug-2002
Report Date (F8): 05-Aug-2002
Date Mfr Rec'd (G4): 05-Aug-2002

Event Report Type: MALFUNCTION
Event Outcome (B2): REQUIRED INTERVENTION
Report Location (F12): Report Source (G3): HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y

Report Date (F8): 001 - PHYSICIAN
Event Location (F12): Reporter Occupation (E3): HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Mar-2002
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** *(redacted)*
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **Email:** *(redacted)*
- **Phone:** *(redacted)*
- **International:** *(redacted)*
- **Fax:** *(redacted)*
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td>Date Mfr Rec’d (G4): 17-Oct-2002</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jun-2002</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: INTRALASE CORP.  
Address: 3 MORGAN  
IRVINE, CA 92618  
UNITED STATES  

Device Available for Evaluation: Y  
Device Evaluated by Manufacturer (H3): Yes  
Remedial Action (H7):

Additional Mfr Narrative (H10 & H11):

21-NOV-2002: THE DEVICE WAS EVALUATED BY AN INTRALASE FIELD SERVICE ENGINEER, WHO REPLACED THE JOYSTICK.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *
Address: [REDACTED]
Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

EVENT REPORT TYPE: MALFUNCTION

Event Date (B3): 12-Dec-2002
Report Date (B4): 12-Dec-2002
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1):
Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
DeviceEvaluated by Manufacturer (H3): Yes
Remedial Action (H7): Correction/Removal No (H9):

Recd: 608
Page: 1,219
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2003-00002</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Mfr Rec’d (G4): 01-Nov-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Nov-2002</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Nov-2002</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>01-Nov-2002</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jul-2002</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td>Address:</td>
<td>3 MORGAN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IRVINE, CA 92618</td>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>02-Apr-2003</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>02-Apr-2003</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Apr-2003</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2032002-2003-00004</td>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>3 MORGAN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>08-MAY-2003: DEVICE EVALUATION CURRENTLY UNDERWAY.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20002
- Catalog: NA
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: [REDACTED]
- Address: [REDACTED]
- Health Professional: Yes
- EMAIL: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]
- Occupation: 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
Page: 1,224
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2003-00005

Mfr Name: INTRA LASE CORP.

Event Date (B3): 26-Jun-2003

Report Date (B4): 26-Jun-2003

Report Date (F8): 26-Jun-2003

Date Mfr Rec’d (G4): 26-Jun-2003

Event Report Type: MALFUNCTION

Event Outcome (B2): REQUIRED INTERVENTION

Report Date (F8): 26-Jun-2003

Event Location (F12): Reporter Occupation (E3):

Device Operator: HEALTH PROFESSIONAL

Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): MANUFACTURE DATE (H4): 01-Oct-2002

Single Use (H5): N

Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.

Address: 3 MORGAN

IRVINE, CA 92618

UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): REPAIR

Correction/Removal No (H9): 2032002-7/23/03-001C

Additional Mfr Narrative (H10 & H11):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Event Date (B3)</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>31-Jul-2003</td>
<td>09-Jul-2003</td>
<td>INJURY</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

**Date Mfr Rec'd (G4):** 09-Jul-2003

**Product Code:** (OP)-EXCIMER LASER SYSTEM (LZS)

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

04-AUG-2003: THE SURGEON DID NOT BELIEVE THAT EVENT WAS CAUSED BY THE INTRALASE FS LASER, THEREFORE A DEVICE EVALUATION WAS NOT PERFORMED.

---

**Event Description (B5):**

Mfr 04-AUG-2003: SUBSEQUENT TO LASIK SURGERY WITH USE OF THE INTRALASE FS LASER TO CREATE THE CORNEAL FLAP, A PATIENT PRESENTED WITH DIFFUSE LAMELLAR KERATITIS (DLK) BILATERALLY. AT APPROXIMATELY ONE WEEK POSTOPERATIVELY, THE DLK HAD PROGRESSED TO STAGE IV AND CENTRAL FOLDS WERE OBSERVED. THE PATIENT WAS TREATED WITH TOPICAL STERIODS; HOWEVER THE FLAPS WERE NOT LIFTED OR RINSED. AT THE 3 WEEK POSTOPERATIVE VISIT, THE PATIENT'S BEST CORRECTED VISUAL ACUITY HAD DECREASED MORE THAN 2 LINES AND RESULTED IN INDUCED ASTIGMATISM.

**Concomitant Medical Products:**

EXCIMER LASER FOR VISION CORRECTION

**Mfr Name:** INTRA LASE CORP.

**Address:** 3 MORGAN
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

---

**Event Location (F12):**

**Report Source (G3):** HEALTH PROFESSIONAL
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** R20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** *(b) (b)*
- **Health Professional:** Yes
- **Email:** *(b) (b)*
- **Phone:** *(b) (b)*
- **International:**
- **Fax:**

- **Occupation:** 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
EXCIMER LASER FOR VISION CORRECTION.

Mfr Name: INTRALASEE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
05-AUG-2003: NO DEVICE MALFUNCTION WAS REPORTED TO INTRALASE AND THE EVENT DOES NOT APPEAR TO BE DEVICE RELATED. NO COMPLAINT OR CONCERN RELATED TO THE LASER SYSTEM WAS COMMUNICATED BY THE USER. THIS EVENT WAS DESCRIBED BY THE USER AS A CLINICAL TECHNIQUE ISSUE DURING A USERS' GROUP MEETING IN 07/03 AND THE DOCTOR COMMENTED THAT THERE WAS NO MALFUNCTION OF THE UNIT. HOWEVER, AS PART OF THE INVESTIGATION, INTRALASE REVIEWED SERVICE RECORDS FOR THIS LASER. A PREVENTIVE MAINTENANCE SERVICE CALL WAS PERFORMED IN 05/2003. AS OF MAY 2003, THE SYSTEM WAS FUNCTIONING WITH SPECIFICATIONS. THE NEXT PREVENTIVE MAINTENANCE VISIT IS SCHEDULED FOR EARLY AUGUST. NO CALLS REQUESTING PRODUCT SERVICE AND NO COMPLAINTS REGARDING SYSTEM FUNCTIONALITY WERE REPORTED SINCE THE PREVENTIVE MAINTENANCE, I.E., DURING THE TIME PERIOD OF THIS MDR.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** b (6)
- **Phone:** b (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Jul-2002</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1): Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>16-Jul-2003</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>16-Jul-2003</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2032002-2003-00009</td>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Rec’d (G8):</td>
<td>15-Aug-2003</td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>16-Jul-2003</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>01-Feb-2002</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.

**Address:** 3 MORGAN

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):** REPLACE

**Correction/Removal No (H9):** 2032002-7/23/03-001C

**Additional Mfr Narrative (H10 & H11):**

21-AUG-2003: THE "HOME" BUTTON ON THE INTRALASE FS LASER WAS DISABLED ON 7/03, IN ACCORDANCE WITH THE FIELD CORRECTIVE ACTION. THIS ACTION WILL PREVENT THE DEVICE MALFUNCTION FROM REOCCURRING. THE DEVICE MET ALL SPECIFICATIONS.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N/A

<table>
<thead>
<tr>
<th>REPORTER INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Address:</td>
</tr>
</tbody>
</table>

Health Professional: Yes

<table>
<thead>
<tr>
<th>EMAIL:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
</tr>
</tbody>
</table>

International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 20-32002-2003-00011
Mfr Name: INTRA LASE CORP.

Event Date (B3): 01-Jan-2003
Report Date (B4): 01-Jan-2003
Report Date (F8): 12-Aug-2003
Date Mfr Rec'd (G4): 12-Aug-2003

Adverse Event (B1): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Problem (B1): N

Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Event Location (F12): REPORTER OCCUPATION (E3): 001 - PHYSICIAN
Report Source (G3): HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Feb-2003
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
EXCIMER LASER FOR VISION CORRECTION.

Mfr Name: INTRA LASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
16-SEP-2003: THE DEVICE WAS EVALUATED BY AN INTRALASE FIELD SERVICE ENGINEER, WHO RECALIBRATED THE LASER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:
- **Name:** *
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN
- **Health Professional:** Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2003-00012</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>02-Oct-2003</th>
</tr>
</thead>
</table>

**Event Date (B3):** 02-Jul-2003  
**Event Report Type:** INJURY  
**Adverse Event (B1):**  
**Problem (B1):** N  
**Event Location (F12):** HEALTH PROFESSIONAL  
**Report Source (G3):** HEALTH PROFESSIONAL  
**Device Operator:** HEALTH PROFESSIONAL

**Event Description (B5):**
Mfr 07-OCT-2003: SUBSEQUENT TO UNEVENTFUL LASIK SURGERY WITH THE INTRALASE FS LASER, THE PT'S VISUAL RECOVERY HAS BEEN DELAYED. PREOPERATIVELY, THE PT'S BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 IN BOTH EYES. AT THE 2-MONTH POSTOPERATIVE VISIT, THE PT'S BCVA WAS 20/50 OS WITH APPROXIMATELY 1 DIOPTER OF OVERCORRECTION. THERE HAVE BEEN NO SECONDARY SURGICAL INTERVENTIONS PERFORMED AT THIS TIME. VISION (BCVA) IN OD EYE WAS 20/25 AT THE 2 MONTH POSTOPERATIVE VISIT.

**Concomitant Medical Products:**
EXCIMER LASER FOR VISION CORRECTION.

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Health Professional:** Yes
- **Email:** *
- **Phone:** *
- **International:** *
- **Fax:** *
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received


Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) Device Operator: HEALTH PROFESSIONAL

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes


Event Description (B5):


Concomitant Medical Products:

B&I 217 EXCIMER LASER FOR VISION CORRECTION.

Mfr Name: INTRALASE CORP.

Address: 3 MORGAN

IRVINE, CA 92618

UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9): Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20002</td>
</tr>
<tr>
<td>Catalog</td>
<td>NA</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

### REPORTER INFORMATION:

Name: *  
Address: [redacted]  
Fax: [redacted]

Health Professional: Yes  
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 30-Jan-2004
Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8): 30-Jan-2004
Date Mfr Rec'd (G4): 30-Jan-2004
Mfr Name: INTRA LASE CORP.
Report Location (F12): Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Date Mfr Rec'd (G4): 26-Feb-2004
MFR Report No: 2032002-2004-00001
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Available for Evaluation: Y
Concomitant Medical Products:

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
04-JUN-2004: AN INTRALASE FIELD SERVICE ENGINEER EXAMINED THE LASER AND RePLACED THE JOYSTICK AND STEPPER CONTROLLER ASSEMBLY. AFTER REPLACING THESE COMPONENTS, THE LASER WAS WITHIN SPECIFICATION AND OPERATING AS INTENDED. AN IN-HOUSE EVALUATION WAS ALSO PERFORMED IN ORDER TO DETERMINE THE FAILURE MODE, WHICH WAS ABLE TO BE REPLICATED. THIS INVESTIGATION REVEALED THAT THE LIKELY CAUSE OF THE DEVICE MALFUNCTION WAS A LOOSE CONNECTION TO THE STEPPER CONTROLLER ASSEMBLY.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (6)
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** [b] (6)
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 01-Mar-2004 |
| Event Report Type: | INJURY |
| Event Date (B3): | 01-Mar-2004 |
| Event Outcome (B2): | REQUIRED INTERVENTION |
| Event Location (F12): | HEALTH PROFESSIONAL |
| Reporter Occupation (E3): | 001 - PHYSICIAN |
| Adverse Event (B1): | Y |
| Problem (B1): | N |
| MFR Report No: | 2032002-2004-00002 |
| Mfr Name: | INTRA LASE CORP. |
| Report Date (B4): | 22-Mar-2004 |
| Report Date (F8): | 22-Mar-2004 |
| Date Mfr Rec'd (G4): | 22-Mar-2004 |
| Mfr Name: | INTRALASE CORP |
| Address: | 3 MORGAN |
| IRVINE, CA 92618 |
| UNITED STATES |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |
| Device Age (F9): | |
| Expiration Date: | |
| Manufacture Date (H4): | 01-Aug-2002 |
| Device Operator: | HEALTH PROFESSIONAL |
| Corrected/Removed No (H9): | |
| Remedial Action (H7): | |
| Additional Mfr Narrative (H10 & H11): | 23-APR-2004: |

Mfr Name: INTRALASE CORP
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

Event Description (B5):
Mfr 23-APR-2004: SUBSEQUENT TO FLAP CREATION FOR LASIK SURGERY WITH THE INTRALASE FS LASER, THE PT'S CORNEAL FLAP WAS THINNER THAN ANTICIPATED. THE FLAP REQUIRED SECONDARY SURGICAL INTERVENTION TO SUTURE THE FLAP. NO RESULTING LOSS OF VISUAL ACUITY.

Concomitant Medical Products:
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received:** 2032002-2004-00003

**Mfr Name:** INTRA LASE CORP.

**Event Date (B3):** 14-Jan-2004

**Report Date (B4):** Omitted

**Report Date (F8):** 23-Mar-2004

**Date Mfr Rec'd (G4):** 23-Mar-2004

**Event Description (B5):**

Mfr 26-APR-2004: DURING THE FLAP CREATION FOR LASIK SURGERY WITH THE INTRALASE FS LASER, THE SIDE CUT WAS CREATED TWICE, RESULTING A SMALL TAG ON THE SIDEKUT. SECONDARY SURGICAL INTERVENTION WAS PERFORMED IN ORDER TO SMOOTH OUT A FOLD OF TISSUE IN THE INTERFACE. THE PT'S VISUAL ACUITY IN THE AFFECTED EYE IS CURRENTLY 20/20. IT IS UNKNOWN AS TO WHETHER OR NOT THE DEVICE MALFUNCTIONED.

**Concomitant Medical Products:**

B&L 217 EXCIMER LASER FOR VISION CORRECTION.

**Mfr Name:** INTRALASE CORP

**Address:** 3 MORGAN
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

26-APR-2004: IN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE IN 1/2004 AND FOUND NO FAILURES WERE DETECTED. THE LASER PERFORMED WITHIN SPECIFICATIONS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

  Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** *(blacked out)*
- **EMAIL:** *(blacked out)*
- **Phone:** *(blacked out)*
- **International:** *(blacked out)*
- **Fax:** *(blacked out)*
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| MFR Report No: | 2032002-2004-00004 | Mfr Name: | INTRA LASE CORP. | Report Date (B4): | Omitted |
| Event Date (B3): | 11-May-2004 | Event Report Type: | INJURY |
| Event Outcome (B2): | REQUIRED INTERVENTION |
| Reporter Occupation (E3): | 001 - PHYSICIAN | Event Location (F12): |
| Device Operator: | HEALTH PROFESSIONAL | Reporter Occupation (E3): |
| Date Mfr Rec'd (G4): | 11-May-2004 |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Availability (F9): | N |
| Expiration Date: | 01-Mar-2003 |
| Device Usage (H8): | R |
| Event Description (B5): | Mfr 09-JUN-2004: SUBSEQUENT TO UNEVENTFUL BILATERAL LASIK SURGERY WITH THE INTRALASE FS LASER, THE PT'S VISUAL RECOVERY HAS BEEN DELAYED. APPROXIMATELY SIX MONTHS POSTOPERATIVELY, SECONDARY SURGICAL INTERVENTION WAS PERFORMED IN ORDER TO LEFT AND RINSE THE FLAP AND SUTURE THE FLAP. |
| Concomitant Medical Products: |

| Mfr Name: | INTRALASE CORP. |
| Address: | 3 MORGAN |
| IRVINE, CA 92618 |
| UNITED STATES |
| Device Evaluable for Evaluation: | Y |
| Device Evaluable by Manufacturer (H3): | Yes |
| Remedial Action (H7): |
| Correction/Removal No (H9): |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:** 
- **Fax:** 

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2004-07-09

MFR Report No: 2032002-2004-00005
Mfr Name: INTRA LASE CORP.

Event Date (B3): 15-Apr-2004
Report Date (B4): 09-Jun-2004
Report Date (F8): 09-Jun-2004
Date Mfr Rec'd (G4): 09-Jun-2004

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): HEALTH PROFESSIONAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Single Use (H5): N
Expiration Date: Manufacture Date (H4): 01-Feb-2003
Device Usage (H8): R

Event Description (B5):
Mfr 09-JUL-2004: SUBSEQUENT TO UNEVENTFUL BILATERAL LASIK SURGERY WITH THE INTRALASE FS LASER, THE PT COMPLAINED OF SENSITIVITY TO FLUORESCENT LIGHTING. ALTHOUGH THERE WERE NO FINDINGS ON THE SLIT LAMP AND NO LOSS OF VISUAL ACUITY, AT APPROXIMATELY TWO WEEKS POSTOPERATIVELY SECONDARY SURGICAL INTERVENTION WAS PERFORMED IN ORDER TO LIFT AND RINSE THE FLAP. THE PATIENT HAS BEEN REFERRED TO A NEUROPHTHALMOLOGIST. THE PT IS CURRENTLY BEING TREATED WITH TOPICAL STERIODS AND RESTASIS.

Concomitant Medical Products:
1. EXCIMER LASER.

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 28-Jul-2004</th>
<th>Event Report Type: INJURY</th>
<th>Adverse Event (B1): Y</th>
<th>Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 08-Aug-2004</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 08-Aug-2004</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):** Manufacture Date (H4): 01-May-2004

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** R

**Event Description (B5):**


**Concomitant Medical Products:**

AUTOCLAVE STERILIZER.

**Mfr Name:** INTRA LASE CORP.

**Address:** 3 MORGAN

IRVINE, CA 92618

UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

31-AUG-2004: A DEVICE EVALUATION WAS NOT WARRANTED BECAUSE THE LASER WAS FUNCTIONING AS INTENDED. THE EVENT WAS BELIEVED TO BE CAUSED BY THE STERILIZER AND NOT THE INTRALASE LASER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
Event Date (B3): 01-Apr-2005
Adverse Event (B1): Y

Report Date (B4): 14-Apr-2005
Problem (B1): N

Report Date (F8): 14-Apr-2005
Event Report Type: INJURY

Date Mfr Rec’d (G4): 14-Apr-2005
Event Outcome (B2): REQUIRED INTERVENTION

Date Last Updated: 11/2/2010 9:17 AM

Mfr Name: INTRA LASE CORP.

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
25-APR-2005:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] [b]
Health Professional: Yes

EMAIL: [b] [b]
Phone: [b] [b]
International: 
Fax: 

Occupation: 001 - PHYSICIAN
Event Description (B5):
Mfr 06-MAY-2005: SUBSEQUENT TO LASIK SURGERY WITH THE INTRALASE FS LASER FOR CREATION OF THE CORNEAL FLAP, THE PATIENT REPORTED SEVERE SENSITIVITY TO LIGHT. THE PATIENT WAS TREATED WITH TOPICAL STEROIDS AND THEIR SYMPTOMS IMPROVED, HOWEVER, 18 MONTHS POSTOPERATIVELY THE PATIENT STILL COMPLAINS OF SENSITIVITY TO ARTIFICIAL LIGHT. THERE HAS BEEN NO LOSS OF VISUAL ACUITY RELATED TO THIS EVENT. IT SHOULD BE NOTED THAT THE PATIENT WAS NO-COMPLAINT WITH THE INITIAL POSTOPERATIVE MEDICATIONS.

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
06-MAY-2005: NO DEVICE MALFUNCTION WAS REPORTED, THEREFORE A DEVICE EVALUATION WAS NOT PERFORMED FOR THIS COMPLAINT. THE PREVENTIVE MAINTENANCE RECORDS WERE REVIEWED AND REVEALED THAT THE DEVICE WAS LAST SERVICED ON 2/05 AND THERE WERE NO UNUSUAL FINDINGS. THERE HAVE BEEN NO OTHER REPORTS OF LIGHT SENSITIVITY ASSOCIATED WITH THIS LASER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **Email:**
- **Phone:** (b)(6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**


Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 3 MORGAN
IRVINE, CA 92588
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
25-MAY-2005: H3: DEVICE EVAL NOT WARRANTED. NO DEVICE MALFUNCTION REPORTED. THE PREVENTIVE MAINTENANCE RECORDS WERE REVIEWED FOR THIS LASER AND SHOWED THAT PM VISITS WERE PERFORMED IN 11/03, 05/04, 08/04, AND 05/05. AT THE TIME OF EACH OF THE PMS, THE LASER WAS PERFORMING WITHIN SPECIFICATIONS.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTEER INFORMATION:

- **Name:** *
- **Address:** [انية (b) *
- **Health Professional:** Yes
- **EMAIL:** 
- **Phone:** [b] (b)
- **International:** 
- **Fax:** 
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
CDRH

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00007</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-May-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Jun-2005</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>01-Jun-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>01-Oct-2004</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>3 MORGAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes

- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:**

- **Occupation:** 001 - PHYSICIAN

Recd: 627

Page: 1,258

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00011</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>03-Aug-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>11-May-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-May-2005</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>06-Jul-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Event Description (B5):

Mfr 04-AUG-2005: SUBSEQUENT TO LASIK SURGERY WITH THE INTRALASC FS LASER FOR CREATION OF THE CORNEAL FLAP, EPITHELIAL INGROWTH WAS OBSERVED A FEW WEEKS POST-OP. SECONDARY SURGICAL INTERVENTION AS PERFORMED TO LIFT AND RINSE THE FLAP. THERE WAS NO NOTED LOSS OF BCVA COMPARED TO BASELINE. THE PT IS DOING WELL.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
04-AUG-2005: H3: NO DEVICE EVALUATION WARRANTED. NO LASER MALFUNCTION REPORTED.

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]

Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax:

Occupation: 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Mar-2005</th>
<th>Event Report Type:</th>
<th>INJURY</th>
<th>Adverse Event (B1):</th>
<th>Y</th>
<th>Problem (B1):</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>28-Jul-2005</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>28-Jul-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00012</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

**Mfr Name:** INTRALASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**

**Date Last Updated: 11/2/2010 9:17 AM**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** *
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2005-00013
Mfr Name: INTRA LASE CORP.
Date Mfr Rec'd (G4): 23-Aug-2005
Event Date (B3): 18-Apr-2003
Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Location (F12): Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEATH PROFESSIONAL
Event Description (B5):

Concomitant Medical Products:
Mfr Name: INTRALASE CORP
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [REDACTED]
- **Health Professional:** Yes

**EMAIL:** [REDACTED]
**Phone:** [REDACTED]
**International:** [REDACTED]
**Fax:** [REDACTED]

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**

**Concomitant Medical Products:**

**Mfr Name:** INTRA LASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
23-NOV-2005: CLINICAL INVESTIGATION PERFORMED BY OPHTHALMOLOGIST WHO INVESTIGATED THE SURGICAL & STERILIZATION TECHNIQUE AND PROVIDED RECOMMENDATIONS. DEVICE WAS EVALUATED IN 2005 WITH NO PROBLEMS FOUND AND OPERATING WITHIN SPECIFICATION.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] [b]

Health Professional: Yes

EMAIL:
Phone: [b] [b]
International:
Fax:

Occupation: 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**
**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00016</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>18-Nov-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-Oct-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Oct-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reporter Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>01-Jan-2001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: INTRA LASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Report Date (B4): | 22-Oct-2005 | Event Outcome (B2): | HOSPITALIZATION | Event Location (F12): |
| Report Date (F8): |            | Reporter Occupation (E3): | 001 - PHYSICIAN | |
| Date Mfr Rec'd (G4): | 22-Oct-2005 | Device Operator: | HEALTH PROFESSIONAL |
| MFR Report No: | 2032002-2005-00017 | Mfr Name: | INTRA LASE CORP. |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): |            | Manufacture Date (H4): | 01-Jan-2001 |
| Expiration Date: |            | Single Use (H5): | N |
| Device Usage (H8): | R |
| Concomitant Medical Products: | |
| Mfr Name: | INTRA LASE CORP. |
| Address: | 9701 JERONIMO ROAD |
| IRVINE, CA 92618 |
| UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE, FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00018</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-Oct-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>22-Oct-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jan-2001</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**

**Concomitant Medical Products:**

**Mfr Name:** INTRALASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
13-DEC-2005: A CLINICAL APPLICATIONS SPECIALIST WAS DISPATCHED AND RECOMMENDATIONS WERE MADE TO THE PHYSICIAN IN REGARD TO OPERATIONAL CONTEXT. PATIENTS THAT WERE TREATED SUBSEQUENTLY SHOWED NO SIGNS OF POST-OPERATIVE CLINICAL ISSUES, WITH EXCELLENT FLAP RESULTS AND VISUAL ACUITY.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20004
Catalog: 20004
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (b)

Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2005-00020</th>
<th>Mfr Name: INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 17-Nov-2005</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 21-Nov-2005</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
</tbody>
</table>


Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [black redacted]
- **Health Professional:** Yes
- **EMAIL:** [black redacted]
- **Phone:** [black redacted]
- **International:** [black redacted]
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00021</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>21-Dec-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Nov-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Concomitant Medical Products:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [redacted]
Health Professional: Yes

EMAIL:
Phone: [redacted]
International:
Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

2032002-2005-00022

Mfr Name: INTRA LASE CORP.

Event Date (B3): 25-Mar-2005
Report Date (B4): 17-Oct-2005
Report Date (F8): 
Date Mfr Rec'd (G4): 30-Nov-2005

Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Y
Problem (B1): N

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Event Description (B5):
Mfr 03-JAN-2006: ONE MONTH AFTER LASIK SURGERY THE PT WAS NOTED TO HAVE ELEVATED INTRACULAR PRESSURE. THE PATIENT'S BEST CORRECTED VISUAL ACUITY DECREASED FROM 20/15 PREOPERATIVELY TO 20/30 POSTOPERATIVELY. THE PT WAS TREATED WITH MEDICATIONS TO ADDRESS THE INCREASED IOP. ADDITIONAL INFO HAS BEEN REQUESTED. THE ASSOCIATION BETWEEN THIS EVENT AND THE LASER IS UNKNOWN AT THIS TIME.

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
03-JAN-2006: H.3.: THE DEVICE INVESTIGATION IS IN PROGRESS AND WILL BE PROVIDED IN A FOLLOW-UP REPORT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **Email:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2005-00023</th>
<th>Mfr Name: INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 23-Sep-2005</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (F8): N/A</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 30-Nov-2005</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 03-JAN-2006: H.3.: THE DEVICE INVESTIGATION IS IN PROGRESS AND WILL BE PROVIDED IN A FOLLOW-UP REPORT.</td>
<td></td>
</tr>
</tbody>
</table>

Mfr 03-JAN-2006: APPROXIMATELY ONE MONTH AFTER LASIK SURGERY THE PATIENT WAS NOTED TO HAVE ELEVATED INTRAOCULAR PRESSURE. THE PATIENT'S BEST CORRECTED VISUAL ACUITY DECREASED FROM 20/20 PREOPERATIVELY TO 20/40+3 POSTOPERATIVELY. AFTER TREATMENT WITH MEDICATIONS, THE PATIENT'S VISUAL ACUITY IMPROVED TO 20/25+. THE ASSOCIATION BETWEEN THIS EVENT AND THE LASER IS UNKNOWN AT THIS TIME.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INTRALASE FS LASER
- **Device Type**: LASER KERATOME
- **Device Type**: 20002
- **Catalog**: NA
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: *
- **Reprocessed & Reused**: N

REPORTER INFORMATION:

- **Name**: *
- **Address**: [b] [b] [b] [b]
- **Health Professional**: Yes
- **Occupation**: 001 - PHYSICIAN
- **EMAIL**: [b] [b] [b]
- **Phone**: [b] [b] [b]
- **International**: [b] [b] [b]
- **Fax**: [b] [b] [b]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 2032002-2005-00028
Mfr Name: INTRA LASE CORP.

Event Date (B3): 09-Dec-2005
Report Date (B4): 09-Dec-2005
Report Date (F8): 12-Dec-2005
Date Mfr Rec'd (G4): 12-Dec-2005

Event Report Type: INJURY
Event Outcome (B2): HOSPITALIZATION
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-May-2004
Expiration Date:

Device Usage (H8): R

Event Description (B5):
Mfr 10-JAN-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. THE PATIENT PRESENTED WITH BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK) POST-OPERATIVELY. BOTH FLAPS WERE LIFTED AND RINSED AND THE PATIENT'S MOST RECENT BCVA IS 20/20 IN BOTH EYES. THE PHYSICIAN REPORTS THE PATIENT'S PROGNOSIS IS GOOD.

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **International:**
- **Fax:**
- **EMAIL:**
- **Phone:** (b) (b)
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 09-Jan-2006
MFR Report No: 2032002-2005-00029
Mfr Name: INTRA LASE CORP.

Event Date (B3): 09-Dec-2005
Report Date (B4): 09-Dec-2005
Report Date (F8): 12-Dec-2005
Date Mfr Rec’d (G4): 12-Dec-2005

Event Report Type: INJURY
Event Outcome (B2): HOSPITALIZATION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-May-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

Date Last Updated: 11/2/2010 9:17 AM
Recd: 641
Page: 1,285
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:**
- **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2005-00030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
</tbody>
</table>

Event Date (B3): 09-Dec-2005
Report Date (B4): 09-Dec-2005
Event Report Type: INJURY
Event Report Type: INJURY
Event Outcome (B2): HOSPITALIZATION
Date Mfr Rec'd (G4): 12-Dec-2005
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Event Location (F12): HEALTH PROFESSIONAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-May-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Adverse Event (B1): Y
Problem (B1): N

Report Date (F8): 001 - PHYSICIAN
Event Outcome (B2): HOSPITALIZATION
Report Source (G3): HEALTH PROFESSIONAL

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reported & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN

Recd: 642  Page: 1,288  Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>13-May-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>17-Jan-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>07-Feb-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Feb-2006</td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-FEB-2006: INTRALASE WAS NOT MADE AWARE OF THIS EVENT UNTIL 2006 AT WHICH TIME THE LASER HAD BEEN DEINSTALLED. THE DEVICE THEREFORE UNAVAILABLE FOR EVALUATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20003</td>
</tr>
<tr>
<td>Catalog</td>
<td>20003</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

| Name           | *                                |
| Address        |                                   |
| Health Professional | Yes                           |
| EMAIL          |                                   |
| Phone          | (b) (b)                          |
| International  |                                   |
| Fax            |                                   |

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00003</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>23-Feb-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>15-Dec-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Jan-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>07-Feb-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr 28-FEB-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. THREE DAYS POSTOPERATIVELY THE PT PRESENTED WITH BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK). TOPICAL STERIOIDS WERE PRESCRIBED AND A FLAP LIFT AND RINSE WAS PERFORMED ON BOTH EYES AT THE 5-DAY POSTOP VISIT. THE PT RESPONDED TO TREATMENT AND THE DLK HAS RESOLVED IN BOTH EYES. THE PT'S MOST RECENT BCVAS WERE 20/25 (OD) AND 20/20 (OS); PREOP BCVA WAS 20/20 OU.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00004
Mfr Name: INTRA LASE CORP.
Report Date (B4): 24-Jan-2006
Report Date (F8): 01-Feb-2006
Date Mfr Rec'd (G4): 01-Feb-2006
MFR Report No: 2032002-2006-00004
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 27-FEB-2006: H3 - INTRALASE WAS NOT MADE AWARE OF THIS EVENT UNTIL JANUARY 24, 2006. THE PREVENTIVE MAINTENANCE (PM) RECORDS WERE REVIEWED FOR HIS LASER WHICH SHOWED THAT A PM WAS PERFORMED ON 11/14/05. THE FIELD SERVICE REPORTS (FSR) WAS REVIEWED FOR THIS LASER WHICH SHOWED THAT AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE AND PERFORMED A PM ON 1/27/06.

Event Description (B5):
Mfr 27-FEB-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. POSTOPERATIVELY THE PATIENT PRESENTED WITH BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK). A FLAP LIFT AND RINSE WAS PERFORMED ON BOTH EYES AT THE 2-DAY POSTOP VISIT. THE PATIENT RESPONDED TO TREATMENT AND THE DLK RESOLVED IN BOTH EYES. THE PATIENT'S CURRENT BCVA WAS NOT PROVIDED, HOWEVER THERE WAS NO REPORT OF A LOSS OF VISUAL ACUITY COMPARED TO PREOP.

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Date Last Updated: 11/2/2010 9:17 AM Recd: 645 Page: 1,293
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** 
- **Address:** 
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

EMAIL: 
Phone: 
International: 
Fax: 

Date Last Updated: 11/2/2010 9:17 AM
**Event Description (B5):**


**Concomitant Medical Products:**

- **Mfr Name:** INTRALASE CORP.
- **Address:** 9701 JERONIMO ROAD
  IRVINE, CA 92618
  UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>08-Mar-2006</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>08-Mar-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-Mar-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operational Age:</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Oct-2001</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

**Remedial Action (H7):**
Correction/Removal No (H9):

**Additional Mfr Narrative (H10 & H11):**
06-APR-2006: THE DEVICE INVESTIGATION IS IN PROGRESS AND WILL BE PROVIDED IN A FOLLOW-UP REPORT.
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

Health Professional: Yes
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2006-01-24

MFR Report No: 2032002-2006-00007
Mfr Name: INTRA LASE CORP.

Event Date (B3): 18-Jan-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Sep-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 28-FEB-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. POSTOPERATIVELY THE PT PRESENTED WITH DIFFUSE LAMELLAR KERATITIS (DLK) IN THE LEFT EYE. THE FLAP WAS LIFTED AND RINSED AT THE 2-DAY VISIT.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): Yes
Additional Mfr Narrative (H10 & H11):
28-FEB-2006: THE PREVENTIVE MAINTENANCE (PM) RECORDS WERE REVIEWED FOR THIS LASER, WHICH SHOWED THAT A PM WAS PERFORMED ON 11/14/05. THE FIELD SERVICE REPORTS (FSR) WERE REVIEWED FOR THIS LASER WHICH SHOWED THAT AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE AND PERFORMED A PM ON 1/27/06. SURGERY SUPPORT WAS PROVIDED BY AN INTRALASE CLINICAL APPLICATION SPECIALIST ON 1/31/06. PMA K031960.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]

Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 24-Jan-2006</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Event Location (F12): Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 24-Jan-2006</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 01-Feb-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Date (F8): 001 - PHYSICIAN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Report Source (G3): HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: INTRALASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax:

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00009</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 28-Jan-2006  
**Report Date (B4):** Omitted  
**Report Date (F8):** 00000000  
**Date Mfr Rec'd (G4):** 01-Feb-2006  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Adverse Event (B1):** Y  
**Problem (B1):** N  
**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:**  
**Manufacture Date (H4):** 01-Sep-2004  
**Single Use (H5):** N  
**Device Usage (H8):** R  

**Event Description (B5):**  

**Concomitant Medical Products:**  
- **Mfr Name:** INTRALASE CORP.  
- **Address:** 9701 JERONIMO ROAD  
  IRVINE, CA 92618  
  UNITED STATES  

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00010
Mfr Name: INTRA LASE CORP.

Event Date (B3): 19-Jan-2006
Report Date (B4): 24-Jan-2006
Report Date (F8): 01-Feb-2006
Date Mfr Rec'd (G4): 01-Feb-2006
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacturer Date (H4): 01-Sep-2004
Expiration Date:
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2006-00011  Mfr Name: INTRA LASE CORP.

Event Date (B3): 27-Jan-2006  Event Report Type: INJURY
Report Date (B4): 31-Jan-2006  Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 01-Feb-2006  Reporter Occupation (E3): 001 - PHYSICIAN
Date Mfr Rec'd (G4): 01-Feb-2006  Device Operator: HEALTH PROFESSIONAL

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

**Brand:** INTRALASE FS LASER  
**Device Type:** LASER KERATOME  
**Device Type:** 20003  
**Catalog:** 20003  
**Serial:** (*confidential*)  
**Lot:** NA  
**Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

**Name:** *  
**Address:** [redacted]  
**Health Professional:** Yes  
**Occupation:** 001 - PHYSICIAN

**EMAIL:** [redacted]  
**Phone:** [redacted]  
**International:** 
**Fax:** 

Recd: 652  
Page: 1,308  
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 29-Nov-2005 | Event Report Type: | INJURY | Adverse Event (B1): | Y |
| Report Date (B4): | 30-Nov-2005 | Event Outcome (B2): | HOSPITALIZATION |
| Report Date (F8): | | Reporter Occupation (E3): | 001 - PHYSICIAN |
| Date Mfr Rec'd (G4): | 15-Feb-2006 | Device Operator: | HEALTH PROFESSIONAL |

**Event Description (B5):**

**Concomitant Medical Products:**

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
14-MAR-2006:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00014
Mfr Name: INTRA LASE CORP.

Event Date (B3): 28-Jan-2006
Event Report Type: INJURY
Adverse Event (B1): Y
Problem (B1): N

Report Date (B4): 13-Feb-2006
Event Outcome (B2): REQUIRED INTERVENTION

Report Date (F8): 23-Feb-2006
Reporter Occupation (E3): 001 - PHYSICIAN

Date Mfr Rec'd (G4): 13-Feb-2006
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Sep-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-FEB-2006: INTRALASE WAS NOT MADE AWARE OF THIS EVENT UNTIL 2006. THE PREVENTIVE MAINTENANCE (PM) RECORDS WERE REVIEWED FOR THIS LASER, WHICH SHOWED THAT PM WAS PERFORMED ON 11/14/05. AT THE TIME THE LASER PERFORMED WITHIN SPECIFICATIONS. THE FIELD SERVICE REPORTS (FSR) WAS REVIEWED FOR THIS LASER WHICH SHOWED THAT AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE AND PERFORMED A PM ON 1/27/06.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:** [Redacted]
**Fax:** [Redacted]

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2006-02-15

Mfr Name: INTRA LASE CORP.
Event Date (B3): 2006-02-15
Report Date (B4): 2006-02-28
Report Date (F8): 2006-02-28
Date Mfr Rec'd (G4): 2006-02-28
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Sep-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

15-MAR-2006: H3: TO ADDRESS A SIMILAR REPORTED EVENT AN INTRALASE CLINICAL APPLICATION SPECIALIST EVALUATED THE FACILITY'S CLEANING TECHNIQUE AND PROVIDED CLEANING RECOMMENDATIONS. WHILE PERFORMING FOLLOW-UP ON THE CLEANING RECOMMENDATIONS THE CLINICAL APPLICATIONS SPECIALIST WAS INFORMED OF THIS EVENT. AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE AND PERFORMED A PM IN 1/2006. AT THAT TIME THE LASER PERFORMED WITHIN SPECIFICATIONS. THE CLINICAL SERVICE REPORT SUBMITTED BY THE CLINICAL APPLICATION SPECIALIST INDICATES THERE WERE NO PROBLEMS FOUND WITH THE LASER OR THE SETTINGS. THE FACILITY REPORTED THAT THE CLEANING RECOMMENDATIONS WERE EFFECTIVE AS THERE HAVE BEEN NO ADDITIONAL CASES OF DLK. THIS INDICATES THEIR CLEANING PROCEDURE MAY HAVE BEEN A CONTRIBUTING FACTOR TO THIS EVENT. 510(K)# K031960.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received**: 14-Feb-2006

**Mfr Name**: INTRA LASE CORP.

**Event Date (B3)**: 14-Feb-2006

**Report Date (B4)**: 22-Feb-2006

**Date Mfr Rec'd (G4)**: 22-Feb-2006

**Device Operator**: HEALTH PROFESSIONAL

**Device Available for Evaluation**: Y

**Device Evaluated by Manufacturer (H3)**: Yes

**Remedial Action (H7)**:

**Concomitant Medical Products**:

Mfr 15-MAR-2006: THE INTRALASA FS LAYER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. POSTOPERATIVELY THE PATIENT PRESENTED WITH BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK). A FLAP LIFT AND RINSE WAS PERFORMED POSTOPERATIVELY. THE PATIENT RESPONDED TO TREATMENT AND THE DLK HAS RESOLVED. THE PATIENT'S MOST RECENT POSTOP BCVA IS 20/20. IT WAS CONVEYED TO INTRALASE THE FACILITY WAS USING BALANCED SALT SOLUTIONS (BSS) WHICH WAS RECENTLY RECALLED BY THE FDA DUE TO HIGH LEVELS OF ENDOTOXINS. THIS MAY HAVE BEEN CONTRIBUTING FACTOR IN THIS DLK INCIDENT.

**Product Code**: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9)**: NULL

**Expiration Date**: NULL

**Manufacture Date (H4)**: 01-May-2005

**Single Use (H5)**: N

**Device Usage (H8)**: R

**Event Description (B5)**:

**Adverse Event (B1)**: Y

**Problem (B1)**: N

**Event Report Type**: INJURY

**Event Outcome (B2)**: REQUIRED INTERVENTION

**Reporter Occupation (E3)**: 001 - PHYSICIAN

**Event Location (F12)**: REPORTER OCCUPATION

**Report Source (G3)**: HEALTH PROFESSIONAL

**Report Date (F8)**: 001 - PHYSICIAN

**Report Date (B4)**: 22-Feb-2006

**Device Evaluated by Manufacturer (H3)**: Yes

**Correction/Removal No (H9)**:

Recd: 656

Page: 1,315
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
15-MAR-2006: H3: THE FIELD SERVICE REPORTS WERE REVIEWED FOR THIS LASER WHICH SHOWED THAT AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE ON 02/13/2006 AND PROVIDED SURGERY SUPPORT. THE INVESTIGATION REVEALED THE LASER REQUIRED ALIGNMENT, COMPONENT REPLACEMENT, AND ADJUSTMENT. AT THIS TIME IT IS UNKNOWN IF THESE ISSUES CONTRIBUTED TO THE EVENT. UPON COMPLETION OF EVALUATION THE LASER MET SPECIFICATIONS. INTRALASE WAS INFORMED BY THE FACILITY THEY HAVE BEEN USING BALANCED SALT SOLUTIONS (BSS) WHICH HAS RECENTLY RECALLED BY THE FDA. THIS MAY HAVE BEEN A CONTRIBUTING FACTOR.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:
- **Name:** *
- **Address:** *(b) (6)*
- **Health Professional:** Yes
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:** *
- **Fax:** *
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>15-Mar-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>17-Mar-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Mar-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Mar-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>HOSPITALIZATION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>01-Sep-2004</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 12-APR-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. AT ONE DAY POSTOP THE PT PRESENTED WITH BILATERAL DIFFUSE LAMEILAR KERATITIS (DLK) AND A FLAP LIFT AND RINSE WAS PERFORMED ON THE RIGHT EYE. THE PT RESPONDED TO TREATMENT AND THE DLK RESOLVED IN BOTH EYES. THE PTS PRE-OP BCVA WAS 20/20 OU. THE PT'S CURRENT BCVA WAS NOT PROVIDED, HOWEVER THE PT'S POSTOPERATIVE UCVA IS 20/30 OU.

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-APR-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:** [Redacted]
**Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2032002-2006-00025</td>
<td>21-Feb-2006</td>
<td>INJURY</td>
<td>Y</td>
<td>INTRA LASE CORP.</td>
<td>REQUIRED INTERVENTION</td>
<td>001 - PHYSICIAN</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

Date Mfr Rec'd (G4): 29-Mar-2006

Device Operator: HEALTH PROFESSIONAL

Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Event Description (B5):

Mfr 02-MAY-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK) NOTED AT ONE DAY POST-OP AND TREATED WITH TOPICAL AND ORAL STEROIDS. AT THE FIVE DAY POST-OP A FLAP LIFT AND RINSE WAS PERFORMED. THE PT RESPONDED TO TREATMENT AND THE DLK HAS RESOLVED ON BOTH EYES. THE PT'S PRE-OP BCVA WAS 20/20 OU AND THE PT'S CURRNT BCVA IS 20/25 OU. THE FACILITY INFORMED INTRALASE THAT DURING THIS PT'S SURGERY, THEY HAD USED THE RECENTLY RECALLED BALANCED SALT SOLUTION (BSS), WHICH HAD BEEN RECALLED BY THE FDA DUE TO HIGH LEVELS OF ENDOTOXINS. THIS MAY HAVE BEEN A CONTRIBUTING FACTOR IN THIS DLK INCIDENT.

Concomitant Medical Products:

BSS - AKORN, DISTRIBUTOR.

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Recd: 658

Page: 1,319

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
02-MAY-2006: IN 4/06, INTRALASE'S DIR OF SURGICAL SUPPORT (OPTOMETRIST) AND MGR OF MEDICAL SURGICAL SUPPORT, (MD, OPHTALMOLOGIST) VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. THE SYSTEM WAS FOUND TO BE WITHIN SPECIFICATIONS. THE STERILIZATION AND SURGICAL TECHNIQUE WAS REVIEWED AND THE DR WAS INSTRUCTED ON HIS SURGICAL TECHNIQUE. DURING THE INVESTIGATION, THE CUSTOMER INFORMED INTRALASE THEY HAVE BEEN USING BALANCED SALT SOLUTION (BSS) WHICH WAS RECENTLY RECALLED DUE TO HIGH LEVELS OF ENDOTOXINS. THIS MAY HAVE BEEN A CONTRIBUTING FACTOR TO THE DLK. 510(K)# K031960.

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **Occupation:** 001 - PHYSICIAN
- **Fax:**
- **International:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00026</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Mar-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>29-Mar-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>29-Mar-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr 02-MAY-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. AT THE FOUR DAY POST-OP THE PT PRESENTED WITH DIFFUSE LAMELLAR KERATITIS (DLK) OS. A FLAP LIFT AND RINSE WAS PERFORMED AND PT WAS TREATED WITH TOPICAL AND ORAL STERIODS. THE PT HAS RESPONDED TO TREATMENT AND THE DLK HAS RESOLVED WITH NO LOSS OF VISUAL ACUITY. THE PT'S PRE-OP BCVA WAS 20/20 OS. THE PT'S CURRENT BCVA IS 20/20 OS. THE FACILITY INFORMED INTRALASE THAT DURING THIS PT'S SURGERY, THEY HAD USED THE RECENTLY RECALLED BALANCED SALT SOLUTION (BSS), WHICH HAD BEEN RECALLED BY THE FDA DUE TO HIGH LEVELS OF ENDOotoXINS. THIS MAY HAVE BEEN A CONTRIBUTING FACTOR IN THIS DLK INCIDENT.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>BSS - AKORN, DISTRIBUTOR.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
02-MAY-2006: IN 4/06, INTRALASE'S DIR OF SURGICAL SUPPORT (OPTOMETRIST) AND MFG OF MEDICAL SURGICAL SUPPORT (MD, OPHTALMOLOGIST) VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. THE SYSTEM WAS FOUND TO BE WITHIN SPECIFICATIONS. THE STERILIZATION AND SURGICAL TECHNIQUE WAS REVIEWED AND THE DR WAS INSTRUCTED ON HIS SURGICAL TECHNIQUE. DURING THE INVESTIGATION, THE CUSTOMER INFORMED INTRALASE THEY HAVE BEEN USING BALANCED SALT SOLUTION (BSS) WHICH WAS RECENTLY RECALLED DUE TO HIGH LEVELS OF ENDOTOXINS. THIS MAY HAVE BEEN A CONTRIBUTING FACTOR TO THE DLK. 510(K)# K031960.

DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20004
- Catalog: 20004
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (6)

Email: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2006-00027  Mfr Name: INTRA LASE CORP.

Date Received: 07-Apr-2006
Event Report Type: INJURY
Adverse Event (B1): Y  Problem (B1): N
Report Date (B4): 07-Apr-2006
Event Outcome (B2): REQUIRED INTERVENTION
Event Location (F12): HEALTH PROFESSIONAL
Date Mfr Rec'd (G4): 07-Apr-2006
Report Source (G3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 08-MAY-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. AT THE ONE DAY POST-OP THE PT PRESENTED WITH TRACE BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK) WHICH WAS TREATED WITH TOPICAL STEROIDS AND THE DR PERFORMED A FLAP LIFT AND RINSE PROACTIVELY AS HE WAS GOING TO BE OUT OF THE OFFICE. THE PT RESPONDED TO TREATMENT AND THE DLK RESOLVED IN BOTH EYES. THE PT'S PRE-OP BCVA WAS 20/20 OD AND 20/40 OS. THE PT'S CURRENT BCVA IS 20/60 AND 20/70 OS. THE PT WAS REFERRED BACK TO HER CO-MANAGING OPTOMETRIST.

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
08-MAY-2006: ON 4/7/06, INTRALASE'S DIR OF SURGICAL SUPPORT (OPTOMETRIST) AND MGR OF MEDICAL SURGICAL SUPPORT (MD, OPHTHALMOLOGIST) VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. THE SYSTEM WAS FOUND TO BE WITHIN SPECIFICATIONS. THE STERILIZATION AND SURGICAL TECHNIQUE WAS REVIEWED AND THE DR WAS INSTRUCTED ON HIS SURGICAL TECHNIQUE. 510 (K) # K031960.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** Yes
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): 26-Dec-2005 | Event Report Type: INJURY | Adverse Event (B1): Y Problem (B1): N |
| Report Date (B4): 21-Mar-2006 | Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) | |
| Report Date (F8): | Reporter Occupation (E3): 001 - PHYSICIAN | Event Location (F12): |
| Date Mfr Rec'd (G4): 06-Apr-2006 | Device Operator: HEALTH PROFESSIONAL | Report Source (G3): HEALTH PROFESSIONAL |

**Event Description (B5):**

Mfr 24-APR-2006: AN INTRALASE EMPLOYEE WAS INFORMED IN 3/06 OF A PATIENT REPORTING IRITIS OU. DURING INVESTIGATION OF THIS REPORT, IT WAS DETERMINED THAT THE PATIENT HAS DECLINED TO PROVIDE CONSENT TO SHARE PATIENT INFORMATION WITH INTRALASE. IN 4/06, THE PATIENT CONTACTED INTRALASE DIRECTLY AND REPORTED THAT SHE DEVELOPED UVEITIS (OU) APPROXIMATELY ONE WEEK AFTER HER 12/19/05 LASIK SURGERY AND REPORTED THE IRIS IN HER OS EYE IS SLOUGHED. PATIENT WAS UNWILLING TO PROVIDE INTRALASE WITH ANY ADDITIONAL INFORMATION.

**Concomitant Medical Products:**

- **Mfr Name:** INTRALASE CORP.
- **Address:** 9701 JERONIMO ROAD
  IRVINE, CA 92618
  UNITED STATES

- **Device Available for Evaluation:** Y
- **Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
Correction/Removal No (H9):

**Additional Mfr Narrative (H10 & H11):**
24-APR-2006: 510(K)# K031960.
CDRH
CDRH
CDRH
MAUDE EVENT REPORT (FOI)
MAUDE EVENT REPORT (FOI)
MAUDE EVENT REPORT (FOI)
SORTED BY
SORTED BY
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

DEVICE INFORMATION:

   Brand: INTRALASE FS LASER
   Device Type: LASER KERATOME
       Device Type: 20002
       Catalog: 20002
       Serial: (*confidential*)
       Lot: NA
       Other ID: *

   Reprocessed & Reused: N

REPORTER INFORMATION:

   Name: [REDACTED]
   Address: [REDACTED]
       EMAIL: [REDACTED]
       Phone: [REDACTED]
       International: [REDACTED]
       Fax: [REDACTED]

       Health Professional: Yes

       Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 31-Mar-2006

MFR Report No: 2032002-2006-00029

Mfr Name: INTRA LASE CORP.

Event Date (B3): 31-Mar-2006

Event Report Type: INJURY

Event Outcome (B2): REQUIRED INTERVENTION

Adverse Event (B1): Y

Problem (B1): N

Event Location (F12): REPORTER OCCUPATION

Report Source (G3): HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): 01-Jan-2006

Expiration Date: Single Use (H5): N

Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.

Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:**
- **Fax:**
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

Date: 02-Jun-2006

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00030</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>03-May-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>03-May-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>08-May-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-May-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 07-JUN-2006: THE INTRALASE FS LASER USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY. AT THE TWELFTH DAY POST-OP THE PATIENT PRESENTED WITH BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK) WHICH WAS TREATED WITH TOPICAL STEROIDS AND A FLAP LIFT AND RINSE WAS PERFORMED. THE PATIENT RESPONDED TO TREATMENT AND THE DLK RESOLVED IN BOTH EYES WITH NO LOSS OF VISUAL ACUITY.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (b) [b] [b] [b] [b] [b]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00031</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>09-Jun-2006</th>
</tr>
</thead>
</table>

**Event Date (B3):** 05-May-2006

**Report Date (B4):** 11-May-2006

**Report Date (F8):** 11-May-2006

**Date Mfr Rec'd (G4):** 11-May-2006

**Event Report Type:** INJURY

**Event Outcome (B2):** REQUIRED INTERVENTION

**Supplier Occupation (E3):** 001 - PHYSICIAN

**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.

**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [REDACTED]

Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00032</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>03-Jun-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Jun-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>06-Jun-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td>Date Mfr Rec’d (G4):</td>
<td>09-Jun-2006</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [censored]
- **Email:** [censored]
- **Phone:** [censored]
- **International:** [censored]
- **Fax:** [censored]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010  9:17 AM
Recd: 665  Page: 1,334  Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00033</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-May-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>16-May-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>16-May-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-May-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-2005</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
</tbody>
</table>

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

16-JUN-2006: H3-AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 06/14/06 AND DETERMINED THAT THE LASER MET SPECIFICATION AND PERFORMED AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20004
Catalog: 20004
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: *(b)(b)*
Health Professional: Yes

EMAIL: *(b)(b)*
Phone: *(b)(b)*
International:
Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2002-2006-00034

Mfr Name: INTRA LASE CORP.

Event Date (B3): 01-May-2006
Report Date (B4): 16-May-2006
Report Date (F8): 16-May-2006
Date Mfr Rec’d (G4): 16-May-2006
Product Code: (OP)-LASER, OPHTHALMIC (HQF)

Device Operator: HEALTH PROFESSIONAL

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12): Reporter Occupation (E3): HEALTH PROFESSIONAL
Report Source (G3): HEALTH PROFESSIONAL

Device Age (F9): Manufacture Date (H4): 01-Aug-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-JUN-2006: H3-AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER IN 06/06 AND DETERMINED THE LASER MET SPECIFICATION AND PERFORMED AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2006-00035</th>
<th>Mfr Name: INTRA LASE CORP.</th>
<th>Date Received: 05-Jun-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 10-May-2006</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4): 12-May-2006</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (F8): 12-May-2006</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 12-May-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Apr-2003</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 07-JUN-2006: IN 05/2006, INTRALASE'S CLINICAL APPLICATION SPECIALIST VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. SURGICAL SETTINGS WERE OPTIMIZED TO DR'S PREFERENCE AND THE SYSTEM WAS FOUND TO BE WITHIN SPECIFICATIONS. PTS THAT WERE TREATED SUBSEQUENTLY SHOWED NO SIGNS OF POST-OPERATIVE CLINICAL ISSUES.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME 20002
- Catalog: 20002
- Serial: (*confidential*)
- Lot: NA
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: [REDACTED]
- Address: [REDACTED]
- Health Professional: Yes
- EMAIL: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]
- Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010
Date Last Updated: 11/2/2010 9:17 AM

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00036</th>
<th>Mfr Name: INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-May-2006</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-May-2006</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>12-May-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4): 01-Jan-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
09-JUN-2006: H3: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST EVALUATED THE DEVICE ON 5/18/06 AT WHICH TIME THE LASER MET SPECIFICATION AND PERFORMED AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:
- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
15-JUN-2006: H3 - AN INTRALASE CLINICAL APPLICATIONS SPECIALIST EVALUATED THE DEVICE ON 5/12/06 AT WHICH TIME THE LASER MET SPECS AND PERFORMED AS INTENDED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INTRALASE FS LASER
- **Device Type**: LASER KERATOME
- **Device Type**: 20002
- **Catalog**: 20002
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: [REDACTED]

- **Reprocessed & Reused**: N

REPORTER INFORMATION:

- **Name**: [REDACTED]
- **Address**: [REDACTED]
- **Health Professional**: Yes
- **Occupation**: 001 - PHYSICIAN
- **EMAIL**: [REDACTED]
- **Phone**: [REDACTED]
- **International**: [REDACTED]
- **Fax**: [REDACTED]
MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received**

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00038</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>10-Oct-2005</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>05-Jun-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>05-Jun-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Mfr Name: INTRALASE CORP.</td>
<td></td>
</tr>
<tr>
<td>Address: 9701 JERONIMO ROAD</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 05-JUL-2006: THE DEVICE WAS EVALUATED ON 10/12/05 BY AN INTRALASE FIELD SERVICE ENGINEER. THE LASER WAS SERVICED AND UPON DEPARTURE THE LASER MET SPECIFICATION AND WAS PERFORMING AS INTENDED.</td>
<td></td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010  9:17 AM

Recd: 671  Page: 1,345
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Health Professional:** Yes
- **EMAIL:** *
- **Phone:** *
- **International:** *
- **Fax:** *
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

Date: 02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 25-Jul-2006

MFR Report No: 2032002-2006-00039  Mfr Name: INTRA LASE CORP.

Event Date (B3): 09-Jan-2004  Event Report Type: INJURY  Adverse Event (B1): Y  Problem (B1): N

Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  Reporter Occupation (E3): 600 - ATTORNEY  Event Location (F12):  

Report Date (B4): 26-Jun-2006  Event Report Type: INJURY  Reporter Occupation (E3): 600 - ATTORNEY  Event Location (F12):  


Device Operator: HEALTH PROFESSIONAL  Device Agent: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Expiration Date: Single Use (H5): N  Device Usage (H8): R

Manufacture Date (H4): 01-Oct-2003  Device Age (F9):  

Concomitant Medical Products:
NA

Device Available for Evaluation: Y  Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):  

Correction/Removal No (H9):  

Additional Mfr Narrative (H10 & H11):

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
          IRVINE, CA 92618
          UNITED STATES

Date Last Updated: 11/2/2010  9:17 AM
Recd: 672  Page: 1,347
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20002
- Catalog: 20002
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]

Health Professional: No

Occupation: 600 - ATTORNEY
The Intralase FS laser has been used to create a corneal flap for LASIK surgery. At three days postoperatively, the patient presented with diffuse lamellar keratitis (DLK) in the left eye. The patient was prescribed topical steroids and the physician performed a flap lift and rinse. The patient's one week postoperative BCVA is 20/20 OU and preoperative was 20/20 OU. The patient has responded to treatment and DLK has resolved. The association between the event and the device is unknown.

Concomitant Medical Products:

NA

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
28-JUL-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST AND FIELD SERVICE ENGINEER EVALUATED THE DEVICE ON 06/23/06 AT WHICH TIME THE LASER MET SPECIFICATIONS AND PERFORMED AS INTENDED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] [b]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [b] [b]
- **Phone:** [b] [b]
- **International:**
- **Fax:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00041</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>19-Jul-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jun-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.

**Address:**

9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

28-JUL-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST AND FIELD SERVICE ENGINEER EVALUATED THE DEVICE ON 06/23/06 AT WHICH TIME THE LASER MET SPECIFICATIONS AND PERFORMED AS INTENDED.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: INTRALASE FS LASER
- **Device Type**: LASER KERATOME
- **Device Type**: 20003
- **Catalog**: 20003
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: *

Reprocessed & Reused: N

REPORTEER INFORMATION:

- **Name**: *
- **Address**: [Redacted]
- **EMAIL**: [Redacted]
- **Phone**: [Redacted]
- **International**: [Redacted]
- **Fax**: [Redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Jun-2006</th>
<th>Event Report Type:</th>
<th>INJURY</th>
<th>Adverse Event (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr rec'd (G4):</td>
<td>23-Jun-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2032002-2006-00042</td>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>23-Jun-2006</td>
<td>Date Rec'd (F8):</td>
<td>18-Jul-2006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**
**Manufacture Date (H4):** 01-Jul-2005

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** R

**Event Description (B5):**


**Concomitant Medical Products:** NA

**Mfr Name:** INTRALASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

20-JUL-2006: H3 - ON 07/14/2006, INTRALASE'S DIRECTOR OF SURGICAL SUPPORT (OPTOMETRIST) AND INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. THE SYSTEM WAS FOUND TO BE WITHIN SPECIFICATIONS. THE STERILIZATION AND SURGICAL TECHNIQUE WAS REVIEWED AND THE DOCTOR WAS INSTRUCTED ON HIS STERILIZATION TECHNIQUE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [hidden]
- **Email:** [hidden]
- **Phone:** [hidden]
- **International:** [hidden]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2006-00043</th>
<th>Mfr Name: INTRA LASE CORP.</th>
<th>Date Received: 14-Jul-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 03-Jun-2006</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 16-Jun-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Apr-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
18-JUL-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST AND A FIELD SERVICE ENGINEER EVALUATED THE DEVICE ON 06/16/06 AND 06/23/06 AT WHICH TIME THE LASER WAS OPTIMIZED TO DOCTORS PREFERENCE, MET SPECIFICATIONS AND PERFORMED AS INTENDED.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2006-06-20

MFR Report No: 2032002-2006-00044
Mfr Name: INTRA LASE CORP.

Event Date (B3): 04-May-2006
Report Date (B4): 22-Jun-2006
Report Date (F8):
Date Mfr Rec'd (G4): 22-Jun-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION

Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12):
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
28-JUL-2006: SURGERY SUPPORT WAS PROVIDED BY AN INTRALASE CLINICAL APPLICATIONS SPECIALIST IN 2006 AND THE LASER WAS WORKING CLINICALLY WITHIN SPECIFICATIONS. AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE DEVICE ON 6/14/06 AND THE LASER MET ALL SPECIFICATIONS.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Repurposed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**EMAIL:**

**Phone:** [b] (b)

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Mfr Name:** INTRALASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
14-AUG-2006: IN 2006, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. THE SYSTEM WAS FOUND TO BE WITHIN SPECIFICATIONS. THE STERILIZATION AND SURGICAL TECHNIQUE WAS REVIEWED AND THE DOCTOR WAS INSTRUCTED ON HIS STERILIZATION TECHNIQUE.
Device Information:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

Reporter Information:

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:**
**Fax:**

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Date Received</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2032002-2006-00046</td>
<td>18-Aug-2006</td>
<td>Event Date (B3):</td>
<td>20-Jul-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td></td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>01-Sep-2003</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products: NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
22-AUG-2006: IN 2006, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) WAS PRESENT DURING SURGERY. THE SURGICAL SETTINGS WERE OPTIMIZED AND THE PHYSICIAN WAS INSTRUCTED TO INCREASE THE FLAP THICKNESS. 07/24/06 AN INTRALASE FIELD SERVICE ENGINEER WAS ON SITE TO EVALUATE THE DEVICE. THE DEPTH WAS CALIBRATED AND THE SURGICAL SETTINGS WERE ADJUSTED AND THE DEVICE MET SPECIFICATIONS.

Date Last Updated: 11/2/2010 9:17 AM

Recd: 679 Page: 1,361
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 001 - PHYSICIAN
<table>
<thead>
<tr>
<th>Mfr Report No: 203202-2006-00047</th>
<th>Mfr Name: INTRA LASE CORP.</th>
<th>Date Mfr Rec'd (G4): Ommitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 20-Jul-2006</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4) Ommitted</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code: (OP)-LASER, OPHTHALMIC (HQF)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Sep-2003</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
22-AUG-2006: IN 2006, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) WAS PRESENT DURING SURGERY. THE SURGICAL SETTINGS WERE OPTIMIZED AND THE PHYSICIAN WAS INSTRUCTED TO INCREASE THE FLAP THICKNESS. ON 7/24/06 AND INTRALASE FIELD SERVICE ENGINEER WAS ON SITE TO EVALUATE THE DEVICE. THE DEPTH WAS CALIBRATED AND SURGICAL SETTINGS WERE ADJUSTED AND THE DEVICE MET SPECIFICATIONS.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00048</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Jul-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Aug-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>01-Aug-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jun-2002</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2006-00049  Mfr Name: INTRA LASE CORP.

| Event Date (B3): 04-Aug-2006 | Event Report Type: INJURY | Adverse Event (B1): Y |
| Report Date (B4): 04-Aug-2006 | Event Outcome (B2): REQUIRED INTERVENTION | Problem (B1): N |
| Date Mfr Rec'd (G4): 04-Aug-2006 | Reporter Occupation (E3): 001 - PHYSICIAN | Event Location (F12): |
| | Device Operator: HEALTH PROFESSIONAL | Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE |

Event Description (B5):

Concomitant Medical Products: NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
25-AUG-2006: ON 8/2/2006, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED PREVENTATIVE MAINTENANCE. THE LASER MET SPECIFICATION AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PERFORMED AN INVESTIGATION INTO SURGICAL TECHNIQUES AND STERILIZATION TECHNIQUES. RECOMMENDATIONS WERE MADE TO THE DOCTOR FOR SURGICAL TECHNIQUES.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20004
Catalog: 20004
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: (b) (6)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 2032002-2006-00050
Mfr Name: INTRA LASE CORP.

Event Date (B3): 04-Aug-2006
Report Date (B4): 04-Aug-2006
Report Date (F8): 04-Aug-2006
Date Mfr Rec'd (G4): 04-Aug-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Event Location (F12):

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12):

Device Operator: HEALTH PROFESSIONAL
Reporter Occupation (E3): 001 - PHYSICIAN

Report Date (F8): 001 - PHYSICIAN
Event Outcome (B2): REQUIRED INTERVENTION

Report Source (G3): HEALTH PROFESSIONAL
Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)

Manufacture Date (H4): 01-Jul-2005
Device Age (F9): Manufacture Date (H4): 01-Jul-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 2004
- **Catalog:** 2004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessor & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** *(b) (6)*
- **Health Professional:** Yes

**EMAIL:** *(b) (6)*

**Phone:** *(b) (6)*

**International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
MFR Report No: 2032002-2006-00051  Mfr Name: INTRA LASE CORP.

Date Received: 07-Sep-2006

Event Date (B3): 20-Sep-2006
Report Date (B4): 09-Aug-2006
Report Date (F8): 09-Aug-2006
Date Mfr Rec'd (G4): 09-Aug-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reportor Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y  Problem (B1): N
Event Location (F12): REPORTER
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Single Use (H5): N
Expiration Date: Device Usage (H8): R

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
11-SEP-2006: ON 08/31/2006, AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) EVALUATED THE DEVICE AND FOUND IT TO BE WITHIN SPECIFICATIONS.

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Recd: 684  Page: 1,371  Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**EMAIL:**

**Phone:**

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 14-Aug-2006

Event Date (B3): 14-Aug-2006
Report Date (B4): 14-Aug-2006
Report Date (F8):
Date Mfr Rec’d (G4): 14-Aug-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Event Location (F12):
Report Source (G3):

Mfr Name: INTRA LASE CORP.

Adverse Event (B1): Y
Problem (B1): N

Device Operator: HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jul-2005
Expiration Date:
Device Usage (H8): R

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2006-00053</th>
<th>Mfr Name: INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 04-Aug-2006</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4): 06-Aug-2006</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8): Date Mfr Rec'd (G4): 30-Aug-2006</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name: INTRA LASE CORP.</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Address: 9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 28-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 08/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 08/30/06 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Phone: [redacted]
- International: [redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

**SORTED BY**

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>MFR Report No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>05-Aug-2006</td>
<td>INJURY</td>
<td>Y</td>
<td>2032002-2006-00054</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (B4):</th>
<th>Event Outcome (B2):</th>
<th>Problem (B1):</th>
<th>Mfr Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>06-Aug-2006</td>
<td>REQUIRED INTERVENTION</td>
<td>N</td>
<td>INTRA LASE CORP.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Mfr Rec’d (G4):</th>
<th>Reporter Occupation (E3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Aug-2006</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Location (F12):</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRA LASE CORP.</td>
<td>9701 JERONIMO ROAD</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):**

- Manufacture Date (H4): 01-Sep-2004
- Single Use (H5): N
- Device Usage (H8): R

**Event Description (B5):**


**Concomitant Medical Products:**

- NA

**Device Available for Evaluation:** Y

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Device Evaluated by Manufacturer (H3):** Yes

**Additional Mfr Narrative (H10 & H11):**

28-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 08/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 08/30/06 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00055</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>25-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-Aug-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Aug-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Aug-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>01-Sep-2004</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>28-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 08/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 08/30/06 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
### Event Description (B5):


### Concomitant Medical Products:

- NA

### Mfr Name: INTRALASE CORP.

**Address:**

9701 JERONIMO RD

IRVINE, CA 92618

UNITED STATES

### Remedial Action (H7):

**Correction/Removal No (H9):**

Additional Mfr Narrative (H10 & H11):

28-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 08/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 08/30/06 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** 
- **Fax:** 

Recd: 689  Page: 1,382  Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00057
Mfr Name: INTRA LASE CORP.

Event Date (B3): 05-Aug-2006
Report Date (B4): 06-Aug-2006
Report Date (F8):
Date Mfr Rec'd (G4): 30-Aug-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Sep-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
28-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 08/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 08/30/06 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

**Health Professional:** Yes
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>18-Aug-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>30-Aug-2006</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>2032002-2006-00058</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Aug-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>30-Aug-2006</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>28-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 08/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER ON 08/30/06 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>DEVICE INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand:</strong> INTRALASE FS LASER</td>
</tr>
<tr>
<td><strong>Device Type:</strong> LASER KERATOME</td>
</tr>
<tr>
<td><strong>Device Type:</strong> 20003</td>
</tr>
<tr>
<td><strong>Catalog:</strong> 20003</td>
</tr>
<tr>
<td><strong>Serial:</strong> (confidential*)</td>
</tr>
<tr>
<td><strong>Lot:</strong> NA</td>
</tr>
<tr>
<td><strong>Other ID:</strong> *</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

<table>
<thead>
<tr>
<th>REPORTER INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong> (b) (b)</td>
</tr>
<tr>
<td><strong>Address:</strong> (b) (b)</td>
</tr>
<tr>
<td><strong>Health Professional:</strong> Yes</td>
</tr>
<tr>
<td><strong>EMAIL:</strong> (b) (b)</td>
</tr>
<tr>
<td><strong>Phone:</strong> (b) (b)</td>
</tr>
<tr>
<td><strong>International:</strong></td>
</tr>
<tr>
<td><strong>Fax:</strong></td>
</tr>
<tr>
<td><strong>Occupation:</strong> 001 - PHYSICIAN</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00059</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>21-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>24-Aug-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>24-Aug-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Aug-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): | | Manufacture Date (H4): | 01-Sep-2004 |
Expiry Date: | | Single Use (H5): | N |
Device Usage (H8): | R |

Event Description (B5):

Concomitant Medical Products:

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-SEP-2006: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE ON 8/24/06 AND THE DEVICE MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE FIELD SERVICE ENGINEER EVALUATED THE LASER IN 2006 AND ADJUSTED FLAP SETTINGS. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Phone:**
- **International:**
- **Fax:**
- **Email:**

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 25-Aug-2006 | Event Report Type: | INJURY | Adverse Event (B1): | Y |
| Date Mfr Rec’d (G4): | 25-Aug-2006 | Reporter Occupation (E3): | 001 - PHYSICIAN |  |
| Mfr Name: | INTRA LASE CORP. | Event Location (F12): |  |

Date Received: 21-Sep-2006

| Product Code: | (OP)-LASER, OPHTHALMIC (HQF) |
| Device Code: |  |
| Device Age (F9): |  |
| Expiration Date: | |
| Manufacture Date (H4): | 01-Jul-2005 |
| Single Use (H5): | N |
| Device Usage (H8): | R |

Event Description (B5):

Concomitant Medical Products:
- NA

Remedial Action (H7):
- Correction/Removal No (H9): Yes
Additional Mfr Narrative (H10 & H11):
25-SEP-2006: ON 8/2/2006, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED PREVENTATIVE MAINTENANCE. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) AND A M.D. CONSULTANT PERFORMED AN INVESTIGATION INTO SURGICAL TECHNIQUES ON TWENTY TWO DAYS LATER, AND MADE RECOMMENDATIONS WITH RESPECT TO USER TECHNIQUE.

DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20004
- Catalog: 20004
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: *
- Address: (b) (6)
- Health Professional: Yes
- EMAIL: (b) (6)
- Phone: (b) (6)
- International: Fax:
- Occupation: 001 - PHYSICIAN
MFR Report No: 2032002-2006-00061  Mfr Name: INTRA LASE CORP.

Event Date (B3): 25-Aug-2006
Report Date (B4): 25-Aug-2006
Report Date (F8):
Date Mfr Rec'd (G4): 25-Aug-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:

Device Evaluated by Manufacturer (H3): Yes

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
25-SEP-2006: 2006, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED PREVENTATIVE MAINTENANCE. THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED. IN ADDITION, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) AND A M.D. CONSULTANT PERFORMED AN INVESTIGATION INTO SURGICAL TECHNIQUES IN 2006 AND MADE RECOMMENDATIONS WITH RESPECT TO USER TECHNIQUE.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *(b) (6)*
- **Health Professional:** Yes

EMAIL: *(b) (6)*

Phone: *(b) (6)*

International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2006-00062
Mfr Name: INTRA LASE CORP.

Date Received: 06-Oct-2006

Event Date (B3): 18-Oct-2005
Report Date (B4): 11-Sep-2006
Report Date (F8):
Date Mfr Rec'd (G4): 11-Sep-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:
Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):
Correction/Removal No (H9):

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Additional Mfr Narrative (H10 & H11):
11-OCT-2006: THIS EVENT WAS REPORTED TO INTRALASE NEARLY ONE YEAR AFTER THE ORIGINAL INCIDENT. A REVIEW OF SERVICE HISTORY RECORDS AROUND THAT DATE SHOW AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED PREVENTATIVE MAINTENANCE ON 08/03/05 AND 10/12/05. UPON DEPARTURE, THE LASER MET SPECIFICATIONS AND WAS PERFORMING AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 2032002-2006-00063
Mfr Name: INTRA LASE CORP.

Date Mfr Rec'd (G4): 05-Sep-2006

Report Date (B4): 05-Sep-2006
Event Date (B3): 01-Sep-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION

Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Date Report (B4): 05-Sep-2006
Event Location (F12): Reporter Occupation (E3): 001 - PHYSICIAN

Report Date (F8): 05-Sep-2006
Adverse Event (B1): Y
Problem (B1): N

Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL

Device Age (F9): Manufacture Date (H4): 01-Jul-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
06-OCT-2006: AN INTRALASE MANAGER OF CLINICAL SUPPORT AND TRAINING PROVIDED SURGERY SUPPORT AND PERFORMED AN INVESTIGATION. THE LASER SETTINGS WERE OPTIMIZED TO DR'S PREFERENCE. ADDITIONALLY, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER ON 9/13-14/06 AND MADE ADJUSTMENTS. DURING THE INVESTIGATION AND UPON DEPARTURE, THE LASER MET SPECS AND PERFORMED AS INTENDED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00064
Mfr Name: INTRA LASE CORP.

Event Date (B3): 15-Sep-2006
Report Date (B4): 15-Sep-2006
Report Date (F8):
Date Mfr Rec'd (G4): 15-Sep-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:

Manufacture Date (H4): 01-Jul-2005
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

16-OCT-2006: IN 2006, AN INTRALASE MANAGER OF CLINICAL SUPPORT AND TRAINING PROVIDED SURGERY SUPPORT AND PERFORMED AN INVESTIGATION. THE LASER SETTINGS WERE OPTIMIZE TO DOCTOR'S PREFERENCE. ADDITIONALLY, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER ON 9/27-28/06 AND VERIFIED THE SYSTEM PERFORMED AS INTENDED, MET SPECIFICATIONS DURING AND UPON DEPARTURE.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** Yes
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010  9:17 AM
Recd: 697  Page: 1,398
Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 15-Sep-2006 | Event Report Type: | INJURY |
| Report Date (F8): | | Event Outcome (B2): | REQUIRED INTERVENTION |
| Date Mfr Rec'd (G4): | 15-Sep-2006 | Reporter Occupation (E3): | 001 - PHYSICIAN |
| Concomitant Medical Products: | NA |
| Mfr Name: | INTRALASE CORP. |
| Address: | 9701 JERONIMO ROAD |
| IRVINE, CA 92618 |
| UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

16-OCT-2006: IN 2006, AN INTRALASE MANAGER OF CLINICAL SUPPORT AND TRAINING PROVIDED SURGERY SUPPORT AND PERFORMED AN INVESTIGATION. THE LASER SETTINGS WERE OPTIMIZED TO DOCTOR'S PREFERENCE. ADDITIONALLY, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER ON 9/27=-28/06 AND VERIFIED THE SYSTEM PERFORMED AS INTENDED, MET SPECIFICATIONS DURING AND UPON DEPARTURE.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:**

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 21-Sep-2006 | Event Report Type: | INJURY |
| Report Date (B4): | 06-Oct-2006 | Event Outcome (B2): | REQUIRED INTERVENTION |
| Mfr Name: | INTRA LASE CORP. | Reporter Occupation (E3): | 001 - PHYSICIAN |
| Device Operator: | HEALTH PROFESSIONAL |
| Event Location (F12): | |
| Concomitant Medical Products: | |
| Mfr Name: | INTRA LASE CORP. |
| Address: | 9701 JERONIMO ROAD |
| IRVINE, CA 92618 |
| UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | No |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type 2:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **EMAIL:** *
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:** *

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00067
Mfr Name: INTRA LASE CORP.
Event Date (B3): 08-Sep-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3):
Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jul-2005
Expiration Date:
Single Use (H5): N
Device Usage (H8): R
Event Description (B5):
Concomitant Medical Products:
NA
Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested
search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to
the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
CDRH

MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2006-00068
Mfr Name: INTRA LASE CORP.
11-Oct-2006

Event Date (B3): 08-Sep-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (B4): 11-Sep-2006
Reporter Occupation (E3): 001 - PHYSICIAN
Report Date (F8): 11-Sep-2006
Device Operator: HEALTH PROFESSIONAL

Date Mfr Rec'd (G4): 11-Sep-2006
Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jul-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 13-OCT-2006: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR BILATERAL LASIK SURGERY IN 2006. THE FLAP ON THE LEFT EYE (OS) WAS CREATED, BUT NO EXCIMER PROCEDURE WAS PERFORMED ON THIS EYE. ONE-DAY POSTOPERATIVELY, THE PATIENT PRESENTED WITH DIFFUSE LAMELLAR KERATITIS (DLK) IN BOTH EYES (OU), A FLAP LIFT AND RINSE WAS PERFORMED ON BOTH EYES (OU) ON THE SAME DAY; A SECOND FLAP LIFT AND RINSE WAS PERFORMED OU THREE DAYS LATER, AND A THIRD FLAP LIFT AND RINSE WAS PERFORMED OU TWO DAYS LATER. THE PATIENT'S PREOPERATIVE BCVA WAS 20/20 ON THE RIGHT EYE (OD) AND 20/30 ON THE LEFT EYE (OS); POSTOPERATIVE BCVA IS CURRENTLY 20/20 OD AND 20/40 OS (UNCORRECTED EYE). THE PATIENT RESPONDED TO TREATMENT AND THE DLK RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Email:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 11-Oct-2006

<table>
<thead>
<tr>
<th>MFR Report No</th>
<th>2032002-2006-00069</th>
<th>Mfr Name</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Sep-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Sep-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>11-Sep-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jul-2005</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 702
Page: 1,407
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** *(b) (6)*
- **Health Professional:** Yes
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)
#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2032002-2006-00070</th>
<th>Mfr Name: INTRA LASE CORP.</th>
<th>Date Mfr Rec'd (G4): 28-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 22-Sep-2006</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 28-Sep-2006</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Problem (B1): N</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 28-Sep-2006</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
</tr>
</tbody>
</table>

#### Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

#### Device Age (F9): MANUFACTURE DATE (H4): 01-Jul-2005

#### Expiration Date: Single Use (H5): N

#### Device Usage (H8): R

#### Event Description (B5):


#### Concomitant Medical Products:

| NA |

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

#### Device Available for Evaluation: Y

#### Device Evaluated by Manufacturer (H3): No

#### Remedial Action (H7):

#### Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20004
- Catalog: 20004
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- Name: *
- Address: (b) (6) [redacted]

**Health Professional:** Yes

**EMAIL:** [redacted]
**Phone:** (b) (6) [redacted]
**International:** [redacted]
**Fax:** [redacted]

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00071
Mfr Name: INTRA LASE CORP.
Report Date (B4): 28-Sep-2006
Event Date (B3): 22-Sep-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Jul-2005
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
26-OCT-2006: ON 9/27-28/06 AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND VERIFIED THE SYSTEM PERFORMED AS INTENDED, MET SPECIFICATIONS DURING AND UPON DEPARTURE. ADDITIONALLY, ON 9/28/06, AN INTRALASE SENIOR CLINICAL APPLICATION SPECIALIST PERFORMED AN INVESTIGATION AND PROVIDED SURGERY SUPPORT. THE LASER SETTINGS WERE OPTIMIZED TO DR'S PREFERENCE AND THE LASER WAS FOUND TO MEET SPECIFICATIONS.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Health Professional:** Yes
- **Name:** *
- **Address:** (b) (6)
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 22-Sep-2006
Report Date (B4): 28-Sep-2006
Event Description (B5):

Concomitant Medical Products:
NA

Device Evaluated by Manufacturer (H3): No
Remedial Action (H7):

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** *
- **EMAIL:** *
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>22-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>28-Sep-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>28-Sep-2006</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>28-Sep-2006</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2032002-2006-00073</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>

Date Recd: 25-Oct-2006
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRASLASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6) [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** (b) (6) [redacted]
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 2032002-2006-00074    Mfr Name: INTRA LASE CORP.

Event Date (B3): 02-Sep-2006    Event Report Type: INJURY
Date Mfr Rec'd (G4): 16-Oct-2006    Reporter Occupation (E3): 001 - PHYSICIAN

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY
02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
Event Date (B3): 08-Sep-2006
Report Date (B4): 16-Oct-2006
Report Date (F8):
Date Mfr Rec’d (G4): 16-Oct-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y  Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
**Device Age (F9):** Manufacture Date (H4): 01-Aug-2002
**Expiration Date:** Single Use (H5): N
**Device Usage (H8):** R

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Mfr Name:** INTRALASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [b] (6)
- **Health Professional:** Yes
- **Email:** [b] (6)
- **Phone:** [b] (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 26-Oct-2006

Event Date (B3): 21-Sep-2006
Report Date (B4): 16-Oct-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Date Mfr Rec'd (G4): 16-Oct-2006
Report Date (F8): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2002
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
MAUDE EVENT REPORT (FOI)

02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>21-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>16-Oct-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>16-Oct-2006</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Event (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address:
9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): 
Correction/Removal No (H9): 

Event Description (B5):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 2002
- **Catalog:** 2002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **EMAIL:**
- **Phone:** [b](6)
- **International:** [b](6)
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

Sorter By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00078</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>31-Aug-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>16-Oct-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>16-Oct-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Aug-2002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused:  N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2006-00079
Mfr Name: INTRA LASE CORP.
Event Date (B3): 29-Sep-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Sep-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
06-NOV-2006: ON 10/4/06 AND 10/16/06, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND VERIFIED THE SYSTEM PERFORMED AS INTENDED, MET SPECS DURING AND UPON DEPARTURE. ADDITIONALLY, ON 10/5/06, AN INTRALASE SENIOR CLINICAL APPLICATION SPECIALIST (SCAS) PERFORMED AN INVESTIGATION. THE LASER SETTINGS WERE OPTIMIZED TO DR'S PREFERENCE AND THE LASER WAS FOUND TO MEET SPECS. FURTHERMORE, ON 11/01/06, INTRALASE'S SCAS PERFORMED AN ADD'L SITE INVESTIGATION AND FOUND POSSIBLE ROOT CAUSES; MULTIPLE LASERS AND PTS IN THE SAME OPERATING ROOM; THE AUTOCLAVE IS LOCATED WITHIN THE SURGICAL SUITE; AND ASEPTIC TECHNIQUES DURING SURGERY.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**

Health Professional: Yes

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name: INTRALASE CORP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: 9701 JERONIMO ROAD</td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Evaluated by Manufacturer (H3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
</tbody>
</table>
06-NOV-2006: ON 10/04/06 AND 10/16/06, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND VERIFIED THE SYSTEM PERFORMED AS INTENDED, MET SPECIFICATIONS DURING AND UPON DEPARTURE. ADDITIONALLY, ON 10/05/06, AN INTRALASE SENIOR CLINICAL APPLICATION SPECIALIST (SCAS) PERFORMED AN INVESTIGATION. THE LASER SETTINGS WERE OPTIMIZED TO DOCTOR’S PREFERENCE AND THE LASER WAS FOUND TO MEET SPECIFICATIONS. FURTHERMORE, ON 11/01/06, INTRALASE’S SCAS PERFORMED AN ADDITIONAL SITE INVESTIGATION AND FOUND POSSIBLE ROOT CAUSES: MULTIPLE LASERS AND PATIENTS IN THE SAME OPERATING ROOM; THE AUTOCLAVE IS LOCATED WITHIN THE SURGICAL SUITE; AND ASEPTIC TECHNIQUES DURING SURGERY.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00081</th>
<th>Mfr Name: INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>30-Sep-2006</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>09-Oct-2006</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>09-Oct-2006</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 09-NOV-2006: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY IN THE LEFT (OS) EYE. POSTOPERATIVELY THE PATIENT PRESENTED WITH STAGE 2 DIFFUSE LAMELLAR KERATITIS (DLK). DOCTOR OPTED NOT TO PERFORM A FLAP LIFT AND RINSE AND PRESCRIBED FREQUENT TOPICAL STERIODS. PRE-OP BCVA 20/20 OS. AT 1-MONTH POST-OP BCVA WITH PINHOLE 20/70 OS. PATIENT WAS REFERRED BACK TO THE ATTENDING DOCTOR AND IS BEING-treated WITH TOPICAL STERIODS. THE PHYSICIAN ALSO OBSERVED SCARRING AND DRY SURFACE. HOWEVER, SCARRING IS EXPECTED TO DISSIPATE WITH THE TOPICAL STERIOD TREATMENT. THE REFERRING PHYSICIAN WILL CONTINUE TO MONITOR PATIENT. IT IS UNKNOWN WHETHER THE PATIENT'S DECREASED VISION IS RELATED TO THE SCARRING OR DLK. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 714  Page: 1,431  Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
09-NOV-2006: H3 - AN INTRALASE FIELD SERVICE ENGINEER PERFORMED PREVENTATIVE MAINTENANCE ON 10/03/06 AND FOUND THE LASER SYSTEM TO MEET SPECIFICATIONS AND PERFORM AS INTENDED UPON DEPARTURE. ADDITIONALLY, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST PERFORMED AN INVESTIGATION ON 10/05/06 AT WHICH TIME THE LASER WAS OPTIMIZED TO DOCTOR'S PREFERENCE, MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. IF ADDITIONAL INFORMATION BECOMES AVAILABLE A FOLLOW-UP REPORT WILL BE SUBMITTED TO FDA.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused:  N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2006-10-23

MFR Report No: 2032002-2006-00082
Mfr Name: INTRA LASE CORP.

Event Date (B3): 20-Oct-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Event Location (F12): REPORTER OCCUPATION:
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Report Date (B4): 23-Oct-2006
Report Date (F8): 23-Oct-2006
Event Location (F12): REPORTER OCCUPATION:

Device Operator: HEALTH PROFESSIONAL

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
28-NOV-2006: ON 10/23-24/06, AN INTRALASE FIELD SERVICE ENGINEER (FSE) EVALUATED THE DEVICE AND FOUND IT TO BE WITHIN SPECIFICATION UPON DEPARTURE. IN ADDITION, AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) PERFORMED SURGERY SUPPORT ON 10/25/06, EVALUATED THE DEVICE AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Health Professional:** Yes
- **EMAIL:** *
- **Phone:** *
- **International:** *
- **Fax:** *
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00083</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>22-Nov-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Oct-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Aug-2006

Expiration Date: Single Use (H5): N

Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

28-NOV-2006: ON 11/07/06, AN INTRALASE FIELD SERVICE ENGINEER (FSE) EVALUATED THE DEVICE AND FOUND IT TO BE WITHIN SPECIFICATION UPON DEPARTURE. IN ADDITION, AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) HAS BEEN CLOSELY MONITORING THIS SITE AND FOUND THE LASER SYSTEM TO MEET SPECIFICATIONS AND PERFORM AS INTENDED. THE DOCTOR IS CURRENTLY INQUIRING INTO ENVIRONMENTAL TESTING OF AIR QUALITY AND SURFACES AT HIS CLINICAL SUITE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00084</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Event Date (B3):</th>
<th>22-Oct-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>23-Oct-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: INTRALASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
28-NOV-2006: ON 10/23/06 - 10/26/06, AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) PROVIDED SURGERY SUPPORT, FOUND SYSTEM MET SPECIFICATIONS, BUT OPTIMIZED SETTINGS TO DOCTOR'S PREFERENCE AND STRESSED THE USE OF STEROID DROPS POSTOPERATIVELY. CAS VERIFIED LASER SYSTEM MET SPECIFICATIONS UPON DEPARTURE. PER CAS, DOCTOR REPORTED NO DLK ON CASES PERFORMED DURING SURGERY SUPPORT. ADDITIONALLY, AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE ON 10/30/06, EVALUATED THE DEVICE AND FOUND IT TO BE WITHIN SPECIFICATION UPON DEPARTURE.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20002
- Catalog: 20002
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: *
- Address: [b] (6)
- Health Professional: Yes
- EMAIL: [b] (6)
- Phone: [b] (6)
- International: 
- Fax: 
- Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 22-Nov-2006

MFR Report No: 2032002-2006-00086
Mfr Name: INTRA LASE CORP.

Event Date (B3): 21-Oct-2006
Report Date (B4): 26-Oct-2006
Report Date (F8): 26-Oct-2006
Date Mfr Rec’d (G4): 26-Oct-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): REPORTER
Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2002
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):  
Correction/Removal No (H9):  

Recd:  719
Page: 1,441
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Email:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00087</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>26-Oct-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>26-Oct-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Oct-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2002
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00088</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Oct-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Nov-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>01-Nov-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-2002</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date Last Updated:** 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

Name: *

Address: (b) (6)

**Health Professional:** Yes

**EMAIL:**

**Phone:** (b) (6)

**International:**

**Fax:**

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

MFR Report No: 2032002-2006-00089
Mfr Name: INTRA LASE CORP.

Event Date (B3): 18-Nov-2006
Report Date (B4): 04-Dec-2006
Report Date (F8): 
Date Mfr Rec'd (G4): 04-Dec-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): R

Manufacture Date (H4): 01-Oct-2005
Single Use (H5): N

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
09-JAN-2007: ON 12/04/06, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SURGICAL FACILITY AND PERFORMED AN INVESTIGATION. THE CAS WAS UNABLE TO DETERMINE A POSSIBLE ROOT CAUSE BASED ON HER ASSESSMENT OF THE PHYSICIAN'S LASER SETTINGS, SURGICAL TECHNIQUES, AND STERILITY PROCESSES. FURTHERMORE, ON 12/07/06, A FIELD SERVICE ENGINEER (FSE) INSPECTED THE LASER AND FOUND THE LASER MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON ARRIVAL AND DEPARTURE OF EACH VISIT.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20004
Catalog: 20004
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: *
Health Professional: Yes

EMAIL: *
Phone: *
International: *
Fax: *

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2006-00090</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>29-Dec-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Dec-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Ommitted</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jun-2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

Date Received
2032002-2007-00001

MFR Report No: 2032002-2007-00001

Mfr Name: INTRA LASE CORP.

Event Date (B3): 28-Nov-2006
Report Date (B4): 11-Dec-2006
Report Date (F8): 11-Dec-2006
Date Mfr Rec'd (G4): 11-Dec-2006

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION

Report Source (G3): HEALTH PROFESSIONAL

Report Date (F8): 001 - PHYSICIAN

Report Date (B4): 11-Dec-2006
Event Location (F12): Reporter Occupation (E3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL


Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** *
- **Address:** *
- **Health Professional:** Yes
- **Email:** *
- **Phone:** (b) (b)
- **International:** *
- **Fax:** *
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00002</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 17-Nov-2006  
**Event Report Date (B4):** 19-Dec-2006  
**Report Date (B4):** 10-Jan-2007  
**Date Mfr Rec'd (G4):** 19-Dec-2006

**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Adverse Event (B1):** Y  
**Problem (B1):** N

**Report Date (F8):** 19-Dec-2006  
**Event Location (F12):**  
**Report Source (G3):** FOREIGN, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Device Operator:** HEALTH PROFESSIONAL

**Device Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Manufacture Date (H4):** 01-Jan-2005  
**Expiration Date:** 
**Single Use (H5):** N  
**Device Usage (H8):** R

**Event Description (B5):**


**Concomitant Medical Products:** NA

**Mfr Name:** INTRA LASE CORP.  
**Address:** 9701 JERONIMO ROAD  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**  
**Correction/Removal No (H9):**

DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: *
- Address: *(b) (6)*
- Health Professional: Yes
- Occupation: 001 - PHYSICIAN
- EMAIL: *(b) (6)*
- Phone: *(b) (6)*
- International: 
- Fax: 

Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>2032002-2007-00003</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>08-Nov-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>05-Jan-2007</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>05-Jan-2007</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>05-Jan-2007</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
</tr>
<tr>
<td>IRVINE, CA 92618</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Health Professional:** Yes
- **EMAIL:** *
- **Phone:** *
- **International:** *
- **Fax:** *
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00004</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Jan-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>10-Jan-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>10-Jan-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** Yes
- **Email:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2002-2007-00005
Mfr Name: INTRA LASE CORP.

Report Date (B4): 10-Jan-2007
Report Date (F8): 10-Jan-2007
Date Mfr Rec'd (G4): 10-Jan-2007

Event Date (B3): 28-Dec-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Nov-2004
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** *
- **Address:** [b] (b)
- **Health Professional:** Yes
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Description (B5):


### Concomitant Medical Products:

NA

### Device Available for Evaluation:

Y

### Remedial Action (H7):

Correction/Removal No (H9):


---

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

**MFR Report No:** 2032002-2007-00006  **Mfr Name:** INTRA LASE CORP.

**Event Date (B3):** 12-Jan-2007  **Event Report Type:** INJURY

**Report Date (B4):** 18-Jan-2007  **Event Outcome (B2):** REQUIRED INTERVENTION

**Report Date (F8):** 001 - PHYSICIAN  **Report Source (G3):** HEALTH PROFESSIONAL

**Date Mfr rec'd (G4):** 16-Jan-2007  **Device Operator:** HEALTH PROFESSIONAL

**Mfr Name:** INTRA LASE CORP.  **Address:** 9701 JERONIMO ROAD  IRVINE, CA 92618  UNITED STATES

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.  **Address:** 9701 JERONIMO ROAD  IRVINE, CA 92618  UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

### Remedial Action (H7):

Correction/Removal No (H9):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand</strong></td>
<td>INTRALASE FS LASER</td>
</tr>
<tr>
<td><strong>Device Type</strong></td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td><strong>Device Type</strong></td>
<td>20003</td>
</tr>
<tr>
<td><strong>Catalog</strong></td>
<td>20003</td>
</tr>
<tr>
<td><strong>Serial</strong></td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td><strong>Lot</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Other ID</strong></td>
<td>*</td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>*</td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td>[b] (b)</td>
</tr>
<tr>
<td><strong>Health</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Professional</strong></td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Email:** [b] (b)  
**Phone:** [b] (b)  
**International:**  
**Fax:**  

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00007  Mfr Name: INTRA LASE CORP.

Event Date (B3): 10-Jan-2007  Event Report Type: INJURY
Report Date (B4): 10-Jan-2007  Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 10-Jan-2007  Reporter Occupation (E3): 001 - PHYSICIAN
Date Mfr Rec'd (G4): 10-Jan-2007  Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y  Problem (B1): N
Event Location (F12):  
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Nov-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R


Concomitant Medical Products: NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

Recd: 730  Page: 1,463  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2007-00008</th>
<th>Mfr Name: INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 25-Jan-2007</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4): 02-Feb-2007</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 02-Feb-2007</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9): Manufacture Date (H4): 01-Mar-2005</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

---

Recd: 731  Page: 1,465  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00009</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>25-Jan-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Feb-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Feb-2007</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr Report No:</td>
<td>FOREIGN, HEALTH PROFESSIONAL, USER FACILITY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Date Received</td>
<td>02-Mar-2007</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


Concomitant Medical Products: NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** *(redacted)*
- **EMAIL:** *(redacted)*
- **Phone:** *(redacted)*
- **International:** *(redacted)*
- **Fax:** *(redacted)*
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

Sorted By

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 2032002-2007-00010
Mfr Name: INTRA LASE CORP.

Event Date (B3): 29-Jan-2007
Report Date (B4): 01-Feb-2007
Report Date (F8):
Date Mfr Rec'd (G4): 01-Feb-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3):
HEALTH PROFESSIONAL,
COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2003
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

MAUDE EVENT REPORT (FOI)

02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

06-MAR-2007: AN INTRALASE FIELD SERVICE ENGINEER (FSE) EVALUATED THE DEVICE FOUR DAYS AFTER EVENT RUNNING MOCK PROCEDURES IN GLASS SLIDES AND GEL FOR 4 HOURS TO ATTEMPT TO DUPLICATE THE REPORTED PROBLEM. HE WAS UNABLE TO DUPLICATE THE REPORTED PROBLEM. HE SENT GLASS SLIDES TO INTRALASE FOR EVALUATION AND THESE SLIDES SHOW A HINGE WAS CREATED IN EACH SLIDE. ADDITIONALLY, 3 DAYS LATER, ANOTHER FSE PERFORMED SURGERY SUPPORT AND DID NOT OBSERVE ANY COMPLICATIONS. THE LASER MET ALL SPECIFICATIONS AND PERFORMED AS INTENDED UPON ARRIVAL AND DEPARTURE. AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE INVESTIGATING THE REPORTED ISSUE. NO OTHER COMPLICATIONS HAVE BEEN REPORTED AND NO FURTHER INTERVENTION IS PLANNED.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2032002-2007-00011
Mfr Name: INTRA LASE CORP.
Event Date (B3): 31-Jan-2007
Report Date (B4): 01-Feb-2007
Report Date (F8):
Date Mfr Rec'd (G4): 01-Feb-2007
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):
Event Description (B5):
Concomitant Medical Products:
NA
Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3):
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

06-MAR-2007: AN INTRALASE FIELD SERVICE ENGINEER (FSE) EVALUATED THE DEVICE TWO DAYS AFTER EVENT RUNNING MOCK PROCEDURES IN GLASS SLIDES AND GEL FOR 4 HOURS TO ATTEMPT TO DUPLICATE THE REPORTED PROBLEM. HE WAS UNABLE TO DUPLICATE THE REPORTED PROBLEM. HE SENT GLASS SLIDES TO INTRALASE FOR EVALUATION AND THESE SLIDES SHOW A HINGE WAS CREATED IN EACH SLIDE. ADDITIONALLY, THREE DAYS LATER, ANOTHER FSE PERFORMED SURGERY SUPPORT AND DID NOT OBSERVE ANY COMPLICATIONS. THE LASER MET ALL SPECIFICATIONS AND PERFORMED AS INTENDED UPON ARRIVAL AND DEPARTURE. AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE INVESTIGATING THE REPORTED ISSUE. NO OTHER COMPLICATIONS HAVE BEEN REPORTED AND NO FURTHER INTERVENTION IS PLANNED.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20002
- **Catalog:** 20002
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2007-00012
Mfr Name: INTRA LASE CORP.
Date Mfr Rec'd (G4): 01-Feb-2007

Event Date (B3): 12-Jan-2007
Report Date (B4): 01-Feb-2007
Report Date (F8): 
Date Mfr Rec'd (G4): 01-Feb-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL,
COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Apr-2006
Expiration Date:
Device Usage (H8): R

Event Description (B5):
Mfr 06-MAR-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY (DATE OF EVENT) THE PATIENT PRESENTED WITH DIFFUSE LAMELLAR KERATITIS (DLK) IN BOTH EYES. A FLAP LIFT AND RINSE WAS PERFORMED FOR EACH EYE AND THE PATIENT WAS TREATED WITH TOPICAL STEROIDS. THE PATIENT'S PREOPERATIVE BEST SPECTACLE CORRECTED VISUAL ACUITY (BSCVA) WAS 20/20 IN BOTH EYES. POSTOPERATIVE UCVA IS 20/20 IN BOTH EYES. THE PATIENT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

06-MAR-2007: IN 2007, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS UPON ARRIVAL, AND DEPARTURE OF VISIT, AND PERFORMED AS INTENDED. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) CONTACTED SITE ON 02/01/07 AND MADE RECOMMENDATIONS TO CHANGE FLAP CREATION SETTINGS. SINCE RECOMMENDED SETTINGS WERE IMPLEMENTED, THE SITE HAS REPORTED NO ADDITIONAL CASES OF DLK.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** *(b) (6)*
- **Email:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:** *
- **Fax:** *
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00013</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>09-Mar-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Jan-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>09-Feb-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>09-Feb-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacturer Date (H4):</td>
<td>01-Oct-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Address: | 9701 JERONIMO ROAD  
IRVINE, CA 92618  
UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

16-MAR-2007: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AT THIS CLINICAL FACILITY IN 2007, PRIOR TO THIS REPORT, AND FOUND THE SYSTEM MET ALL SPECIFICATIONS. ON 01/30/07 CAS WAS INFORMED BY SITE OF NON-DLK INFLAMMATION. CAS DISCUSSED LOWERING ENERGY SETTINGS WITH SITE AND PLANNED TO VISIT SITE THE WEEK OF 02/05/07. CAS' SCHEDULED VISIT WAS RESCHEDULED BY THE SITE FOR 02/22/07 AND WAS ALSO TOLD INSTRUMENTS ARE STERILIZED BY AN OUTSIDE COMPANY. ON 02/09/07 THE CAS OBTAINED PATIENT INFORMATION AND FOUND THE EVENT WAS DLK WITH A FLAP LIFT AND RINSE. ON FEBRUARY 22, 2007 DURING SITE VISIT THE CAS FOUND THE SITE HAD REDUCED THE ENERGY SETTINGS AS DISCUSSED EARLIER. CAS INSPECTED THE SYSTEM AND FOUND IT MET ALL SPECIFICATIONS AND PERFORMED AS INTENDED. THERE HAVE BEEN NO ADDITIONAL REPORTS OF DLK.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** *(b) (6)*
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:** *(b) (6)*
- **Fax:**

**Reprocessed & Reused:** N
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>09-Feb-2007</td>
<td>INJURY</td>
<td>Y</td>
<td>05-Apr-2007</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>EVENT REPORT</th>
<th>02-Nov-2010</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date Mfr Rec'd (G4):</th>
<th>Event Description (B5):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Outcome (B2):</th>
<th>Reporter Occupation (E3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>REQUIRED INTERVENTION</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Operator (F12):</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Location (F12):</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Device Evaluated by Manufacturer (H3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRALASE CORP.</td>
<td>9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Device Evaluated by Manufacturer (H3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Recd:</th>
<th>Date Last Updated: 11/2/2010 9:17 AM</th>
</tr>
</thead>
<tbody>
<tr>
<td>737</td>
<td>Page: 1,477</td>
</tr>
</tbody>
</table>
Additional Mfr Narrative (H10 & H11):
11-APR-2007: ON 01/26/07 TO 01/30/07 AND INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE AND PERFORMED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATION AND PERFORMED AS INTENDED UPON DEPARTURE. ON 03/06/07 AND 03/09/07, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) FOUND THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE LASER SETTINGS WERE MODIFIED ACCORDING TO PHYSICIAN’S PREFERENCES AND CAS ALSO INSTRUCTED PHYSICIANS AT SITE ON LIGHT DOCKING TECHNIQUE AND ITS EFFECTIVENESS ON SURGERY OUTCOMES. NOTE: PTS TREATED PRIOR TO OR AFTER THIS CASE, AS WELL AS THE FELLOW EYE, DID NOT DEVELOP DLK. THE ROOT CAUSE OF THE DLK REMAINS UNK.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20002
Catalog: 20002
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: (b) (b)

EMAIL: (b) (b)
Phone: (b) (b)
International: (b) (b)
Fax: 

Health Professional: Yes
Occupation: 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>21-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>20-Mar-2007</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Jan-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
</tbody>
</table>

#### Event Description (B5):


#### Concomitant Medical Products:

NA

#### Mfr Name: INTRA LASE CORP.
**Address:**
9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

23-APR-2007: ON 9/11/06, AN INTRALASE FIELD SERVICE ENGINEER (FSE) PERFORMED SCHEDULED PREVENTATIVE MAINTENANCE AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. ON 3/2/07, AN FSE AND A CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE, MODIFIED LASER SETTINGS PER DOCTOR’S REQUEST AND MADE RECOMMENDATIONS WITH REGARDS TO SURGICAL TECHNIQUE. RECOMMENDATIONS WERE DECLINED AND DOCTOR WAS ADVISED TO POTENTIAL OUTCOME(S). THE LASER MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. SINCE THE REPORT OF THIS EVENT, A CAS HAS BEEN IN CONTACT WITH THE SITE TO OBTAIN PATIENT FOLLOW UP. PER THE CAS, THE PATIENT HAS RECOVERED AND NO OTHER COMPLICATIONS HAVE BEEN REPORTED. NO FURTHER TREATMENT IS PLANNED.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00016</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>05-Apr-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Feb-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-Mar-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

| Product Code:           | (OP)-LASER, OPHTHALMIC (HQF) |
| Device Age (F9):        |                                  |
| Expiration Date:        |                                  |
| Manufacture Date (H4):  | 01-Aug-2006                  |
| Single Use (H5):        | N                              |
| Device Usage (H8):      | R                              |

Event Description (B5):


Concomitant Medical Products:

NA

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9): 

Date Last Updated: 11/2/2010 9:17 AM

DEVICE INFORMATION:
- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: *
- Address: (b) (6)
- Health Professional: Yes
- EMAIL: (b) (6)
- Phone: (b) (6)
- International: 
- Fax: 
- Occupation: 001 - PHYSICIAN
## MAUDE EVENT REPORT (FOI)

### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00017</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Feb-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>08-Mar-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Aug-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recd:</td>
<td>740</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Page:</td>
<td>1,483</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN
MFR Report No: 2032002-2007-00018  Mfr Name: INTRA LASE CORP.

Event Date (B3): 02-Feb-2007  Event Report Type: INJURY  Adverse Event (B1): Y  Problem (B1): N
Report Date (F8): 15-Mar-2007  Event Location (F12): 
Date Mfr Rec’d (G4): 15-Mar-2007  Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE


Concomitant Medical Products: NA

Device Available for Evaluation: Y  Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **REPORTER INFORMATION:**
- ** EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00019</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Feb-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Concomitant Medical Products: NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (confidential)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: (b) (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 16-Feb-2007
Report Date (B4): 15-Mar-2007
Date Mfr Rec'd (G4): 15-Mar-2007

MFR Report No: 2032002-2007-00020
Mfr Name: INTRA LASE CORP.
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Source (G3): HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Device Operator: HEALTH PROFESSIONAL

Date Received
2032002-2007-00020
Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
         IRVINE, CA 92618
         UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):

Event Description (B5):

Concomitant Medical Products:
NA

Recd: 743
Page: 1,489
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>19-Feb-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>21-Mar-2007</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2007</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

---

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
</tbody>
</table>

**Event Report Type:** INJURY
**Event Outcome (B2):** REQUIRED INTERVENTION

**Reporter Occupation (E3):** 001 - PHYSICIAN
**Device Operator:** HEALTH PROFESSIONAL

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

---

**Recd:** 744 **Page:** 1,491 **Date Last Updated:** 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** *
- **Address:** [b] (6)
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** [b] (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Feb-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>08-Mar-2007</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>08-Mar-2007</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>08-Mar-2007</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2032002-2007-00022</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Aug-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

11-APR-2007: ON 02/06/07, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE FOLLOWING MONTH, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE ADVICE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT, EVEN THOUGH THE SITE USES POWDER FREE GLOVES.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [b] (6)
- **Health Professional:** Yes
- **Email:** [b] (6)
- **Phone:** [b] (6)
- **International:** [b] (6)
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00023
Mfr Name: INTRA LASER CORP.

Event Date (B3): 02-Mar-2007
Report Date (B4): 08-Mar-2007
Report Date (F8):
Date Mfr Rec'd (G4): 08-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (B4): 08-Mar-2007
Event Location (F12): REPORTER OCCUPATION: 001 - PHYSICIAN
Report Source (G3): HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 11-APR-2007: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY (THE FOLLOWING DAY), THE PATIENT PRESENTED WITH GRADE 2+ DIFFUSE LAMELLAR KERATITIS (DLK) IN LEFT (OS) EYE. A FLAP LIFT AND RINSE WAS PERFORMED ON OS ON EVENT DAY. OD IS CLEAR. PATIENT WAS TREATED WITH ORAL AND TOPICAL STEROIDS AND A BANDAGE CONTACT LENS WAS PLACED. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20. POSTOPERATIVE UCVA IS 20/30. THE PATIENT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
11-APR-2007: ON 02/06/07, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE FOLLOWING MONTH, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE ADVISE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT, EVEN THOUGH THE SITE USES POWDER FREE GLOVES.

DEVICE INFORMATION:

| Brand:  | INTRALASE FS LASER |
| Device Type: | LASER KERATOME |
| Device Type: | 20003 |
| Catalog: | 20003 |
| Serial: | (*confidential*) |
| Lot: | NA |
| Other ID: | * |

Reprocessed & Reused: N

REPORTER INFORMATION:

| Name: | * |
| Address: | (b) (6) |
| Health Professional: | Yes |
| EMAIL: | (b) (6) |
| Phone: | (b) (6) |
| International: | |
| Fax: | |
| Occupation: | 001 - PHYSICIAN |
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2007-00024

Event Date (B3): 09-Mar-2007
Report Date (B4): 15-Mar-2007
Report Date (F8):
Date Mfr Rec'd (G4): 15-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

MFR Report No: 2032002-2007-00024
Mfr Name: INTRA LASE CORP.

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12):
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2006
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Concomitant Medical Products:

Mfr 11-APR-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY (THE FOLLOWING DAY), THE PATIENT PRESENTED WITH GRADE 3+ DIFFUSE LAMELLAR KERATITIS (DLK) IN THE RIGHT (OD) EYE AND GRADE TRACE TO 1+ DLK IN THE LEFT (OS) EYE. A FLAP LIFT AND RINSE WAS PERFORMED ON RIGHT (OD) EYE ONLY ON EVENT DAY; A SECOND LIFT AND RINSE WAS PERFORMED OD THREE DAYS LATER; AND A THIRD LIFT AND RINSE WAS PERFORMED OD THE NEXT DAY. PATIENT WAS TREATED WITH TOPICAL STERIODS. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POSTOPERATIVE UNCORRECTED VISUAL ACUITY (UCVA) IS 20/25 OD AND 20/20-1 OS. THE PATIENT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Remedial Action (H7):
Correction/Removal No (H9):

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

11-APR-2007: ON 02/06/07, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE FOLLOWING MONTH, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE ADVICE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT, EVEN THOUGH THE SITE USES POWDER FREE GLOVES.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** 
- **Health Professional:** Yes
- **Email:**
- **Phone:** (b) (6)
- **International:** 
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
### Event Description (B5):

Mfr 11-APR-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY (THE FOLLOWING DAY), THE PATIENT PRESENTED WITH GRADE 4+ DIFFUSE LAMELLAR KERATITIS (DLK) IN THE RIGHT (OD) EYE AND GRADE 2+ DLK IN THE LEFT (OS) EYE. A FLAP LIFT AND RINSE WAS PERFORMED IN BOTH EYES (OU) ON EVENT DAY; A SECOND LIFT AND RINSE WAS PERFORMED OU THE FOLLOWING DAY; A THIRD LIFT AND RINSE WAS PERFORMED OU THE NEXT DAY; AND A FOURTH LIFT AND RINSE WAS PERFORMED ON RIGHT (OD) EYE ONE DAY LATER. PATIENT WAS TREATED WITH TOPICAL STEROIDS. POSSIBLE HAZE OR CENTRAL TOXIC KERATOPATHY WAS NOTED FOR OD EYE ON THE SAME DAY. THE PATIENT WAS SEEN AGAIN ONE WEEK LATER, AND THE DLK HAD RESOLVED OU, BUT THERE WAS EDEMA WITHOUT SCARRING IN OD EYE. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POSTOPERATIVE UNCORRECTED VISUAL ACUITY (UCVA) IS 20/40 OD AND 20/20 OS. THE ASSOCIATE BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

### Concomitant Medical Products:

- **NA**

### Device Available for Evaluation:

- Y

### Device Evaluated by Manufacturer (H3):

- Yes

### Remedial Action (H7):

### Correction/Removal No (H9):

- 748

---

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

Date Received: 203202-2007-00025

**Mfr Report No: 2032002-2007-00025**

**Mfr Name: INTRA LASE CORP.**

**Event Date (B3): 09-Mar-2007**

**Report Date (B4): 15-Mar-2007**

**Report Date (F8):**

**Date Mfr Rec'd (G4): 15-Mar-2007**

**Mfr Name: INTRA LASE CORP.**

**Address: 9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES**

**Device Available for Evaluation: Y**

**Device Evaluated by Manufacturer (H3): Yes**

**Correction/Removal No (H9): 748**

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4): 01-Aug-2006**

**Expiration Date:**

**Single Use (H5): N**

**Device Usage (H8): R**

**Event Report Type:** INJURY

**Event Outcome (B2):** REQUIRED INTERVENTION

**Reporter Occupation (E3): 001 - PHYSICIAN**

**Device Operator:** HEALTH PROFESSIONAL

**Event Location (F12):**

**Health Professional, User Facility, Company Representative**

**Adverse Event (B1): Y**

**Problem (B1): N**

**Event Report Source (G3): HEALTH PROFESSIONAL**

**Report Source (G3): USER FACILITY, COMPANY REPRESENTATIVE**

**Recd: 748**

**Date Last Updated: 11/2/2010 9:17 AM**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

11-APR-2007: ON 02/06/07, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE FOLLOWING MONTH, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE ADVICE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT, EVEN THOUGH THE SITE USES POWDER FREE GLOVES. OTHER: VENTILATION SYSTEM NOT WORKING EFFECTIVELY AND WHITE POWDER FOUND ON EQUIPMENT.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [b] [6] [b] [6] [b] [6]
- **Health Professional:** Yes

**EMAIL:**

- **Phone:** [b] [6]
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
## MAUDE EVENT REPORT (FOI)

### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00026</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>15-Mar-2007</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Aug-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Date Last Updated:** 11/2/2010 9:17 AM
11-APR-2007: ON 02/06/07, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE FOLLOWING MONTH, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE ADVICE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT, EVEN THOUGH THE SITE USES POWDER FREE GLOVES.

DEVICE INFORMATION:
- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: *
- Address: (b) (6)
- Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: Fax:

Occupation: 001 - PHYSICIAN
## MAUDE EVENT REPORT (FOI)
### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>09-Mar-2007</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2032002-2007-00027</td>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:
- **Name:** *
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2007-00028

Mfr Name: INTRA LASE CORP.

Report Date (B4): 16-Mar-2007

Event Date (B3): 16-Mar-2007

Event Report Type: INJURY

Event Outcome (B2): REQUIRED INTERVENTION

Reporter Occupation (E3): 001 - PHYSICIAN

Device Operator: HEALTH PROFESSIONAL

MFR Report No: 2032002-2007-00028

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Date Last Updated: 11/2/2010 9:17 AM

Recd: 751
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

10-APR-2007: ON 2/6/07, a field service engineer inspected the laser and performed a scheduled preventative maintenance. The laser system met spec and performed as intended. On 3/15/07, an Intralase clinical applications specialist (CAS) provided surgery support and observed the site has been modifying their laser settings on a continuous basis, against the advice of the CAS. Additionally, the site has had on-going construction adjacent to the surgical suite since 2006 that is stirring up dust and debris in the area. An environmental CO evaluated the surgical site and noted that the ventilation system was not working effectively, most likely due to an air filter that was improperly installed. White powder was observed on equipment and noted in the environmental report, even though the site uses powder free gloves.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTEr INFORMATION:**

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00029</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Mar-2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>16-Mar-2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>16-Mar-2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRA LASE CORP.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td>IRVINE, CA 92618</td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mfr 10-APR-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY, THE PT PRESENTED WITH GRADE TRACE TO 1+ DIFFUSE LAMELLAR KERATITIS (DLK) IN THE RIGHT (OD) EYE AND GRADE 2+ IN THE LEFT (OS) EYE. A FLAP LIFT AND RINSE WAS PERFORMED ON LEFT (OS) EYE ON SAME DAY. PT WAS TREATED WITH TOPICAL STEROIDS. THE PT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POSTOPERATIVE UNCORRECTED VISUAL ACUITY (UCVA) IS 20/20-1 OU. THE PT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNK.

Concomitant Medical Products:

- NA

Date Last Updated: 11/2/2010  9:17 AM
Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** INTRALEASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes

**EMAIL:** [Redacted]

**Phone:** [Redacted]

**International:** [Redacted]

**Fax:**

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00030</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2007</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>20-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Event Description (B5): |

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Device Available for Evaluation: | Y            |
| Device Evaluated by Manufacturer (H3): | Yes |
| Remedial Action (H7):             |             |
| Correction/Removal No (H9):        |             |

DEVICE INFORMATION:
- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: *
- Address: [HIDDEN]
- Health Professional: Yes
- Occupation: 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00032</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>19-Apr-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
The Intralase FS laser was used to create bilateral corneal flaps for LASIK surgery in 2007. One day postoperatively, the patient presented with Stage 1 Diffuse Lamellar Keratitis (DLK) in both eyes (OU). A flap lift and rinse was performed OU one day later. The patient was treated with topical steroids. The patient's preoperative best corrected visual acuity (BCVA) was 20/20 OU. Postoperative BCVA is 20/20 OU. The patient responded to treatment and DLK has resolved. The association between the event and the device is unk.

Concomitant Medical Products:
NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:**
- **Email:**
- **Phone:** *
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00034</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>19-Apr-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>20-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9): 

Event Description (B5):
Mfr 25-APR-2007: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY IN 2007. ONE WEEK POSTOPERATIVELY, THE PT PRESENTED WITH STAGE 2 DIFFUSE LAMELLAR KERATITIS (DLK) IN RIGHT (OD) EYE. A FLAP LIFT AND RINSE WAS PERFORMED OD ONE DAY LATER. PT WAS TREATED WITH TOPICAL STEROIDS. THE PT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OD. POSTOPERATIVE BCVA IS 20/30 OD. THE PT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNK.

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9): 

Recd: 757
Page: 1,517
Date Last Updated: 11/2/2010 9:17 AM
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Email:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**

**Occupation:** 001 - PHYSICIAN
MFR Report No: 2032002-2007-00035
Mfr Name: INTRA LASE CORP.

Event Date (B3): 20-Mar-2007
Report Date (B4): 21-Mar-2007
Date Mfr Rec'd (G4): 21-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Oct-2004
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20003</td>
</tr>
<tr>
<td>Catalog</td>
<td>20003</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

| Name             | *                                  |
| Address          | [Redacted]                         |
| Email            | [Redacted]                         |
| Phone            | [Redacted]                         |
| International    | [Redacted]                         |
| Fax              |                                    |
| Health Professional: | Yes                          |

Occupation: 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

#### Date Received

20-Mar-2007

#### MFR Report No:

2032002-2007-00036

#### Mfr Name:

INTRA LASE CORP.

#### Event Date (B3):

20-Mar-2007

#### Report Date (B4):

21-Mar-2007

#### Report Date (F8):

21-Mar-2007

#### Date Mfr Rec’d (G4):

21-Mar-2007

#### Event Report Type:

INJURY

#### Event Outcome (B2):

REQUIRED INTERVENTION

#### Reporter Occupation (E3):

001 - PHYSICIAN

#### Device Operator:

HEALTH PROFESSIONAL

#### Adverse Event (B1):

Y

#### Problem (B1):

N

#### Event Location (F12):

REPORTER OCCUPATION

#### Report Source (G3):

HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

#### Product Code:

(OP)-LASER, OPHTHALMIC (HQF)

#### Device Available for Evaluation:

Y

#### Device Evaluated by Manufacturer (H3):

No

#### Remedial Action (H7):

Correction/Removal No (H9):

---

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRALASE CORP.

**Address:**

9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:**

Y

**Device Evaluated by Manufacturer (H3):**

No

**Remedial Action (H7):**

Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (b)
- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2007-00037
Mfr Name: INTRA LASE CORP. 19-Apr-2007

Event Date (B3): 21-Mar-2007
Report Date (B4): 21-Mar-2007
Report Date (F8):
Date Mfr Rec'd (G4): 21-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (B4): 21-Mar-2007
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Adverse Event (B1): Y
Problem (B1): N

Report Date (F8):
Date Mfr Rec'd (G4):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): 
Expiration Date: 

Manufacture Date (H4): 01-Oct-2004
Single Use (H5): N
Device Usage (H8): R

Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):


Concomitant Medical Products:

NA

Device Available for Evaluation: Y

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: *
- Address: (b) (b)
- Email: (b) (b)
- Phone: (b) (b)
- International: (b) (b)
- Fax: (b) (b)

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00038
Mfr Name: INTRA LASE CORP.

Event Date (B3): 22-Mar-2007
Report Date (B4): Omitted
Report Date (F8):
Date Mfr Rec’d (G4):

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (B4): Omitted
Report Source (G3): HEALTH PROFESSIONAL

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):

Event Description (B5):

Concomitant Medical Products:
NA

Device Age (F9):
Expiration Date:

Manufacture Date (H4): 01-Oct-2004
Single Use (H5): N
Device Usage (H8): R

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Remedial Action (H7):
Correction/Removal No (H9):

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [REDACTED]
Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2007-00039
Mfr Name: INTRA LASE CORP.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Event Outcome (B2):</th>
<th>Event Location (F12):</th>
</tr>
</thead>
</table>

| Report Date (B4): | 21-Mar-2007
| Report Date (F8): |
| Date Mfr Rec'd (G4): | 21-Mar-2007

| Reporter Occupation (E3): | Device Operator: |
| 001 - PHYSICIAN | HEALTH PROFESSIONAL |

| Product Code: | Device Age (F9): | Manufacture Date (H4): | Expiration Date: |
| (OP)-LASER, OPHTHALMIC (HQF) | | 01-Oct-2004 | |

| Single Use (H5): | Device Usage (H8): |
| N | R |

| Event Description (B5): |

| Concomitant Medical Products: |
| NA |

| Mfr Name: | Address: |
| INTRALASE CORP. | 9701 JERONIMO ROAD |
| | IRVINE, CA 92618 |
| | UNITED STATES |

| Device Available for Evaluation: | Device Evaluated by Manufacturer (H3): |
| Y | Yes |

| Remedial Action (H7): |

| Correction/Removal No (H9): |

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: **N**

REPORTER INFORMATION:
- **Name:** *
- **Address:** *(b)(6)*
- **Email:** *(b)(6)*
- **Phone:** *(b)(6)*
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
<table>
<thead>
<tr>
<th>Event Date (B3): 23-Mar-2007</th>
<th>Event Report Type: INJURY</th>
<th>Adverse Event (B1): Y</th>
<th>Report Date (F8): Omitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td>Problem (B1): N</td>
<td>Report Date (F8):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>HEALTH PROFESSIONAL, USER</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>FACILITY, COMPANY</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>REPRESENTATIVE</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Event Description (B5):**


**Concomitant Medical Products:**

**Mfr Name:** INTRALASE CORP.

**Address:** 9701 JERONIMO ROAD

**IRVINE, CA 92618**

**UNITED STATES**

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Date Last Updated: 11/2/2010  9:17 AM**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: (b) (b)
Health Professional: Yes

EMAIL: (b) (b)
Phone: (b) (b)
International: (b) (b)
Fax: (b) (b)

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00041  Mfr Name: INTRA LASE CORP.

Event Date (B3): 20-Mar-2007  Event Report Type: INJURY
Report Date (F8): 21-Mar-2007  Reporter Occupation (E3): 001 - PHYSICIAN
Date Mfr Rec'd (G4): 21-Mar-2007  Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y  Problem (B1): N
Event Location (F12): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): 01-Oct-2004  Manufacture Date (H4): 01-Oct-2004
Expiration Date:  N  Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products: NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *(b) (b)*
- **Email:** *(b) (b)*
- **Phone:** *(b) (b)*
- **International:** *(b) (b)*
- **Fax:** *
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2007-04-23

MFR Report No: 2032002-2007-00043
Mfr Name: INTRA LASE CORP.

Event Date (B3): 23-Mar-2007
Report Date (B4): 23-Mar-2007
Report Date (F8):
Date Mfr Rec'd (G4): 23-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 23-Mar-2007
Event Location (F12):

Adverse Event (B1): Y
Problem (B1): N
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)

Device Age (F9): Manufacture Date (H4): 01-Aug-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): Correction/Removal No (H9):

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Date Last Updated: 11/2/2010 9:17 AM
Additional Mfr Narrative (H10 & H11):
25-APR-2007: ON 02/06/2007, A FIELD SERVICE ENGINEER PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE FOLLOWING MONTH, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE DEVICE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. EVEN THOUGH THE SITE USES POWDER FREE GLOVES, WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT. VENTILATION SYSTEM NOT WORKING EFFECTIVELY AND WHITE POWDER FOUND ON EQUIPMENT.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 001 - PHYSICIAN
MFR Report No: 2032002-2007-00044
Mfr Name: INTRA LASER CORP.

Event Date (B3): 23-Mar-2007
Report Date (B4): 23-Mar-2007
Report Date (F8):
Date Mfr Rec'd (G4): 23-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y  Problem (B1): N

Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Aug-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 25-APR-2007: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY IN 2007. POSTOPERATIVELY THE PT PRESENTED WITH STAGE 2+ DIFFUSE LAMELLAR KERATITIS (DLK) IN LEFT (OS) EYE. THE NEXT DAY, A FLAP LIFT AND RINSE WAS PERFORMED ON OS. THE DOCTOR OPTED TO PERFORM THE FLAP LIFT AND RINSE AS HE WAS NOT GOING TO BE IN THE OFFICE FOR SEVERAL DAYS. PT WAS TREATED WITH TOPICAL STEROIDS AND A BANDAGE SOFT CONTACT LENS WAS PLACE ON OS. THE PT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POSTOPERATIVE UNCORRECTED VISUAL ACUITY (UCVA) IS 20/15 OD AND 20/20+2 OS. THE PATIENT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
25-APR-2007: ON 02/06/07, A FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. ON 03/15/07, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND OBSERVED THE SITE HAS BEEN MODIFYING THEIR LASER SETTINGS ON A CONTINUOUS BASIS, AGAINST THE ADVISE OF THE CAS. ADDITIONALLY, THE SITE HAS HAD ON-GOING CONSTRUCTION ADJACENT TO THE SURGICAL SUITE SINCE 2006 THAT IS STIRRING UP DUST AND DEBRIS IN THE AREA. AN ENVIRONMENTAL COMPANY EVALUATED THE SURGICAL SITE AND NOTED THAT THE VENTILATION SYSTEM WAS NOT WORKING EFFECTIVELY, MOST LIKELY DUE TO AN AIR FILTER THAT WAS IMPROPERLY INSTALLED. EVEN THOUGH THE SITE USES POWDER FREE GLOVES, WHITE POWDER WAS OBSERVED ON EQUIPMENT AND NOTED IN THE ENVIRONMENTAL REPORT. VENTILATION SYSTEM NOT WORKING EFFECTIVELY AND WHITE POWDER FOUND ON EQUIPMENT.

OTHER: VENTILATION SYSTEM NOT WORKING EFFECTIVELY AND WHITE POWDER FOUND ON EQUIPMENT.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (6)
Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00045
Mfr Name: INTRA LASE CORP.

Date Received: 02-Nov-2010
Date Rept Rec'd: 30-Mar-2007
Report Date (B4): 30-Mar-2007
Event Date (B3): 30-Mar-2007
Event Description (B5):
Mfr 02-MAY-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY, THE NEXT DAY, THE PT PRESENTED WITH STAGE 1+ DIFFUSE LAMELLAR KERATITIS (DLK) IN BOTH (OU) EYES. A FLAP LIFT AND RINSE WAS PERFORMED PRIOR TO THAT DAY. PT WAS TREATED WITH TOPICAL STEROIDS. THE PT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POSTOPERATIVE UNCORRECTED VISUAL ACUITY (BCVA) IS 20/25 OD AND 20/25+2 OS. THE PT IS RESPONDING TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNK.

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:
Manufacture Date (H4): 01-Aug-2006

Single Use (H5): N
Device Usage (H8): R

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3):
HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Report Date (B4): 30-Mar-2007
Report Date (F8): 30-Mar-2007
Report Date (F12): 30-Mar-2007

Date Last Updated: 11/2/2010 9:17 AM
Recd: 768 Page: 1,539

DEVICE INFORMATION:
- Brand: INTRALASE FS LASER
- Device Type: LASER KERATOME
- Device Type: 20003
- Catalog: 20003
- Serial: (*confidential*)
- Lot: NA
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: *
- Address: [ ]
- Health Professional: Yes
- EMAIL: [ ]
- Phone: [ ]
- International: [ ]
- Fax: [ ]
- Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2032002-2007-00046

Mfr Name: INTRA LASE CORP.

Event Date (B3): 30-Mar-2007
Report Date (B4): 30-Mar-2007
Report Date (F8):
Date Mfr Rec'd (G4): 30-Mar-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Location (E3):
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12):
Report Source (G3):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Description:

Device Age (F9): Manufacture Date (H4): 01-Aug-2006
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:

NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00047</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>27-Apr-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>30-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Reporter Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Mar-2007</td>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 02-MAY-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. ONE DAY POSTOPERATIVELY, THE NEXT DAY, THE PT PRESENTED WITH STAGE 1+ DIFFUSE LAMELLAR KERATITIS (DLK) IN BOTH (OU) EYES AND A FLAP LIFT AND RINSE WAS PERFORMED. PT WAS TREATED WITH TOPICAL STERORDS AND A BANDAGE SOFT CONTACT LENS (BSCL) WAS PLACED OU. THE FOLLOWING DAY, THE DR OPTED TO PERFORM A SECOND FLAP LIFT AND RINSE OU, NO BSCL PLACED. THE PT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 BOTH (OU) EYES. POSTOPERATIVE BCVA IS 20/20-1 OD AND 20/30+1 OS. PT IS RESPONDING TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNK.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>INTRALASE CORP.</td>
<td>Address:</td>
<td>9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 770  
Page: 1,543  
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [redacted]
Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00048</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>25-Apr-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>26-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Mar-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
</tbody>
</table>

Product Code: (OP)-LASER, OPHTHALMIC (HQF)

Device Age (F9): Manufacture Date (H4): 01-Sep-2006

Expiration Date:

Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products: NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

30-APR-2007: ON 2/27/07 AND 2/28/07, AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE, ADJUSTED MICROSCOPE CONTRAST VALUE TO IMPROVE VIDEO IMAGE, PROVIDED SURGERY SUPPORT AND VERIFIED SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. ON 3/30/07 AND 4/19/07, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE, AND FOUND THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. THE LASER SETTINGS WERE MODIFIED ACCORDING TO PHYSICIAN'S PREFERENCES. STAFF AT SITE REPORTED TWO WEEKS PRIOR TO SURGICAL IN 2007, THE SITE HAD CONSTRUCTION DOWN THE CORRIDOR TO THE SURGICAL SUITE. THIS MAY HAVE BEEN CONTRIBUTING FACTOR TO THE DLK.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

EMAIL: (b) (b)
Phone: (b) (b)
International: 
Fax: 
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00049</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>04-May-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Apr-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>12-Apr-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):**

**Expiration Date:**

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** INTRA LASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
09-MAY-2007: IN 2007, A FIELD SERVICE ENGINEER (FSE) PERFORMED A SCHEDULED PREVENTATIVE MAINTENANCE. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. ONE WEEK LATER, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) VISITED THE SITE, MODIFIED LASER SETTINGS ACCORDING TO DOCTOR'S PREFERENCE AND FOUND THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20002</td>
</tr>
<tr>
<td>Catalog</td>
<td>20002</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Health Professional:</td>
<td>Yes</td>
</tr>
<tr>
<td>EMAIL:</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Phone:</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>International:</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00050</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Mar-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>30-Mar-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Mar-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Jul-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

- NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

---

Recd: 773  Page: 1,549  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

04-MAY-2007: IN 2007, AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE AND PERFORMED SCHEDULED PREVENTATIVE MAINTENANCE-NO ADJUSTMENTS WERE REQUIRED. THIRTEEN DAYS LATER, AN FSE RETURNED TO SITE DUE TO DLK REPORT AND CALIBARATED Z-BASELINE OFFSET AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PATIENT FOLLOW UP STATUS AND TRYING TO IDENTIFY A POSSIBLE ROOT CAUSE. ALTHOUGH A SINGLE ROOT CAUSE WAS NO IDENTIFIED, THE SITE MADE THE FOLLOWING CHANGES: INTRODUCED USE OF HEAD COVERINGS FOR STAFF, DISPOSABLE COVERS FOR BUTTONS ON SYSTEM WHICH ARE CHANGED AFTER EVERY PROCEDURE, USE OF DIFFERENT CANNULAE, SPECULUMS, MODIFIED ENERGY BY 0.05UJ LOWER AND CLEANED THE HUMIDIFIER AND VENTILATION SYSTEM. SINCE IMPLEMENTATION OF CHANGES NOTED ABOVE, THE SITE HAS SEEN A REDUCTION IN DLK CASES.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *
Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: * EMAIL: *
Phone: (b) (6)
International: Fax:
Health Professional: Yes
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received 2032002-2007-00051 Mfr Name: INTRA LASE CORP.

MFR Report No: 2032002-2007-00051 Mfr Name: INTRA LASE CORP.

Event Date (B3): 27-Mar-2007 Event Report Type: INJURY Adverse Event (B1): Y

Report Date (B4): 09-Apr-2007 Event Outcome (B2): REQUIRED INTERVENTION Problem (B1): N

Report Date (F8): Date Mfr Rec'd (G4): 09-Apr-2007 Event Location (F12): Reporter Occupation (E3): 001 - PHYSICIAN

Device Operator: HEALTH PROFESSIONAL

Device Evaluated by Manufacturer (H3): Yes

Device Available for Evaluation: Y

Concomitant Medical Products:

NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)

Device Age (F9): Manufacture Date (H4): 01-Jul-2006

Expiration Date: Single Use (H5): N

Device Usage (H8): R

Event Description (B5):


Concomitant Medical Products:

NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):
07-MAY-2007: ON 3/06/07 AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE AND PERFORMED SCHEDULED PREVENTATIVE MAINTENANCE - NO ADJUSTMENTS WERE REQUIRED. THE FOLLOWING MONTH, AN FSE RETURNED TO SITE DUE TO DLK REPORT AND CALIBRATED Z-BASELINE OFFSET AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PATIENT FOLLOW UP STATUS AND TRYING TO IDENTIFY A POSSIBLE ROOT CAUSE. ALTHOUGH A SINGLE ROOT CAUSE WAS NOT IDENTIFIED, THE SITE MADE THE FOLLOWING CHANGES: INTRODUCED USE OF HEAD COVERINGS FOR STAFF, DISPOSABLE COVERS FOR BUTTONS ON SYSTEM WHICH ARE CHANGED AFTER EVERY PROCEDURE, USE OF DIFFERENT CANNULAE, SPECULUMS, MODIFIED ENERGY BY 0.05UJ LOWER AND CLEANED THE HUMIDIFIER AND VENTILATION SYSTEM. SINCE IMPLEMENTATION OF CHANGES NOTED ABOVE, THE SITE HAS SEEN A REDUCTION IN DLK CASES.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: (b) (6)
Health Professional: Yes

EMAIL: 
Phone: (b) (6)
International: 
Fax: 

Occupation: 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

04-MAY-2007: IN 2007, AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE AND PERFORMED SCHEDULED PREVENTATIVE MAINTENANCE - NO ADJUSTMENTS WERE REQUIRED. THE FOLLOWING MONTH, AN FSE RETURNED TO SITE DUE TO DLK REPORT AND CALIBARATED Z-BASELINE OFFSET AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PATIENT FOLLOW UP STATUS AND TRYING TO IDENTIFY A POSSIBLE ROOT CAUSE. ALTHOUGH A SINGLE ROOT CAUSE WAS NO IDENTIFIED, THE SITE MADE THE FOLLOWING CHANGES: INTRODUCED USE OF HEAD COVERINGS FOR STAFF, DISPOSABLE COVERS FOR BUTTONS ON SYSTEM WHICH ARE CHANGED AFTER EVERY PROCEDURE, USE OF DIFFERENT CANNULAE, SPECULUMS, MODIFIED ENERGY BY 0.05UJ LOWER AND CLEANED THE HUMIDIFIER AND VENTILATION SYSTEM. SINCE IMPLEMENTATION OF CHANGES NOTED ABOVE, THE SITE HAS SEEN A REDUCTION IN DLK CASES.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** (b) (6)
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
          IRVINE, CA 92618
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
04-MAY-2007: IN 2007, AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE AND PERFORMED SCHEDULED PREVENTATIVE MAINTENANCE-NO ADJUSTMENTS WERE REQUIRED. THE FOLLOWING MONTH, AN FSE RETURNED TO SITE DUE TO DLK REPORT AND CALIBRATED Z-BASELINE OFFSET AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED UPON DEPARTURE. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PATIENT FOLLOW UP STATUS AND TRYING TO IDENTIFY A POSSIBLE ROOT CAUSE. ALTHOUGH A SINGLE ROOT CAUSE WAS NO IDENTIFIED, THE SITE MADE THE FOLLOWING CHANGES: INTRODUCED USE OF HEAD COVERINGS FOR STAFF, DISPOSABLE COVERS FOR BUTTONS ON SYSTEM WHICH ARE CHANGED AFTER EVERY PROCEDURE, USE OF DIFFERENT CANNULAE, SPECULUMS, MODIFIED ENERGY BY 0.05UJ LOWER AND CLEANED THE HUMIDIFIER AND VENTILATION SYSTEM. SINCE IMPLEMENTATION OF CHANGES NOTED ABOVE, THE SITE HAS SEEN A REDUCTION IN DLK CASES.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KARATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20003</td>
</tr>
<tr>
<td>Catalog</td>
<td>20003</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] (6)</td>
</tr>
</tbody>
</table>

Health Professional: Yes

<table>
<thead>
<tr>
<th>EMAIL</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
</tbody>
</table>

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00054</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Mar-2007</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>02-May-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-May-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

| Product Code: | (OP)-LASER, OPHTHALMIC (HQF) |
| Device Age (F9): | |
| Expiration Date: | |
| Manufacture Date (H4): | 01-Jun-2006 |
| Single Use (H5): | N |
| Device Usage (H8): | R |

### Event Description (B5):


### Concomitant Medical Products:

NA

### Device Available for Evaluation: Y

Device Available for Evaluation by Manufacturer (H3): Yes

### Remedial Action (H7): Corrected/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-JUN-2007: ON 4/19/07, A FIELD SVC ENGINEER (FSE) PERFORMED PREVENTIVE MAINTENANCE, AND THE LASER MAINTENANCE PERFORMED AS INTENDED, AND MET SPECIFICATIONS. ON 5/08/07, AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) VISITED THE SITE, AND PERFORMED AN INVESTIGATION IN ATTEMPT TO DETERMINE A ROOT CAUSE. PER CAS, THE SURGEON BELIEVES THE REPORTED ISSUE IS RELATED TO SOMETHING IN THE OFFICE AND NOT THE LASER SYS. SURGEON IS SEEKING CAS EXPERTISE TO HELP IDENTIFY A ROOT CAUSE. CAS MADE RECOMMENDATIONS REGARDING POTENTIAL CONTRIBUTORS RELATED TO INSTRUMENT PREPARATION AND STERILIZATION PRACTICES. THE CAS DID NOT IDENTIFY ANY UNUSUAL ENVIRONMENTAL OR SURGICAL TECHNIQUE ISSUES.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Email: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Health Professional: Yes
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Nov-2010

Event Date (B3): 29-Apr-2007
Report Date (B4): 02-May-2007
Report Date (F8):
Date Mfr Rec'd (G4): 08-May-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):

Report Source (G3): USER FACILITY, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Jun-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 13-JUN-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007, IN BOTH (OU) EYES. ONE DAY POSTOPERATIVELY (THE FOLLOWING DAY), THE PT PRESENTED WITH DIFFUSE LAMELLAR KERATITIS (DLK) WITH CENTRAL TOXIC KERATOPATHY (CTK). THE PT WAS TREATED WITH TOPICAL STEROIDS. THE PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. THE PT'S CURRENT POSTOPERATIVE BCVA IS 20/50 + OD AND BCVA 20/30+OS. ADD'L INFO HAS BEEN REQUESTED FROM THE SITE, BUT NONE HAS BEEN FORTHCOMING. IF ADD'L INFO IS RECEIVED, A SUPPLEMENTAL MEDWATCH SHALL BE FILED WITH FDA. THE PHYSICIAN DOES NOT BELIEVE THE EVENT IS DEVICE RELATED.

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
13-JUN-2007: AN FIELD SVC ENGINEER (FSE) PERFORMED PREVENTIVE MAINTENANCE ON 04/19/07, AND THE LASER SYS PERFORMED AS INTENDED, AND MET SPECIFICATIONS. ON 05/08/07, AN INTRALASE CLINICAL APPLICATION SPECIALIST (CAS) VISITED THE SITE AND PERFORMED AN INVESTIGATION IN ATTEMPT TO DETERMINE A ROOT CAUSE. PER CAS, THE SURGEON BELIEVES THE REPORTED ISSUE IS RELATED TO SOMETHING IN THE OFFICE AND NOT THE LASER SYS. SURGEON IS SEEKING CAS EXPERTISE TO HELP IDENTIFY A ROOT CAUSE. CAS MADE RECOMMENDATIONS REGARDING POTENTIAL CONTRIBUTORS RELATED TO INSTRUMENT PREPARATION AND STERILIZATION PRACTICES. THE CAS DID NOT IDENTIFY ANY USUAL ENVIRONMENTAL OR SURGICAL TECHNIQUE ISSUES.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>22-May-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>29-May-2007</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>03-Jun-2007</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>02-Jul-2007</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

---

**MFR Report No:** 2032002-2007-00056

**Mfr Name:** INTRALASE CORP.

**Event Report Type:** INJURY

**Event Outcome (B2):** REQUIRED INTERVENTION

**Reporter Occupation (E3):** 001 - PHYSICIAN

**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):** Manufacture Date (H4): 01-Jul-2006

**Expiration Date:** Single Use (H5): N

**Device Usage (H8):** R

**Adverse Event (B1):** Y  Problem (B1): N

**Event Location (F12):**

**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KEROTOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20003</td>
</tr>
<tr>
<td>Catalog</td>
<td>20003</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Email</th>
<th>Phone</th>
<th>International</th>
<th>Fax</th>
<th>Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>[b] (6)</td>
<td>[b] (6)</td>
<td></td>
<td></td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

**Health Professional:** Yes
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00057</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>26-May-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>29-May-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>03-Jun-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Report Source (G3):</td>
<td>USER FACILITY, COMPANY REPRESENTATIVE, HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)

**Device Age (F9):**

**Manufacture Date (H4):** 01-Jul-2006

**Expiration Date:**

**Single Use (H5):** N

**Device Usage (H8):** R
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2007-00058</th>
<th>Mfr Name: INTRALASE CORP.</th>
<th>Date Received: 02-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 24-May-2007</td>
<td>Event Report Type: INJURY</td>
<td>Event Location (F12): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Report Date (B4): 30-May-2007</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 04-Jun-2007</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product Code: (OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Feb-2007</td>
</tr>
<tr>
<td></td>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: INTRALASE CORP.</td>
<td>Address: 9701 JERONIMO ROAD IRVINE, CA 92618 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 781 Page: 1,565 Date Last Updated: 11/2/2010 9:17 AM

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** [b] (6)
- **Address:** [b] (6)
- **Email:** [b] (6)
- **Phone:** [b] (6)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00059
Mfr Name: INTRA LASE CORP.

- Event Date (B3): 07-Jun-2007
- Report Date (B4): 06-Jun-2007
- Report Date (F8): 11-Jun-2007
- Event Report Type: INJURY
- Event Outcome (B2): REQUIRED INTERVENTION
- Event Location (F12): FOREIGN, HEALTH PROFESSIONAL, USER FACILITY
- Reporter Occupation (E3): 001 - PHYSICIAN
- Device Operator: HEALTH PROFESSIONAL
- Date Mfr Rec'd (G4): 10-Jul-2007
- Product Code: (OP)-LASER, OPHTHALMIC (HQF)
- Device Age (F9): Manufacture Date (H4): 01-Aug-2006
- Expiration Date: Single Use (H5): N
- Device Usage (H8): R
- Adverse Event (B1): Y
- Problem (B1): N

Event Description (B5):

Concomitant Medical Products: NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
   IRVINE, CA 92618
   UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

12-JUL-2007: ON JUNE 7, 2007 A FIELD SVC ENGINEER (FSE) INSPECTED THE LASER AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PT DETAILS. THE CAS ASSESSED THE SURGEON'S LASER SETTINGS, SURGICAL TECHNIQUE, AND STERILITY PROCESS TO DETERMINE POSSIBLE ROOT CAUSE(S). THE FACILITY REPORTED LASER SETTINGS ARE CHANGED PRIOR TO SURGERY PER SURGEON'S INSTRUCTIONS AND PTS ARE TREATED ONE AT A TIME. SURGEON STARTED USING A NEW FLAP LIFTER, INSTALLED NEW CEILING IN THE LASER ROOM, INSTALLED AIR CONDITIONING UNIT, AND THERE IS NO VENTILATION SYSTEM IN PLACE. THE SITE USES DISPOSABLE SURGICAL INSTRUMENTS, AND PRE-SET SURGERY TRAYS AT START OF SURGERY DAY. SURGEON RINSES WITH BALANCED SALT SOLUTION APPLIED THROUGH CANNULA. ALTHOUGH THE SURGEON BELIEVES DLK IS MOST LIKELY DUE TO A NEW FLAP LIFTER AND NOT THE INTRALASE FS LASER SYS, A ROOT CAUSE HAS NOT BEEN CONFIRMED FOR THE REPORTED EVENT.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00060  Mfr Name: INTRA LASE CORP.

Event Date (B3): 07-Jun-2007  Event Report Type: INJURY
Report Date (B4): 06-Jun-2007  Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 11-Jun-2007  Reporter Occupation (E3): 001 - PHYSICIAN
Date Mfr Rec'd (G4): 10-Jul-2007  Device Operator: HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): 01-Aug-2006  Single Use (H5): N
Expiration Date: 01-Aug-2006  Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Remedial Action (H7):
Correction/Removal No (H9):

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Recd: 783  Page: 1,569  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
12-JUL-2007: ON JUNE 7, 2007 A FIELD SVC ENGINEER (FSE) INSPECTED THE LASER AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PT DETAILS. THE CAS ASSESSED THE SURGEON'S LASER SETTINGS, SURGICAL TECHNIQUE, AND STERILITY PROCESS TO DETERMINE POSSIBLE ROOT CAUSE(S). THE FACILITY REPORTED LASER SETTINGS ARE CHANGED PRIOR TO SURGERY PER SURGEON'S INSTRUCTIONS AND PTS ARE TREATED ONE AT A TIME. SURGEON STARTED USING A NEW FLAP LIFTER, INSTALLED NEW CEILING IN THE LASER ROOM, INSTALLED AIR CONDITIONING UNIT, AND THERE IS NO VENTILATION SYSTEM IN PLACE. THE SITE USES DISPOSABLE SURGICAL INSTRUMENTS, AND PRE-SET SURGERY TRAYS AT START OF SURGERY DAY. SURGEON RINSES WITH BALANCED SALT SOLUTION APPLIED THROUGH CANNULA. ALTHOUGH THE SURGEON BELIEVES DLK IS MOST LIKELY DUE TO A NEW FLAP LIFTER AND NOT THE INTRALASE FS LASER SYS, A ROOT CAUSE HAS NOT BEEN CONFIRMED FOR THE REPORTED EVENT.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20003</td>
</tr>
<tr>
<td>Catalog</td>
<td>20003</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

| Name:            |                           |
| Address:         | (b) (6)                   |

Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2007-06-08
Mfr Name: INTRA LASE CORP.

Event Date (B3): 08-Jun-2007
Report Date (B4): 08-Jun-2007
Report Date (F8): 11-Jun-2007
Date Mfr Rec'd (G4): 10-Jul-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): 01-Aug-2006
Expiration Date:
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-JUL-2007: ON JUNE 7, 2007 A FIELD SVC ENGINEER (FSE) INSPECTED THE LASER AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PT DETAILS. THE CAS ASSESSED THE SURGEON'S LASER SETTINGS, SURGICAL TECHNIQUE, AND STERILITY PROCESS TO DETERMINE POSSIBLE ROOT CAUSE(S). THE FACILITY REPORTED LASER SETTINGS ARE CHANGED PRIOR TO SURGERY PER SURGEON'S INSTRUCTIONS AND PTS ARE TREATED ONE AT A TIME. SURGEON STARTED USING A NEW FLAP LIFTER, INSTALLED NEW CEILING IN THE LASER ROOM, INSTALLED AIR CONDITIONING UNIT, AND THERE IS NO VENTILATION SYSTEM IN PLACE. THE SITE USES DISPOSABLE SURGICAL INSTRUMENTS, AND PRE-SET SURGERY TRAYS AT START OF SURGERY DAY. SURGEON RINSES WITH BALANCED SALT SOLUTION APPLIED THROUGH CANNULA. A ROOT CAUSE HAS NOT BEEN CONFIRMED FOR THE REPORTED EVENT.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN
Event Date (B3): 06-Jun-2007
Report Date (B4): 06-Jun-2007
Report Date (F8):
Date Mfr Rec'd (G4): 11-Jun-2007
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Device Operator: HEALTH PROFESSIONAL
Event Location (F12):
Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, USER FACILITY
Adverse Event (B1): Y Problem (B1): N
Concomitant Medical Products: NA
Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

12-JUL-2007: ON JUNE 7, 2007 A FIELD SVC ENGINEER (FSE) INSPECTED THE LASER AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PT DETAILS. THE CAS ASSESSED THE SURGEON'S LASER SETTINGS, SURGICAL TECHNIQUE, AND STERILITY PROCESS TO DETERMINE POSSIBLE ROOT CAUSE(S). THE FACILITY REPORTED LASER SETTINGS ARE CHANGED PRIOR TO SURGERY PER SURGEON'S INSTRUCTIONS AND PTS ARE TREATED ONE AT A TIME. SURGEON STARTED USING A NEW FLAP LIFTER, INSTALLED NEW CEILING IN THE LASER ROOM, INSTALLED AIR CONDITIONING UNIT, AND THERE IS NO VENTILATION SYSTEM IN PLACE. THE SITE USES DISPOSABLE SURGICAL INSTRUMENTS, AND PRE-SET SURGERY TRAYS AT START OF SURGERY DAY. SURGEON RINSES WITH BALANCED SALT SOLUTION APPLIED THROUGH CANNULA. ALTHOUGH THE SURGEON BELIEVES DLK IS MOST LIKELY DUE TO A NEW FLAP LIFTER AND NOT THE INTRALASE FS LASER SYS, A ROOT CAUSE HAS NOT BEEN CONFIRMED FOR THE REPORTED EVENT.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN

Recd: 785  Page: 1,574  Date Last Updated: 11/2/2010 9:17 AM
Event Description (B5):

Concomitant Medical Products:

NA

Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
12-JUL-2007: ON JUNE 7, 2007 A FIELD SVC ENGINEER (FSE) INSPECTED THE LASER AND FOUND THE SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. SINCE REPORT OF EVENT, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PT DETAILS. THE CAS ASSESSED THE SURGEON'S LASER SETTINGS, SURGICAL TECHNIQUE, AND STERILITY PROCESS TO DETERMINE POSSIBLE ROOT CAUSE(S). THE FACILITY REPORTED LASER SETTINGS ARE CHANGED PRIOR TO SURGERY PER SURGEON'S INSTRUCTIONS AND PTS ARE TREATED ONE AT A TIME. SURGEON STARTED USING A NEW FLAP LIFTER, INSTALLED NEW CEILING IN THE LASER ROOM, INSTALLED AIR CONDITIONING UNIT, AND THERE IS NO VENTILATION SYSTEM IN PLACE. THE SITE USES DISPOSABLE SURGICAL INSTRUMENTS, AND PRE-SET SURGERY TRAYS AT START OF SURGERY DAY. SURGEON RINSES WITH BALANCED SALT SOLUTION APPLIED THROUGH CANNULA. A ROOT CAUSE HAS NOT BEEN CONFIRMED FOR THE REPORTED EVENT.

**DEVICE INFORMATION:**
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:**
- **Address:** (b) (6)
- **Email:**
- **Phone:**
- **International:** (b) (6)
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00064</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received</th>
<th>27-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Apr-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>28-Jun-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Report Source (G3):</td>
<td>FOREIGN, HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>01-Sep-2004</td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

VISX

**Mfr Name:** INTRALASE CORP.
**Address:** 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>INTRALASE FS LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER KERATOME</td>
</tr>
<tr>
<td>Device Type</td>
<td>20003</td>
</tr>
<tr>
<td>Catalog</td>
<td>20003</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Health Professional: Yes
Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00065</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>28-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>25-May-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>05-Jul-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>9701 JERONIMO ROAD</td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92618</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

| Correction/Removal No (H9): | |

Recd: 788 Page: 1,579 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

02-AUG-2007: AN INTRALASE FIELD SERVICE ENGINEER (FSE) PERFORMED PREVENTIVE MAINTENANCE ON MAY 04, 2007 AND THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT IN 2007 AND HAS BEEN IN CONTACT WITH THE SITE OBTAINING PATIENT FOLLOW-UP STATUS, AS WELL AS TRYING TO IDENTIFY A POTENTIAL ROOT CAUSE FOR DLK. THE CASE AND SITE BELIEVE THAT THE DLK IS NOT LASER SYSTEM OR SURGICAL TECHNIQUE RELATED. THE SITE BELIEVES THAT THE INFLAMMATION WAS CAUSED BY UNFILTERED AIR BEING DRAWN INTO THE ROOM FROM OPEN AIR DUCTS IN THE CEILING. THE SITE HAS INDICATED THE AIR DUCTS HAVE BEEN BLOCKED AND THEY HAVE STARTED PRE-TREATING PATIENTS WITH TOPICAL STEROIDS PRIOR TO TREATMENT. THE FOLLOWING MONTH, THE CAS PERFORMED SURGERY SUPPORT AS FOLLOW TO DLK REPORT AND THERE WERE NO MORE ISSUES REPORTED.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

OCCUPATION: 001 - PHYSICIAN

EMAIL: [b] (6)
Phone: [b] (6)
International Fax:
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00066</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received:</th>
<th>06-Sep-2007</th>
</tr>
</thead>
</table>

**Event Date (B3):** 02-Jul-2007  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Reporter Occupation (E3):** 001 - PHYSICIAN  
**Device Operator:** HEALTH PROFESSIONAL  
**Adverse Event (B1):** Y  
**Problem (B1):** N  
**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):** R

**Event Description (B5):**  

**Concomitant Medical Products:** NA

**Mfr Name:** INTRALASE CORP.  
**Address:** 9701 JERONIMO ROAD  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**  
**Correction/Removal No (H9):**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN
Event Date (B3): 22-Aug-2007
Report Date (B4): 04-Sep-2007
Report Date (F8): 
Date Mfr Rec’d (G4): 04-Sep-2007
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION

Mfr Report No: 2032002-2007-00067
Mfr Name: INTRA LASE CORP.

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12): 

Event Description (B5):
Mfr 11-SEP-2007: THE INTRALASE FS LASER WAS USED TO CREATE BILATERAL CORNEAL FLAPS FOR LASIK SURGERY IN 2007. POSTOPERATIVELY (EIGHT DAYS LATER) THE PATIENT WAS PRESENTED WITH CENTRAL DIFFUSE LAMELLAR KERATITIS (DLK) IN BOTH EYES (OU). THE RIGHT (OD) EYE WITH STAGE 2+ DLK AND THE LEFT (OS) WITH 4+ DLK AND SLIGHT CORNEAL MELTING. A FLAP LIFT AND RINSE WAS PERFORMED ON LEFT EYE ONLY. THE PATIENT WAS TREATED WITH STEROIDS. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20. PATIENT'S POSTOPERATIVE BCVA IS 20/30 +0.25+0.25X115 OS WITH MILD HAZE AND 20/20 OD. THE PATIENT IS RESPONDING TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNK.

Concomitant Medical Products:
NA

Mfr Name: INTRALASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

11-SEP-2007: AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) HAS BEEN IN CONTACT WITH THE SITE OBTAINING PATIENT FOLLOW-UP STATUS, AS WELL AS TRYING TO IDENTIFY A POTENTIAL ROOT CAUSE FOR DLK. THE CAS VISITED THE SITE IN 2007 AND PERFORMED AN INVESTIGATION. IN SUMMARY, THE PROBABLE ROOT CAUSE APPEARS TO BE ASSOCIATED WITH THE SITE NOT DRAINING THEIR STERILIZER REGULARLY. THE CAS ADVISED SITE REGARDING STERILIZATION PRACTICES AND THE SITE HAS SINCE CHANGED THEIR STATIM 2000 STERILIZER TO A GRAHAM AUTOCLAVE STERILIZER. IN ADDITION, SURGICAL INSTRUMENTS ARE NOW PUT IN AN ULTRASONIC CLEANER, PACKAGED, AND THEN AUTOCLAVED. DLK HAS RESOLVED SINCE NOTED CHANGES WERE IMPLEMENTED.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (b) (b)
- **International:** (b) (b)
- **Fax:** [Redacted]

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
MFR Report No: 2032002-2007-00068  Mfr Name: INTRA LASE CORP.

Event Date (B3): 24-Aug-2007  Report Date (B4): 24-Aug-2007
Report Date (F8):
Date Mfr Rec'd (G4): 24-Aug-2007

Event Report Type: INJURY  Event Outcome (B2): REQUIRED INTERVENTION
Event Location (F12):
Report Source (G3):

Device Usage (H8): R  Device Age (F9):
Manufacture Date (H4): 01-Feb-2007
Single Use (H5): N

Event Description (B5):
Mfr 25-SEP-2007: THE INTRALASE FS LASER WAS USED TO CREATE A CORNEAL FLAP FOR LASIK SURGERY IN 2007 ON PATIENT'S LEFT (OS) EYE. THE DOCTOR REPORTED HE EXPERIENCED A DIFFICULT FLAP LIFT, EXCESSIVE OPAQUE BUBBLE LAYER (OBL) AND CENTRATION DIFFICULTIES AS PATIENT HAD LOOSE EPITHELIUM. A BANDAGE CONTACT LENS (BCL) WAS PLACED DUE TO AN IRREGULAR CORNEAL SURFACE. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20-2 OS. PATIENT'S POSTOPERATIVE BCVA IS 20/60 OS. CURRENT BCVA HAS BEEN REQUESTED FROM THE FACILITY, BUT INFORMATION HAS NOT BEEN PROVIDED AS OF 9/21/07. IF ADDITIONAL INFORMATION BECOMES AVAILABLE, A SUPPLEMENTAL REPORT WILL BE SUBMITTED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Concomitant Medical Products:
NA

Device Available for Evaluation: Y  Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

25-SEP-2007: AN INTRALASE FIELD SERVICE ENGINEER (FSE) VERIFIED COMPLETE SYSTEM OPERATION, AND FOUND THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED.

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00069</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received: 28-Sep-2007</th>
</tr>
</thead>
</table>

**Event Date (B3):** 09-Aug-2007  
**Report Date (B4):** 29-Aug-2007  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 29-Aug-2007  

**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE  

**Device Operator:** HEALTH PROFESSIONAL  
**Problem (B1):** N  
**Report Date (B4):** 29-Aug-2007  

**Product Code:** (OP)-KNIFE (HNO)  
**Device Age (F9):**  
**Expiration Date:**  

**Manufacture Date (H4):** 01-Oct-2006  
**Single Use (H5):** N  
**Device Usage (H8):** R  

**Event Description (B5):**

**Concomitant Medical Products:**
NA

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 2003
- **Catalog:** 2003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032002-2007-00070</th>
<th>Mfr Name:</th>
<th>INTRA LASE CORP.</th>
<th>Date Received: 28-Sep-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>23-Aug-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4)</td>
<td>29-Aug-2007</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-KNIFE (HNO)</td>
<td>Manufacturer Date (H4):</td>
<td>01-Oct-2006</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

- NA

Mfr Name: INTRALASE CORP
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
CDRH
MAUDE EVENT REPORT (FOI)
02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2032002-2007-00071  Mfr Name: INTRA LASE CORP.

Date Received: 2007-00071

Date Rec'd (G4): 21-Sep-2007

Event Date (B3): 16-Sep-2007

Report Date (B4): 21-Sep-2007

Report Date (F8):

Date Mfr Rec'd (G4): 21-Sep-2007

Product Code: (OP)-KNIFE (HNO)

Device Code: (OP)-KNIFE (HNO)

Device Age (F9):

Expiration Date:

Device Evaluated by Manufacturer (H3): Yes

Device Available for Evaluation: Y

Concomitant Medical Products:

NA

Mfr Name: INTRA LASE CORP.

Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES

Remedial Action (H7):

Correction/Removal No (H9):

Event Description (B5):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
23-OCT-2007: IN 2007, AN INTRALASE FIELD SERVICE ENGINEER INSPECTED THE LASER AND PERFORMED PREVENTATIVE MAINTENANCE AS PART OF HIS ASSESSMENT. THE LASER SYSTEM MET SPECIFICATIONS AND PERFORMED AS INTENDED. ON THREE DAYS LATER, AN INTRALASE CLINICAL APPLICATIONS SPECIALIST (CAS) PROVIDED SURGERY SUPPORT AND PERFORMED AN INVESTIGATION IN EFFORT TO IDENTIFY A POTENTIAL ROOT CAUSE FOR DLK. THE CAS ACCESSED THE LASER SYSTEM, SURGICAL TECHNIQUE, STERILITY AND SURGICAL INSTRUMENTATION PRACTICES. THERE WERE NO ANOMALIES NOTED AND THE LASER MET SPECIFICATIONS AND PERFORMED AS INTENDED.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
Event Date (B3): 19-Oct-2007
Report Date (B4): 19-Nov-2007
Report Date (F8):
Date Mfr Rec'd (G4): 19-Nov-2007
MFR Report No: 2032002-2007-00072
Mfr Name: INTRA LASE CORP.
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Event Location (F12):
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Manufacture Date (H4): 01-Apr-2006
Expiration Date:
Single Use (H5): N
Device Usage (H8): R
Event Description (B5):
(APPROXIMATELY A WEEK LATER), PATIENT WAS NOTED TO HAVE ELEVATED INTRAOCULAR PRESSURE (IOP) IN THE RIGHT (OD) EYE DUE TO
PIGMENTARY GLAUCOMA. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/15 OD. POSTOPERATIVELY, THE
PATIENT'S BCVA IS 20/40 OD. PATIENT TREATED WITH MEDICATIONS TO ADDRESS THE INCREASED IOP. UPDATED PATIENT STATUS WAS REQUESTED,
BUT INFORMATION HAS NOT BEEN PROVIDED TO FILUTOWSKI EYE INSTITUTE BY CO-MANAGED OFFICE AS OF APPROX TWO MONTHS LATER.
HOWEVER, IF ADDITIONAL INFORMATION BECOMES AVAILABLE, SUPPLEMENTAL REPORT WILL BE SUBMITTED TO FDA. THE ASSOCIATION BETWEEN
THE EVENT AND THE DEVICE IS UNKNOWN.
Concomitant Medical Products:
Mfr Name: INTRA LASE CORP.
Address: 9701 JERONIMO ROAD
IRVINE, CA 92618
UNITED STATES
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

**DEVICE INFORMATION:**

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Health Professional: Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 07-Feb-2008
Report Date (B4): 07-Feb-2008
Report Date (F8): 07-Feb-2008
Date Mfr Rec'd (G4): 07-Feb-2008

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Manufacture Date (H4): 01-Oct-2006
Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: AMO MANUFACTURING USA, LLC
Address: IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
10-MAR-2008: A CLINICAL DEVELOPMENT SPECIALIST (CDS) HAS BEEN IN CONTACT WITH THE PHYSICIAN SINCE 2008 OBTAINING PATIENT FOLLOW-UP STATUS. ACCORDING TO THE PHYSICIAN, THE ROOT CAUSE OF THE REPORTED EVENT OF INCOMPLETE SIDE CUT AND DISSECTION THAT LEAD TO THE PATIENT'S CORNEA BEING PERFORATED WAS RELATED TO PATIENT MOVEMENT. PATIENT IS DOING GREAT AND IS CONSIDERING SURFACE ABLATION IN THE FUTURE. SYSTEM WAS CHECKED AND WAS WITHIN SPECIFICATIONS. ABORTED PROCEDURE - INCOMPLETE FLAP - MANUAL DISSECTION.

DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID:

Reprocessed & Reused:  N

REPORTER INFORMATION:

Name:  
Address: (b) (6)

EMAIL: (b) (6)
Phone: (b) (6)
International:  
Fax:  

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2032002-2008-00003</th>
<th>Mfr Name: INTRA LASE CORP.</th>
<th>Adverse Event (B1): Y</th>
<th>Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 19-May-2008</td>
<td>Event Report Type: INJURY</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 20-Jun-2008</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 23-Jun-2008</td>
<td>Report Date (F8): OTHER</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: AMO MANUFACTURING USA, LLC
Address: IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
30-JUL-2008: A CLINICAL DEVELOPMENT SPECIALIST (CDS) HAS BEEN IN CONTACT WITH THE PHYSICIAN SINCE 2008 OBTAINING PATIENT FOLLOW-UP STATUS. DLK AND SPK HAS RESOLVED. ON THE DAY BEFORE, AN INTRALASE FIELD SERVICE ENGINEER (FSE) VISITED THE SITE AND PERFORMED A FIELD VALIDATION. NO PROBLEMS DIRECTLY RELATED TO DLK WAS FOUND WITH THE SYSTEM. PERFORM PM. OTHER, SUPERFICIAL PUNCTATE KERATITIS (SPK); FLAP STRIAE; EPITHELIAL SCRAPED.

DEVICE INFORMATION:
- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Health Professional:** Yes
- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2032006-2006-00065</th>
<th>Mfr Name:</th>
<th>DENOVO</th>
<th>Date Received</th>
<th>12-Oct-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>15-Sep-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Sep-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>15-Sep-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td></td>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>15-Sep-2006</td>
<td>Mfr 16-OCT-2006:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Sep-2006</td>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Mfr Name: INTRALASE CORP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Address: 9701 JERONIMO ROAD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IRVINE, CA 92618</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>16-OCT-2006:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20004
- **Catalog:** 20004
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [REDACTED]
- **Health Professional:** Yes

**EMAIL:** [REDACTED]
**Phone:** [REDACTED]
**International:** [REDACTED]
**Fax:** [REDACTED]

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Report Details

**MFR Report No:** 2134812-2004-00439  
**Mfr Name:** VASCULAR SOLUTIONS, INC.

**Event Date (B3):** 28-Sep-2004  
**Report Date (B4):** 08-Nov-2004  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 29-Sep-2004  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:** 30-Nov-2005  

**Event Description (B5):**

Mfr 10-NOV-2004: PHYSICIAN WAS PERFORMING ENDOVENOUS LASER TREATMENT (FIBER PULL BACK STEP) WHEN HE FELT A WARMTH ON THE PALM OF HIS HAND. THERE WAS A RED GLOW (LASER POSITIONING BEAM) AND THE SHEATH HAD A HOLE IN IT AT THE LEVEL OF HIS PALM. HIS GLOVE HAD A BLACK SPOT WITH A MINOR BURN ON THE PHYSICIAN'S PALM BENEATH IT. HE PROMPTLY PLACED HIS HAND IN ICE WATER. THERE HAD BEEN NO RESISTANCE NOTED IN PULLING BACK THE SHEATH/FIBER. THE PHYSICIAN DETERMINED THAT THE PT'S VEIN HAD BEEN SUFFICIENTLY TREATED TO ENSURE A GOOD CLINICAL OUTCOME.

**Concomitant Medical Products:**

**Mfr Name:** VASCULAR SOLUTIONS, INC.  
**Address:** *MINNEAPOLIS, MN *UNITED STATES

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

10-NOV-2004: PHYSICIAN ALSO REPORTED ANOTHER FIBER FROM THE SAME LOT # HAD BROKEN DURING USE IN A PREVIOUS PT.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: VARI-LASE ENDOVENOUS LASER KIT
- Device Type: LASER PRODUCT
- Device Type: 7040
- Catalog: 10-0417
- Serial: (*confidential*)
- Lot: 300948
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Email: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
- Health Professional: Yes
- Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2134812-2005-00442
Mfr Name: VASCULAR SOLUTIONS, INC. 02-Mar-2005
Event Date (B3): 10-Dec-2004
Report Date (B4): 01-Mar-2005
Report Date (F8): 
Date Mfr Rec’d (G4): 02-Feb-2005
MFR Report No: 2134812-2005-00442
Event Report Type: INJURY
Event Outcome (B2): 
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): 
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY
Report Date (F8): 001 - PHYSICIAN
Event Description (B5):
Mfr 04-MAR-2005: ONE WEEK FOLLOWING A VARI-LASE ENDOVENOUS LASER PROCEDURE, THE PT RETURNED TO THE CLINIC WITH PAIN RELATED TO A 5-10 MM SKIN BURN AT THE SHEATH SITE AND PHLEBITIS. THE SITE WAS TREATED WITH NEOSPORIN AND COMPRESSION. THE EVENT WAS RESOLVED WITH NO FURTHER COMPLICATIONS.
Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS
Address: *
    MINNEAPOLIS, MN *
    UNITED STATES
Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
04-MAR-2005:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VARI-LASE PROCEDURE KIT
Device Type: LASER INSTRUMENT FIBER
Device Type: 7000
Catalog: *
Serial: (*confidential*)
Lot: UNK
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: (*)
International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2134812-2005-00443
Mfr Name: VASCULAR SOLUTIONS, INC. 17-Mar-2005
Event Date (B3): 10-Dec-2004
Report Date (B4): 01-Mar-2005
Report Date (F8): 18-Feb-2005
Date Mfr Rec'd (G4): 17-Mar-2005
Event Report Type: INJURY
Event Outcome (B2): 001 - PHYSICIAN
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Manufacture Date (H4):
Single Use (H5): Y
Expiration Date:
Device Usage (H8): I
Event Description (B5):
Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: *
MINNEAPOLIS, MN *
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 21-MAR-2005:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE PROCEDURE KIT
- **Device Type:** LASER INSTRUMENT FIBER
- **Device Type:** 7000
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Recd: 801  Page: 1,606  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>05-Jan-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>22-Mar-2005</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>18-Feb-2005</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Feb-2005</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2134812-2005-00444</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>05-Jan-2005</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

| Mfr Name: | VASCULAR SOLUTIONS, INC. |
| Address: | MINNEAPOLIS, MN | UNITED STATES |

**Remedial Action (H7):**

Correction/Removal No (H9): 

Additional Mfr Narrative (H10 & H11): 24-MAR-2005:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE PROCEDURE KIT
- **Device Type:** LASER INSTRUMENT FIBER
- **Device Type:** 7000
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2005-00456</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>20-Jul-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Aug-2005</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>22-Jul-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 24-AUG-2005: THE PATIENT UNDERWENT AN ENDOVENOUS LASER TREATMENT. A REPORT FROM THE PHYSICIAN INDICATES THAT DURING A FOLLOW-UP VISIT, A FRAGMENT WHICH MAY BE A PIECE OF LASER FIBER WAS VISIBLE VIA ULTRASOUND. VSI IS WAITING FOR ADDITIONAL INFORMATION REGARDING THE CIRCUMSTANCES AND RESOLUTION OF THE EVENT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>* MINNEAPOLIS, MN * UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>24-AUG-2005: THIS EVENT REMAINS UNDER INVESTIGATION.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Received: 22-Aug-2005

Report Date (F8): 19-Aug-2005

Event Location (F12):|

Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VARI-LASE ENDOVENOUS LASER PROCEDURE KIT
Device Type: LASER INSTRUMENT FIBER AND PROCEDURE KIT
Device Type: 7000
Catalog: *
Serial: (*confidential*)
Lot: UNK
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: 

Health Professional: Yes

EMAIL: 
Phone: (*)
International:
Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2005-00457</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
<th>Date Received</th>
<th>26-Aug-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>26-Jul-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>26-Jul-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufature Date (H4):
Expiration Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: *
MINNEAPOLIS, MN *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
29-AUG-2005: THIS EVENT REMAINS UNDER INVESTIGATION.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER PROCEDURE KIT
- **Device Type:** LASER INSTRUMENT FIBER AND PROCEDURE KIT
- **Device Type:** 7000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [ ]
- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

Health Professional: Yes

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2005-00460</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
<th>Date Received:</th>
<th>16-Sep-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Aug-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Sep-2005</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Aug-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Evaluated by Manufacturer (H3): Yes

Event Description (B5):

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: *
MINNEAPOLIS, MN *
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-SEP-2005: VISUAL INSPECTION VERIFIED THAT THE SEATH WAS BURNED, BUT NO CONNECTION CAN BE MADE BETWEEN THE BURNED SHEATH AND THE THROMBUS WHICH WAS REMOVED.
CDRH
MAUDE EVENT REPORT (FOI)
02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** VARI-LASE ENDOVENOUS LASER PROCEDURE KIT
- **Device Type:** LASER INSTRUMENT FIBER AND PROCEDURE KIT
- **Device Type:** 7040
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010  9:17 AM
Recd: 805  Page: 1,614

[Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2005-00461</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
<th>Date Received:</th>
<th>16-Sep-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Aug-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Event Location (F12):</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>16-Sep-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Aug-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 01-Aug-2001
Expiration Date:
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>MINNEAPOLIS, MN * UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER PROCEDURE KIT
- **Device Type:** LASER INSTRUMENT FIBER AND KIT
- **Device Type:** 7000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 301351
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** *
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>30-Aug-2005</th>
<th>Event Report Type:</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>30-Sep-2005</td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

Mfr Name: VASCULAR SOLUTIONS
Address: MINNEAPOLIS, MN UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
01-NOV-2005: THE INVESTIGATION OF THIS THIS INCIDENT IS NOT YET COMPLETE.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER PROCEDURE KIT
- **Device Type:** LASER FIBER AND PROCEDURE KIT
- **Device Type:** 7040
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 301336
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

Health Professional: Yes

Occupation: UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>10-Oct-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>09-Nov-2005</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>10-Oct-2005</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>10-Oct-2005</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>*</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 10-NOV-2005: AN ENDOVENOUS LASER TREATMENT WAS PERFORMED IN 05. UPON REMOVAL OF THE SHEATH AND FIBER, THE USER NOTED THAT A PIECE OF SHEATH HAD REMAINED IN THE THIGH OF THE PATIENT. THE ENTIRE SAPHEOUS VEIN WAS THROMBOSED AROUND THE PIECE OF SHEATH AND WAS NOT REMOVED. TO DATE, THE SHEATH REMAINS IN THE THIGH AND THERE HAVE BEEN NO FURTHER COMPLICATIONS. ALTHOUGH THIS CASE HAS NOT YET REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT OR DAMAGE, IT HAS BEEN REPORTED DUE TO THE POSSIBILITY OF FUTURE INTERVENTION.

**Concomitant Medical Products:**

| Mfr Name: | VASCULAR SOLUTIONS, INC. |
| Address: | MINNEAPOLIS, MN * UNITED STATES |
| Device Available for Evaluation: | N |
| Device Evaluated by Manufacturer (H3): | Device not Returned to Manufacturer |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 10-NOV-2005: |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** VARI-LASE ENDOVENOUS KIT
- **Device Type:** LASER FIBER AND PROCEDURE KIT
- **Device Type:** 7000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** *
- **International:**
- **Fax:**

**Health Professional:** Yes

**Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2006-00006</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Jan-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>29-Mar-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>09-Jan-2006</td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>31-May-2007</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 03-APR-2006: AFTER PERFORMING AN ENDOVENOUS LASER PROCEDURE IN THE GREAT SAPHENOUS VEIN, THE PHYSICIAN NOTED THAT APPROX 2CM OF THE LASER AT THE DISTAL END WAS MISSING. AT THIS TIME THERE ARE NO KNOWN PT COMPLICATIONS AND IT IS UNK WHETHER OR NOT THE LASER FIBER TIP BROKE OFF IN THE PT. THIS EVENT IS BEING REPORTED AS A POSSIBLE DEVICE MALFUNCTION.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: *</td>
<td>MINNEAPOLIS, MN 55169</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS PROCEDURE KIT
- **Device Type:** LASER INSTRUMENT FIBER & PROCEDURE KIT
- **Device Type:** 7040
  - **Catalog:** *
  - **Serial:** (*confidential*)
  - **Lot:** 301531
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2134812-2006-00011  Mfr Name: VASCULAR SOLUTIONS, INC.

Event Date (B3): 21-Jul-2006  Event Report Type: MALFUNCTION
Report Date (B4): 31-Jul-2006
Report Date (F8):
Date Mfr Rec’d (G4): 24-Jul-2006

Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiry Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: * MINNEAPOLIS, MN 55369 UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 23-AUG-2006:

Date Last Updated: 11/2/2010  9:17 AM

MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VARI-LASE ENDOVENOUS LASER KIT
Device Type: LASER FIBER AND PROCEDURE KIT
Device Type: 7062
Catalog: *
Serial: (*confidential*)
Lot: UNK
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: [b] (b)

Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Occupation: 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
Event Description (B5):
Mfr 08-AUG-2006: AN ENDOVENOUS LASER PROCEDURE WAS PERFORMED WITH NO REPORTED COMPLICATIONS. UPON A FOLLOW-UP VENOUS DOPPLER EXAMINATION, A DEEP VEIN THROMBOSIS (DVT) THAT EXTENDED INTO THE EPIGASTRIC VEIN WAS OBSERVED. THE PATIENT'S DOSAGE OF LOVENOX WAS INCREASED IN RESPONSE TO THE DVT. NO FURTHER COMPLICATIONS WERE REPORTED.

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: *
MINNEAPOLIS, MN 55369
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
08-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER FIBER AND PROCEDURE KIT
- **Device Type:** 7000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 503375
- **Other ID:** *
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** *
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
AN ENDOVENOUS LASER PROCEDURE WAS PERFORMED IN 2006, WITH NO REPORTED COMPLICATIONS. THREE WEEKS LATER, THE PT WAS ADMITTED TO THE EMERGENCY ROOM AND TREATED FOR DEEP-VEIN THROMBOSIS. THE THROMBOSIS WAS LYSED AND WAS REPORTED TO HAVE RESOLVED. THE RELATIONSHIP OF THIS DEEP-VEIN THROMBOSIS TO THE ENDOVENOUS LASER TREATMENT HAS NOT BEEN ESTABLISHED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** VERI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER FIBER AND PROCEDURE KIT
- **Device Type:** 7063
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 503522
- **Other ID:** *
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:**
- **Phone:** (*)
- **International:**
- **Fax:**
- **Recd:** 812
- **Page:** 1,628
- **Date Last Updated:** 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2134812-2006-00017
Mfr Name: VASCULAR SOLUTIONS, INC.
Event Date (B3): 13-Sep-2006
Report Date (B4): 30-Oct-2006
Report Date (F8): 
Date Mfr Rec'd (G4): 29-Sep-2006
Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): * - INVALID DATA
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Problem (B1): N
Event Location (F12): Report Source (G3): USER FACILITY, COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): *

Event Description (B5):

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7): 
Correction/Removal No (H9): 

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: *
MINNEAPOLIS, MN 55369
UNITED STATES

Date Last Updated: 11/2/2010 9:17 AM
Additional Mfr Narrative (H10 & H11):

20-MAR-2007: RESULTS; DESCRIPTION. NO SIMILAR REPORTS HAVE BEEN MADE TO VSI FOR THIS LOT NUMBER (LOT #301831). THE DEVICE WAS RETURNED TO VSI AND EVALUATED. ALSO, A SIMULATED-USE EXPERIMENT RECREATED A SIMILAR DEVICE CONDITION AS THE RETURNED DEVICE. CONCLUSION; DESCRIPTION. ALTHOUGH A SIMILAR DEVICE CONDITION AS THE RETURNED DEVICE WAS RECREATED IN A SIMULATED-USE EXPERIMENT, A CONCLUSION AS TO THE CAUSE OF THE STRETCHED SHEATH COULD NOT BE MADE.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER FIBER AND PROCEDURE KIT
- **Device Type:** 7000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 301831
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:**
  - (b) (6)
  - [redacted]
- **Phone:** (*)
- **International:**
- **Fax:**

- **Health Professional:** No Information
- **Occupation:** * - INVALID DATA
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

|-----------------|---------------------|-----------|--------------------------|----------------------|-------------|

Event Date (B3): 12-Oct-2006  
Report Date (B4): 02-Nov-2006  
Report Date (F8):  
Date Mfr Rec'd (G4): 12-Oct-2006

Event Report Type: INJURY  
Event Date (B3): 12-Oct-2006

Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
Report Date (B4): 02-Nov-2006

Event Location (F12):  
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

Adverse Event (B1): Y  
Problem (B1): N

MFR Report No:  
Report Date (F8):  
Date Mfr Rec'd (G4): 12-Oct-2006

Event Description (B5):

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.  
Address: *MINNEAPOLIS, MN 55369  
UNITED STATES

Device Available for Evaluation: N  
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11): 03-NOV-2006:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VARI-LASE ENDOVENOUS LASER KIT
Device Type: LASER FIBER AND PROCEDURE KIT
Device Type: 7040
Catalog: *
Serial: (*confidential*)
Lot: 503234
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: *

EMAIL: *
Phone: (*)
International: *
Fax: *

Health Professional: Yes

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2134812-2006-00019</th>
<th>Mfr Name: VASCULAR SOLUTIONS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 02-Oct-2006</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (B4): 07-Nov-2006</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 13-Oct-2006</td>
<td>Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): I</td>
</tr>
<tr>
<td></td>
<td>Event Description (B5):</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mfr Name: VASCULAR SOLUTIONS, INC.</td>
</tr>
<tr>
<td></td>
<td>Address: *</td>
</tr>
<tr>
<td></td>
<td>MINNEAPOLIS, MN 55369</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Available for Evaluation: N</td>
</tr>
<tr>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
</tr>
<tr>
<td></td>
<td>Device not Returned to Manufacturer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>
DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER FIBER
- **Device Type:** 7020
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 302445
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** *
- **Address:** *(b) (b)*
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **Email:**
- **Phone:** (*)
- **International:**
- **Fax:**

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received:** 2134812-2007-00008

**Mfr Name:** VASCULAR SOLUTIONS, INC.

| Event Date (B3):       | 07-May-2007 |
| Report Date (B4):      | 22-May-2007 |
| Date Mfr Rec'd (G4):   | 08-May-2007 |

**Event Report Type:** INJURY

**Event Date (B3):** 07-May-2007

**Report Date (F8):** 22-May-2007

**Date Mfr Rec'd (G4):** 08-May-2007

**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

**Device Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):**

**Event Description (B5):**


**Concomitant Medical Products:**

UNKNOWN

**Mfr Name:** VASCULAR SOLUTIONS, INC.

**Address:** MINNEAPOLIS, MN 55369

UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

24-MAY-2007:

---

Recd: 816

Page: 1,635

Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER INSTRUMENT
- **Device Type:** 7000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** 302300.4
- **Other ID:**

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:** [REDACTED]
- **Email:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** -

Date Last Updated: 11/2/2010  9:17 AM
Recd: 816  Page: 1,636
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 09-May-2007 | Event Report Type: | INJURY |
| Report Date (B4): | 22-May-2007 | Event Outcome (B2): | REQUIRED INTERVENTION |
| Report Date (F8): | | Reporter Occupation (E3): | 001 - PHYSICIAN |
| Date Mfr Rec'd (G4): | 14-May-2007 | Device Operator: | HEALTH PROFESSIONAL |
| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) | |
| Device Age (F9): | | |
| Expiration Date: | | |
| Single Use (H5): | Y |
| Device Usage (H8): | I |
| Concomitant Medical Products: | UNKNOWN |
| Mfr Name: | VASCULAR SOLUTIONS, INC. |
| Address: | MINNEAPOLIS, MN 55369 |
| UNITED STATES |
| Device Available for Evaluation: | N |
| Device Evaluated by Manufacturer (H3): | Device not Returned to Manufacturer |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 24-MAY-2007: |

Recd: 817 | Page: 1,637 | Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER INSTRUMENT
- **Device Type:** 7101
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** 540287
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2007-00010</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
<th>Date Received</th>
<th>13-Jun-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-May-2007</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
<td>Address:</td>
<td>MINNEAPOLIS, MN 55369 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
<td>Address:</td>
<td>MINNEAPOLIS, MN 55369 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 818 Page: 1,639
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER INSTRUMENT
- **Device Type:** 700C
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** 504258
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:** [REDACTED]
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

Health Professional: Yes

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>16-Aug-2007</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>25-Jul-2007</td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Code:</td>
<td></td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
<td>Address:</td>
<td>MINNEAPOLIS, MN 55369</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>21-AUG-2007: METHOD: DEVICE EXPERIENCE NARRATIVE STATED THAT OPERATOR ADJUSTED THE FIBER LOCK TO THE WRONG MARK FOR THE SHEATH USED. BASED ON THE NARRATIVE, DEVICE APPEARED TO OPERATE CORRECTLY.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>VARI-LASE ENDOVENOUS LASER KIT</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT</td>
</tr>
<tr>
<td>Device Type</td>
<td>7073</td>
</tr>
<tr>
<td>Catalog</td>
<td></td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>540924</td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>[REDACTED]</td>
</tr>
<tr>
<td>Address</td>
<td>[REDACTED]</td>
</tr>
<tr>
<td>EMAIL</td>
<td>[REDACTED]</td>
</tr>
<tr>
<td>Phone</td>
<td>[REDACTED]</td>
</tr>
<tr>
<td>International</td>
<td>[REDACTED]</td>
</tr>
<tr>
<td>Fax</td>
<td>[REDACTED]</td>
</tr>
<tr>
<td>Health Professional:</td>
<td>Yes</td>
</tr>
<tr>
<td>Occupation</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2008-00004</th>
<th>Mfr Name: VASCULAR SOLUTIONS, INC.</th>
<th>Date Received: 12-May-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>14-Jan-2008</td>
<td>Event Report Type: INJURY</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-May-2008</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>29-Feb-2008</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5): Y</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: VASCULAR SOLUTIONS, INC.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: MINNEAPOLIS, MN 55369</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>16-MAY-2008:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VARI-LASE ENDOVENOUS LASER KIT
- **Device Type:** LASER INSTRUMENT
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]

    - Health Professional: Yes

    - **EMAIL:**
    - **Phone:**
    - **International:**
    - **Fax:**

    - **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2009-00014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 01-May-2009

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):**

**Report Date (F8):** 29-May-2009

**Date Mfr Rec'd (G4):** 01-May-2009


**Concomitant Medical Products:**

- **Mfr Name: VASCULAR SOLUTIONS, INC.**
- **Address: 6464 SYCAMORE COURT
MINNEAPOLIS, MN
UNITED STATES**

- **Device Available for Evaluation:** Y
- **Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

18-SEP-2009: NO PATIENT IMPACT OR HARM REPORTED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** VARI-LASE BRIGHT TIP FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 10-0557
- **Serial:** (*confidential*)
- **Lot:** 544860
- **Other ID:**

Reprocessed & Reused: N

REPORter INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

Health Professional: Yes

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2134812-2009-00017

Mfr Name: VASCULAR SOLUTIONS, INC.

Event Date (B3): 29-May-2009
Event Report Type: MALFUNCTION
Event Outcome (B2):
Adverse Event (B1):
Problem (B1): N

Event Location (F12):
Report Source (G3):
HEALTH PROFESSIONAL
HEALTH PROFESSIONAL,
COMPANY REPRESENTATIVE

MFR Report No: 2134812-2009-00017
Report Date (B4): 29-Jul-2009
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Date Mfr Rec'd (G4): 01-Jun-2009
Report Date (F8):

Event Description (B5):

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: 6464 SYCAMORE COURT
MINNEAPOLIS, MN 55369
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

06-NOV-2009:

DEVICE INFORMATION:

Brand: VARI-LASE PROCEDURE KIT
Device Type: LASER FIBER
Device Type: 7115
Catalog: 
Serial: (*confidential*)
Lot: 545543
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [D] (5)
Address: [D] (5)

Email: 
Phone: 
International: 
Fax: 

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

Date Received: 2134812-2009-00022

**Mfr Name:** VASCULAR SOLUTIONS, INC.

**Event Date (B3):** 02-Aug-2009

**Report Date (B4):** 09-Sep-2009

**Report Date (F8):**

**Date Mfr Rec’d (G4):** 13-Aug-2009

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):** HOSPITALIZATION

**Reporter Occupation (E3):** 001 - PHYSICIAN

**Device Operator:** PHYSICIAN

**Adverse Event (B1):** Y

**Problem (B1):** Y

**Event Location (F12):**

**Report Source (G3):** HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Manufacture Date (H4):**

**Expiration Date:**

**Single Use (H5):** Y

**Device Usage (H8):** I

**Event Description (B5):**

Mfr 10-SEP-2009: PATIENT DEVELOPED AN ABSCESS AFTER HAVING LASER TREATMENT. PATIENT NEEDED TO BE HOSPITALIZED AND UNDER WENT SURGERY. A FOREIGN BODY WAS REMOVED FROM THE ABSCESS AND WAS FOUND TO BE A PORTION OF THE FIBER’S CERAMIC TIP.

**Concomitant Medical Products:**

**Mfr Name:** VASCULAR SOLUTIONS INC.

**Address:** 6464 SYCAMORE COURT
MINNEAPOLIS, MN 55369
UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

10-SEP-2009: (B) (4) : DEVICE NOT RETURNED TO MANUFACTURER.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VARI-LASE BRIGHT TIP FIBER  
Device Type: LASER FIBER  
Device Type: UNKNOWN  
Catalog: (*)confidential*)  
Serial:  
Lot: UNKNOWN  
Other ID:  
Reprocessed & Reused: N

REPORTER INFORMATION:

Name:  
Address: [redacted]  
EMAIL:  
Phone:  
International:  
Fax:  
Health Professional: Yes  
Occupation: 001 - PHYSICIAN  

[823] Record: 823  
[1,650] Page: 1,650  
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2134812-2009-00034</th>
<th>Mfr Name:</th>
<th>VASCULAR SOLUTIONS, INC.</th>
<th>Date Received</th>
<th>13-Nov-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Oct-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>12-Nov-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>VASCULAR SOLUTIONS, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>6464 SYCAMORE COURT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MINNEAPOLIS, MN 55369</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13-NOV-2009: DEVICE EVALUATION IN PROCESS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** VARI-LASE LASER CONSOLE
- **Device Type:** LASER CONSOLE
- **Device Type:** 7500 D
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No Answer
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 24-Aug-2009
Report Date (B4): 23-Dec-2009
Report Date (F8): Date Mfr Rec'd (G4): 23-Nov-2009

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): Device Operator: PHYSICIAN

Adverse Event (B1): Y
Problem (B1): Y
Event Location (F12): Reporter Occupation (E3): Device Operator: PHYSICIAN
Event Location (F12): Reporter Occupation (E3): Device Operator: PHYSICIAN
Report Source (G3): HEALTH PROFESSIONAL

Device Operator: PHYSICIAN
Device Operator: PHYSICIAN

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): 05-Aug-2009
Expiration Date: 01-May-2011

Device Usage (H8): U
Single Use (H5): Y

Event Description (B5):

Concomitant Medical Products:

Mfr Name: VASCULAR SOLUTIONS, INC.
Address: 6464 SYCAMORE COURT
MINNEAPOLIS, MN 55369
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
23-DEC-2009: (B) (4): NOT RETURNED TO MANUFACTURER.

**DEVICE INFORMATION:**

- **Brand:** VARI-LASE STANDARD PROCEDURE KIT
- **Device Type:** LASER FIBER AND PROCEDURE KIT
- **Device Type:** 7112
- **Catalog:** 7112
- **Serial:** (*confidential*)
- **Lot:** 546508
- **Other ID:** 10-0506-14

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>14-Feb-2003</th>
<th>Event Report Type:</th>
<th>*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td>Date Mfr Rec'd (G4):</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

| Mfr Name: | CLARUS MEDICAL, LLC. |

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 18-MAR-2003: THE PHYSICIAN THAT AFTER A DISCECTOMY PROCEDURE THE PATIENT REPORTED BI-LATERAL FOOT DROP AND DYSESTHESIA. THE PATIENT IS BEING TREATED BY A PHYSICIAN FOR THESE PROBLEMS.

**Concomitant Medical Products:**

**Mfr Name:** CLARUS MEDICAL, LLC.

**Address:**
1000 BOONE AVE. NORTH
SUITE 300
MINNEAPOLIS, MN 55427
UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

18-MAR-2003: CO HAS TALKED TO THE HOSPITAL STAFF AND PHYSICIAN AND NO ONE IS ALLEGING A DEVICE FAILURE. NO DEVICE WAS RETURNED FROM THE INCIDENT.
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: CLARUS LASE
Device Type: LASER ASSISED SPINAL DISCECTOMY
Device Type: 1100-010
Catalog: 1100-010
Serial: (*confidential*)
Lot: UNK
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Health Professional: Yes

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2183911-2004-00002</th>
<th>Mfr Name:</th>
<th>CLARUS MEDICAL, LLC.</th>
<th>Date Received</th>
<th>19-Apr-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>11-Apr-2004</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>* - INVALID DATA</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>UNKNOWN</td>
<td>Report Source (G3):</td>
<td>SUMMONS</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 27-OCT-2004: MFR REC'D A SUMMONS IN REGARDS TO THIS MATTER. ALL THAT IS KNOWN IS THE DATE OF THE EVENT AND A CLAIM OF INJURY TO THE PT, BY THE PT. PLACE OF EVENT, PHYSICIAN AND TYPE(MODEL), SERIAL NUMBER OF DEVICE CLAIMED TO CAUSE THE INJURY ARE ALL UNK.

Concomitant Medical Products:

| Mfr Name: | CLARUS MEDICAL, LLC. |
| Address: | *
| MINNEAPOLIS, MN *
| UNITED STATES |

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-OCT-2004: DEVICE NOT RETURNED. THIS IS THE FIRST CO HAS HEARD OF AN ADVERSE EVENT FROM THIS CLAIM. THE MODEL NUMBER AND S/N OF THE DEVICE ARE UNK AT THIS TIME.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER KIT DEVICE
Device Type: LASER ASSISTED ENDOSCOPIC SPINAL DISECTOMY
Device Type: UNK
Catalog: UNK
Serial: (*confidential*)
Lot: UNK
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: *
Address: *

EMAIL: 
Phone: (*)
International: 
Fax: 

Health Professional: No Information

Occupation: * - INVALID DATA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2183911-2007-00001  Mfr Name: CLARUS MEDICAL, LLC.

Event Date (B3): 28-Jul-2003  Event Report Type: OTHER
Report Date (B4): 17-Jan-2007  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8): 15-Jan-2007  Reporter Occupation (E3): OTHER
Date Mfr Rec'd (G4): 17-Jan-2007

Device Operator: HEALTH PROFESSIONAL  Report Source (G3): INDEPENDENT SALES REP

Mfr Name: CLARUS MEDICAL, LLC.
Address: *
MINNEAPOLIS, MN 55427
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Event Description (B5):

Concomitant Medical Products:

Device Evaluated by Manufacturer (H3):

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
25-JAN-2007: NO PROBLEM WITH THE DEVICE OR PROCEDURE WERE REPORTED BY THE SALES REP. OR ATTENDING PHYSICIAN. CLARUS MEDICAL FIRST AWARE OF POTENTIAL PT INJURY WHEN NOTIFIED OF A LAWSUIT BY AN INDEPENDENT SALES REP ON 01/15/2007. NO DEVICE HAS BEEN RETURNED FOR EVALUATION. NO DEVICE WAS EVALUATED SINCE ALL OF THE INFO WE HAVE INDICATES, THIS WAS NOT A DEVICE PROBLEM.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASER
- **Device Type:** LASER DISCECTOMY DEVICE
- **Device Type:** NI
- **Catalog:** NI
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** OTHER
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 2183929-1997-00001</th>
<th>Mfr Name: VASAMEDICS, L.L.C.</th>
<th>Adverse Event (B1): Y</th>
<th>Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 11-Feb-1997</td>
<td>Event Report Type: INJURY</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 10-Mar-1997</td>
<td>Reporter Occupation (E3): OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 14-Feb-1997</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code: (CV)-ULTRASOUND (DPW)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jul-1991</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: VASAMEDICS L.L.C.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 2963 YORKTON BLVD. ST PAUL, MN 55117 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7): INSPECTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASERFLO
- **Device Type:** LASER DOPPLER BLOOD FLOW MONITOR
- **Device Type:** BPM2
- **Catalog:** BPM2
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** OTHER
**Event Description (B5):**

**Concomitant Medical Products:**
UNK

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**
13-APR-2006: 510(K)# IS K023182.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LASER - INDIgo OPTIMA LASER SYSTEM
- **Device Type:** LASER INSTRUMENT SURGICAL, POWERED
- **Catalog:** LS83F
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

EMAIL: [Redacted]
Phone: [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2210968-2006-00378</th>
<th>Mfr Name:</th>
<th>ETHICON, INC.</th>
<th>Date Received</th>
<th>24-May-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-Apr-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>24-May-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>24-Apr-2006</td>
<td>Reporter Occupation (E3):</td>
<td>UNK - UNKNOWN</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>24-Apr-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Apr-2006</td>
<td>MFR Report No:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

UNK

**Mfr Name:** ETHICON, INC.

**Address:** *

SOMERVILLE, NJ 08876
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):** 26-MAY-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: DIFFUSER TIP FIBEROPTIC - INDIGO OPITMA LASER SYS
- **Device Type**: LASER INSTRUMENT, SURGICAL, POWERED
- **Catalog**: LF001
- **Serial**: (*confidential*)
- **Lot**: Y4550C
- **Other ID**: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name**: (b) (6)
- **Address**: (b) (6)
- **EMAIL**: (b) (6)
- **Phone**: (b) (6)
- **International**: (b) (6)
- **Fax**: (b) (6)
- **Health Professional**: No
- **Occupation**: UNK - UNKNOWN

Recd: 831  Page: 1,666  Date Last Updated: 11/2/2010 9:17 AM
### Event Description (B5):

ONE WEEK AFTER THE PROCEDURE AND THE PATIENT EXPERIENCED A BURNING SENSATION UPON URINATION. A URINE SAMPLE WAS TAKEN AND
THE PATIENT’S BLADDER WAS EMPTYING NORMALLY. THE PATIENT STATE THAT THE PHYSICIAN DID NOT INDICATE THE PRESENCE OF A URINARY
TRACT INFECTION, BUT THE PATIENT WAS PRESCRIBED CIPRO. THE FOLLOWING WEEK THE PATIENT UNDERWENT A SUCCESSFUL CIRCUMCISION.

### Concomitant Medical Products:

UNK

### Device Available for Evaluation:

N

### Device Evaluated by Manufacturer (H3):

Device not Returned to Manufacturer

### Remedial Action (H7):

### Correction/Removal No (H9):

NA

### Additional Mfr Narrative (H10 & H11):

21-MAR-2007: CONCLUSION: NOT CONCLUSION CAN BE DRAWN AT THIS TIME. SHOULD ADDITIONAL INFORMATION BE OBTAINED, A SUPPLEMENTAL
3500A FORM WILL BE SUBMITTED ACCORDINGLY.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DIFFUSER TIP FIBEROPTIC-INDIGO OPTIMA LASER SYS
Device Type: LASER INSTRUMENT, SURGICAL, POWERED
Device Type: NA
Catalog: UNK
Serial: (*confidential*)
Lot: UNK
Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b) [b] (b)
Address: [b] (b)

EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Health Professional: No

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-1996-00011</th>
<th>Mfr Name:</th>
<th>COHERENT MEDICAL GROUP</th>
<th>Date Received</th>
<th>30-Oct-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>16-Aug-1996</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>16-Aug-1996</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

NA

**Mfr Name:** COHERENT MEDICAL GROUP

**Address:** 3270 WEST BAY SHORE ROAD
PALO ALTO, CA 94303
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer:** No

Date Last Updated: 11/2/2010 9:17 AM
07-NOV-1996: H3 USER FACILITY DISCOVERED INCORRECTLY INSTALLED CO-OBSERVATION TUBE AFTER PERSONNEL COMPLAINED OF "BRIGHTNESS" OF THE LIGHT THRU THE TUBE. USER FACILITY CORRECTLY INSTALLED THE CO-OBSERVATION TUBE AND NOTIFIED COHERENT OF INCIDENT. DEVICE WAS NOT EVALUATED BY COHERENT. IS THE FREQUENCY OF OCCURRENCE OF EVENT ADDRESSED IN DEVICE LABELING? NO. IS FREQUENCY GREATER FOR THIS EVENT THAN IS USUAL? UNK. IS THE SEVERITY OF OCCURRENCE OF EVENT ADDRESSED IN DEVICE LABELING? NO. IS SEVERITY GREATER FOR THIS EVENT THAN IS USUAL? UNK. PREPARATION OR SUBMISSION TO FDA OF THIS REPORT DOES NOT CONSTITUTE AN ADMISSION THAT THE MEDICAL DEVICE CAUSED OR CONTRIBUTED TO DEATH OR SERIOUS INJURY.

DEVICE INFORMATION:

Brand: ZEISS 30 SL/M
Device Type: LASER DELIVERY SYSTEM
Device Type: 0613-461-01
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: 
Address: 
EMAIL: 
Phone: 
International: 
Fax: 
Health Professional: No
Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 2914019-1999-00002  Mfr Name: LUMENIS, INC.  Date 03-Jun-1999

Event Date (B3): 04-May-1999    Event Report Type: OTHER
Report Date (B4): 06-May-1999    Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8):       Reporter Occupation (E3): 500 - RISK MANAGER
Date Mfr Rec'd (G4): 06-May-1999  Device Operator: OTHER
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):       Manufacture Date (H4): 01-Jan-1997
Expiration Date:       Device Evaluated by Manufacturer (H3): No
Device Usage (H8): U

Event Description (B5):
Mfr 11-JUN-1999: A FIELD SERVICE ENGINEER WAS SERVICING A VERSAPULSE LASER WHEN A REFLECTED BEAM HIT HIS EYE.

Concomitant Medical Products:
NA

Mfr Name: COHERENT MEDICAL GROUP
Address: 2400 CONDENSA ST.
SANTA CLARA, CA 95051
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
11-JUN-1999: H.3- NO EVAL OF LASER NECESSARY. CO'S FIELD SERVICE ENGINEER WAS SERVICING A VERSAPULSE LASER. HIS FACE HAD SWEAT ON IT AND AS A RESULT THE SAFETY GOGGLES SLIPPED DOWN AND HIS RETINA WAS HIT BY THE REFLECTED BEAM AT 532MM. HIS RIGHT EYE WAS HIT AND STARTED TO BLEED. HE WENT TO THE HOSPITAL AND RECEIVED MEDICATION IN THE FORM OF EYE DROPS AND DRUGS. THERE IS NO PERMANENT DAMAGE AT THIS TIME. HE WAS WEARING THE PROPER EYE WEAR. HE IS BACK TO WORK AND THE DOCTOR HAS CONFIRMED EVERYTHING IS GOING WELL WITH HIS EYE. CO HAS CONDUCTED ADDITIONAL LASER SAFETY TRAINING FOR ALL FIELD SERVICE ENGINEERS. INCIDENT WAS ALSO REPORTED TO THE GERMAN AUTHORITIES.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>VERSAPULSE AESTHETIC C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>NA</td>
</tr>
<tr>
<td>Catalog</td>
<td>0634-007-01</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>K960032</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N/A</td>
</tr>
</tbody>
</table>

REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>No</td>
</tr>
<tr>
<td>EMAIL:</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>Phone:</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td>500 - RISK MANAGER</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010  9:17 AM
Recd: 834 Page: 1,672
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-1999-00003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS, INC.</td>
</tr>
</tbody>
</table>

Event Date (B3): 08-Jul-1999
Report Date (B4): 08-Jul-1999
Report Date (F8): 08-Jul-1999
Date Mfr Rec'd (G4): 08-Jul-1999

Event Report Type: MALFUNCTION
Event Outcome (B2):
 Reporter Occupation (E3): 001 - PHYSICIAN
 Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12):
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): Manufacture Date (H4): 01-Oct-1994
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 17-AUG-1999: THE LASER CREATED A LARGER BURN ON PT THAN INTENDED. NO POWER SETTING HAD BEEN CHANGED. THE DR DESCRIBED PT'S INJURY AS NOT SERIOUS. THE BURN WAS IN THE PERIPHERAL RETINA AND WILL PERHAPS CAUSE A LARGER SCAR.

Concomitant Medical Products:
NA

Mfr Name: COHERENT MEDICAL GROUP
Address: 2400 CONDENSA ST
          SANTA CLARA, CA 95051
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):
17-AUG-1999:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Device Brand</th>
<th>ULTIMA SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>NA</td>
</tr>
<tr>
<td>Catalog</td>
<td>0619-844-01</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>K913127</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**REPORTER INFORMATION:**

| Name | [b] (6) |
| Address | [b] (6) |

| Health Professional | Yes |

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 2914019-2001-00001
Mfr Name: LUMENIS, INC.

Event Date (B3): 02-Feb-2001
Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Y
Problem (B1): N

Report Date (B4): 05-Feb-2001
Report Date (F8): 05-Feb-2001
Date Mfr Rec’d (G4): 05-Feb-2001
Event Location (F12): OUTPATIENT TREATMENT FACILITY

Mfr Name: LUMENIS, INC.
Address: 13-Apr-2001

Event Description (B5):
Mfr 17-APR-2001: A NURSE WAS TREATING A PATIENT FOR HAIR REMOVAL IN THE EYE AREA. THE PATIENT HAD EYES CLOSED AND WAS WEARING THE METAL EYE PROTECTORS. THE PATIENT FELT SOME DISCOMFORT IN ONE OF THE EYES AND WAS TREATED BY AN OPHTHALMOLOGIST FOR IRITIS. THE OPHTHALMOLOGIST STATED THAT THE PATIENT HAS PERMANENT DAMAGE TO THE IRIS, AN TINY AREA DEFORMED. HOWEVER, THIS HAS CAUSED NO DAMAGE TO EYESIGHT ACCORDING TO THE OPHTHALMOLOGIST.

Concomitant Medical Products:
NA

Mfr Name: COHERENT MEDICAL GROUP
Address: 2400 CONDENSA ST.
SANTA CLARA, CA 95051
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

H.3 - THE LIGHTSHEER SYSTEM WAS EVALUATED BY THE SERVICE DEPARTMENT AT COHERENT STAR FOR ANY POSSIBLE MALFUNCTIONS. BEAM PROFILE WAS FOUND TO BE CONSISTENT WITH PROFILES FROM OTHER SYSTEMS. THERMAL AND FINAL TESTS WERE PERFORMED AND THE SYSTEM PASSED BOTH TESTS. NO SYSTEM FAULT ERRORS WERE FOUND. SYSTEM TESTS AND EVALUATION INDICATED THE SYSTEM PERFORMED WITHIN MANUFACTURING SPECIFICATIONS. THE LIGHTSHEER SC/EC DIODE LASER SYSTEM USE MANUAL, P/N 10-03498-01.AA, HAS A DANGER NOTE: "DO NOT TREAT EYEBROWS, EYELASHES, OR OTHER AREAS WITHIN THE BONY AREA SURROUNDING THE ORBIT. THE LASER LIGHT EMITTED BY THE LIGHTSHEER IS CAPABLE OF CAUSING SERIOUS EYE DAMAGE OR BLINDNESS. FOR MAXIMUM SAFETY, METAL EYE GOGGLES MUST BE WORN BY THE PATIENT FOR ALL FACIAL TREATMENTS.

DEVICE INFORMATION:

Brand: LIGHTSHEER SYSTEM
Device Type: LASER
Device Type: NA
Catalog: 50-02717-00
Serial: (*confidential*)
Lot: NA
Other ID: K973324

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Health Professional: Yes
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2914019-2001-00002

Mfr Name: LUMENIS, INC.

Event Date (B3): 02-Feb-2001
Event Report Type: OTHER

Report Date (B4): 12-Feb-2001
Event Outcome (B2): REQUIRED INTERVENTION

Date Mfr Rec'd (G4): 11-Apr-2001
Reporter Occupation (E3): OTHER

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 24-APR-2001: A PT HAS CLAIMED 2ND DEGREE BURNS AND PERMANENT DISCOLORATION AFTER LASER HAIR REMOVAL TREATMENT. PT SOUGHT MEDICAL TREATMENT FOR BURNS. COHERENT HAS BEEN UNABLE TO CONFIRM SERIOUSNESS OF INJURY.

Concomitant Medical Products:
NA

Mfr Name: COHERENT MEDICAL GROUP
Address: 2400 CONDENSKA STREET
          SANTA CLARA, CA 95051
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Adverse Event (B1): Y  Problem (B1): N
Event Location (F12): OUTPATIENT TREATMENT FACILITY
Report Source (G3): COMPANY REPRESENTATIVE

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

24-APR-2001: THE EVENT WAS FIRST REPORTED TO COHERENT ON 2/12/2001. COHERENT WAS UNABLE TO CONFIRM PT'S CONDITION WITHIN THE 30 DAY TIME FRAME DUE TO A LAWSUIT PENDING. DECISION WAS MADE ON 4/11/2001 TO REPORT THE INCIDENT, THOUGH NO CONFIRMATION OF SERIOUSNESS OF BURN COULD BE OBTAINED. PT SOUGHT MEDICAL TREATMENT FOR SECOND DEGREE BURNS THE SAME WEEKEND AS THE TREATMENT WAS PERFORMED. THE PT IS CLAIMING PERMANENT DISCOLORATION AS WELL. THE HAIR REMOVAL TREATMENT WAS PERFORMED ON THE PT'S NECK. OBSERVATION BY COHERENT SALES REPRESENTATIVE DURING TREATMENT DETERMINED THE DR DID NOTHING IMPROPER. THREE TEST SHOTS WERE PERFORMED IN THE TREATMENT AREA WITH NO ADVERSE REACTION. LASER PARAMETERS WERE WITHIN NORMAL RANGE FOR SKIN TYPE. THE PT WAS CONSIDERED A FITZPATRICK CLASSIFICATION SKIN TYPE V. THE BURN AND PIGMENTATION CHANGE IS MOST LIKELY DUE TO THE PT'S PARTICULAR SKIN PHYSIOLOGY. THESE ARE LISTED IN THE MANUAL UNDER COMPLICATIONS AND SIDE EFFECTS AS BLISTERING AND HYPOPIGMENTATION/HYPERPIGMENTATION. H.3 - THE LASER WAS A DEMONSTRATION UNIT. IT WAS SENT BACK TO COHERENT STAR FOR EVALUATION. THE CHILL TIP TEMPERATURE WAS FOUND TO BE OUT OF CALIBRATION. ACCORDING TO ANALYSIS AND COMPUTER MODELING, THE EFFECT OF THE MISCALIBRATION IS SIMILAR TO AN EFFECTIVE FLUENCE INCREASE OF 2.5% PER DEGREE C. THIS IMPLIES THAT A 2 DEGREE C, OUT OF SPEC CONDITION, WOULD REPRESENT AT 5.0% FLUENCE CHANGE. THIS EFFECTIVE EXCESS FLUENCE IS WITHIN THE FDA REQUIREMENT FOR THE ABSOLUTE ENERGY OUTPUT TO BE WITHIN +/-20%. THIS EFFECTIVE EXCESS FLUENCE WOULD BE PRESENT IN TEST SHOTS, WHICH WOULD ALSO NEGATE AND/OR MINIMIZE THE MISCALIBRATION EFFECT. THE SYSTEM PERFORMED AS EXPECTED DURING THE THERMAL TEST AND THE EPI TEMPERATURE REMAINED STABLE. THE BEAM PROFILE WAS EXAMINED IN THE FULL RANGE OF FLUENCE AND PULSE WIDTHS. ALL THE PROFILES APPEARED AS EXPECTED. THE ENERGY OUTPUT WAS EXAMINED OVER THE FULL RANGE OF FLUENCE AND PULSE WIDTHS. ALL THE OUTPUTS WERE WITHIN THE SPECIFIC TOLERANCE OF +/- 10%. THEREFORE, THE TESTING DID NOT REVEAL ANY MALFUNCTIONS OR IRREGULARITIES THAT WOULD HAVE PREVENTED THE UNIT FROM PERFORMING AS INTENDED. THE LIGHTSHEER DIODE LASER SYSTEM MANUAL, P/N 10-03497-00. AB, STATES UNDER COMPLICATIONS AND ADVERSE EFFECTS: "OTHER SIDE EFFECTS MAY INCLUDE HYPOPIGMENTATION AND HYPERPIGMENTATION. SIDE EFFECTS OF TREATMENT ARE FLUENCE-DEPENDENT AND SKIN TYPE DEPENDENT. APPROXIMATELY 20% OF PTS DEVELOPED TRANSIENT PIGMENTATION CHANGES WHICH USUALLY RESOLVED IN 1-3 MONTHS, BUT IN SOME CASES LASTED UP TO 12 MONTHS. NO SCARRING OR PERMANENT PIGMENTARY CHANGE WAS OBSERVED IN ANY PATIENT." AND "DANGER: THE LASER CAN CAUSE EPIDERMAL INJURY. THE RISK INCREASES WITH GREATER LASER FLUENCE AND SKIN PIAGMENTATION." THE LIGHTSHEER USER MANUAL ADDENDUM, 10-04103-00.AA, UNDER COMPLICATIONS AND SIDE EFFECTS INCLUDE: "CRUSTING AND, RARELY, BLISTERING MAY OCCUR WHICH TYPICALLY RESOLVES WITHIN 48-72 HOURS."

DEVICE INFORMATION:

Brand: LIGHTSHEER SYSTEM
Device Type: LASER
Device Type: NA
Catalog: 50-02531-00
Serial: (*confidential*)
Lot: NA
Other ID: K973324

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

EMAIL:

Phone: (*)
International: 
Fax: 

Health Professional: No

Occupation: OTHER

Date Last Updated: 11/2/2010 9:17 AM
Page: 1,679
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2005-00031</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Feb-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>30-Jun-2005</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>09-Mar-2005</td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>09-Mar-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td>01-Jan-1992</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 04-AUG-2006: THE C02 LASER WOULD NOT FUNCTION IN THE SUPER PULSE MODE, SO IT WAS SWITCHED TO CONTINUOUS. IT CONTINUED TO FIRE EVEN AFTER THE PEDAL WAS RELEASED. DEVICE USAGE PROBLEM: DEVICE FAILED (E.G. BROKE, COULDN'T GET IT TO WORK OR STOPPED WORKING.) THIRD PARTY SERVICE (FORTEC MEDICAL) PROVIDED REPORT, &quot;VERIFIED NEAR/FAR ARM ALIGNMENT OPERATION. RESEATED CONNECTIONS. CPU HOLDS MEMORY. COOLANT PUMP VERY NOISY.&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>PER USER FACILITY MDR REPORT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS (ISRAEL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>PO BOX 240</td>
<td></td>
<td></td>
</tr>
<tr>
<td>YOKNEAM,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ISRAEL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Received</td>
<td>30-Jun-2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>09-Mar-2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

04-AUG-2006: LUMENIS TECH SUPPORT REVIEWED THE COMPLAINT AND THIRD PARTY SERVICE REPORT AS A COURTESY TO CUSTOMER; ANALYSIS FOLLOWS. "LUMENIS CANNOT VALIDATE A THIRD PARTY SERVICE REPORT. ANALYZING THE COMPLAINT REPORTED ON MDR, WE HAVE NOT SEEN ANY TRENDING, WHICH RELATED TO THE CUSTOMER'S COMPLAINT OF UNABLE TO FUNCTION IN SUPER PULSE MODE. THE FOOT PEDAL COULD MALFUNCTION IF IT WAS JAMMED. THE THIRD PARTY SERVICE REPORT PROVIDED ON THE MDR DOES NOT SEEM TO ADDRESS THE COMPLAINTS REPORTED BY CUSTOMER ON THE MDR." CUSTOMER WAS FAXED LETTER ON 6/2005 WITH INVESTIGATION CONCLUSIONS AND LUMENIS SERVICE CONTACT INFORMATION. RNP REQUESTED AND NOT PROVIDED; CONFIDENTIAL PER CUSTOMER. DEVICE NOT EVALUATED BY LUMENIS AS CUSTOMER REQUESTED SERVICE INSTEAD FROM A THIRD PARTY SERVICE PROVIDER. TRENDING; REVIEW OF THIRD PARTY SERVICE PROVIDER REPORT. MANUFACTURER CAN NOT CONFIRM THAT THE THIRD PARTY SERVICE REPORT CONCLUSIONS HAVE ADDRESSED THE COMPLAINTS REPORTED BY CUSTOMER IN THE USER FACILITY MDR REPORT.

**DEVICE INFORMATION:**

- **Brand:** CO2
- **Device Type:** LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** 1055

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 29-Mar-2006
Report Date: 28-Apr-2006
Date Mfr Rec'd: 05-Apr-2006
Event Description:

Mfr 02-MAY-2006: TWO OR THREE MILLIMETERS BROKE OFF THE TIP OF A SLIMLINE 365 FIBER FROM LOT 3175/0705 DURING A PROCEDURE IN 2006 AT THE HOSP. THE FIBER FRAGMENT, WHICH IS BIOCOMPATIBLE, REMAINED IN THE KIDNEY LUMENIS REPORTED THE INCIDENT TO LUMENIS REGULATORY IN 2006. LUMENIS ANTICIPATED A VISIT TO THE HOSP TO OBTAIN ADDITIONAL INCIDENT AND PT DETAILS.

Concomitant Medical Products:
NONE REPORTED

Device Available for Evaluation: *
Device Evaluated by Manufacturer: No

Remedial Action:

Additional Mfr Narrative:
02-MAY-2006: THE PHYSICIAN REPORTED TO LUMENIS THAT THERE HAD BEEN NO PT INJURY; NO OTHER PT DETAILS WERE PROVIDED. THE PHYSICIAN ALSO REPORTED THAT THE SLIMLINE 365 FIBER HAD NOT MALFUNCTIONED. THE FIBER WAS NOT RETURNED TO LUMENIS FOR EVALUATION. THIS FIBER LOT WAS MFG IN JULY 2005. THE SLIMLINE 365 IS A REUSABLE FIBER, IT WAS NOT REPORTED TO LUMENIS WHETHER THE FIBER HAD BEEN USED AND REPROCESSED PRIOR TO THIS CASE. HOSP, THE ENDUSER, HAS CLOSED ITS INVESTIGATION OF THE INCIDENT.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SURGICAL FIBER
- **Device Type:** LASER FIBER DELIVERY DEVICE
- **Device Type:** SLIMLINE 365
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 3175/07/05
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**

Mfr 12-DEC-2006: THIS INCIDENT WAS REPORTED TO LUMENIS ON 11/02/2006. LASER FIBER BLEW AT 13 KJ DURING A HOLAP (LASER PROSTATECTOMY) PROCEDURE. PRISM DETACHED FROM END OF FIBER. PRISM LOCATED AND REMOVED FROM BLADDER. CHECK CYSTOSCOPY PERFORMED. FIBER COLLECTED BY SUPPLIER FOR INVESTIGATION. PER THE PHYSICIAN, THERE WAS NO HARM TO THE PATIENT.

**Concomitant Medical Products:**

REQUESTED AND NONE REPORTED

Mfr Name: *  
Address: 13 HAYETZIRA STREET  
*  
UNKNOWN

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

12-DEC-2006: THIS ADVERSE INCIDENT REPORT APPEARS TO BE ONE OF THE BATCH OF DEVICES THAT WERE MEANT TO HAVE BEEN RECALLED BY LUMENIS. LUMENIS HAS INITIATED CORRECTIVE ACTION REGARDING THE MISCOMMUNICATION OF THE MEDICAL DEVICE RECALL DETAILS TO THE ENDUSER. AS OF 12/1/2006, DEVICE EVALUATION IS STILL PENDING; UPDATE REQUESTED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SURGICAL FIBER
- **Device Type:** LASER FIBER DELIVERY DEVICE
- **Catalog:** 0623-703-01
- **Serial:** (*confidential*)
- **Lot:** 4171/06/06
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER

**EMAIL:** [redacted]

**Phone:** [redacted]

**International:**

**Fax:** [redacted]
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2007-00057</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
<th>Date Received:</th>
<th>23-Nov-2007</th>
</tr>
</thead>
</table>

**Event Date (B3):** 26-Oct-2007  
**Report Date (B4):** 23-Nov-2007  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):** 26-Oct-2007  

**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Reporter Occupation (E3):** OTHER  
**Device Operator:** HEALTH PROFESSIONAL  
**Adverse Event (B1):** Y  
**Problem (B1):** N  
**Event Location (F12):** HOSPITAL  
**Report Source (G3):** COMPANY REPRESENTATIVE  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):** R  

**Event Description (B5):**
Mfr 27-NOV-2007: IT WAS REPORTED THAT A PATIENT'S BLADDER WAS PERFORATED DURING A PROSTATE ENUCLEATION PROCEDURE. THE USER FACILITY DETERMINED THE ROOT CAUSE TO BE EXCESSIVE SUCTION APPLIED IN COMBINATION WITH THE NEPHROSCOPE, IRRIGATION, AND MORCELLATOR DEVICES USED DURING SAID PROCEDURE. THE BLADDER WAS SUTURED BY THE PHYSICIAN TO REMEDY THE PERFORATION. THE PATIENT IS FINE. EVENT WAS ORIGINALLY REPORTED BY A LUMENIS SALES REPRESENTATIVE ATTENDING THE TREATMENT.

**Concomitant Medical Products:**

**Mfr Name:** LUMENIS LTD.  
**Address:** 13 RAYETZIRA ST.  
YOKNEAM,  
ISRAEL  

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** VERSAPULSE POWERSUITE 100W
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** VP POWERSUITE
- **Catalog:** 0638-803-01
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)
SORTED BY

Date Received 30-Nov-2007

MFR Report No: 2914019-2007-00060
Mfr Name: LUMENIS, INC.

Event Date (B3): 04-Sep-2007
Report Date (B4): 30-Oct-2007
Report Date (F8): 30-Oct-2007
Date Mfr Rec'd (G4): 30-Oct-2007

Event Report Type: MALFUNCTION
Event Outcome (B2):
Reporter Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3): USER FACILITY, DISTRIBUTOR

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Mfr 29-FEB-2008: "EVENT DESCRIPTION: THE SURGEON WAS INSERTING THE PROBE THROUGH AN ADAPTER. TWO FIBERS IN THE PROBE BROKE DURING INSERTION. NO HARM TO THE PT. DEVICE USAGE PROBLEM: DEVICE FAILED (E.G. BROKE, COULDN'T GET IT TO WORK OR STOPPED WORKING)". NO FURTHER INFO IS AVAILABLE AT THIS TIME.

Concomitant Medical Products:

Mfr Name: LUMENIS, INC.
Address: *

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
29-FEB-2008: LUMENIS IS AWAITING FURTHER INFO FROM USER FACILITY. A F/U REPORT WILL BE ISSUED IF ADD'L INFO IS REC'D, OR IF THE DEVICES ARE REC'D FOR EVAL.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SLIMLINE EZ SINGLE USE
- **Device Type:** LASER FIBER, HOLMIUM
- **Device Type:** 840-893
- **Catalog:** 840-893
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [b] (b) [b]
- **Address:** [b] (b) [b]
- **Health Professional:** No
- **Occupation:** OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2008-00005</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
<th>Date Received</th>
<th>01-Apr-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Feb-2008</td>
<td>Report Date (B4):</td>
<td>01-Apr-2008</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>11-Feb-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4):

Expiry Date: Single Use (H5): N

Device Usage (H8): U

Event Description (B5):

Mfr 04-APR-2008: IT WAS REPORTED THAT THE IPL HANDPIECE FAILED ON THE LUMENIS ONE CAUSING A BURN TO THE PT'S FACE. LUMENIS MADE REASONABLE ATTEMPTS; HOWEVER, NO ADDITIONAL MEDICAL DETAILS WERE MADE AVAILABLE FROM THE USER FACILITY REGARDING THE REPORTED EVENT.

Concomitant Medical Products:

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):

Correction/Removal No (H9): Additional Mfr Narrative (H10 & H11):

04-APR-2008: THE IPL HANDPIECE, 560NM FILTER, SMALL LIGHTGUIDE AND SWITCHING MODULE WERE REQUESTED TO BE SENT TO MFR FOR INVESTIGATION. SHOULD THE ITEMS BE RETURNED AS REQUESTED, A ROOT CAUSE EVALUATION WILL BE CONDUCTED. THE RESULTS WILL BE UPDATED IN A FOLLOW-UP MDR.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LUMENISONE
- **Device Type:** LASER, SURGICAL, FOR USE IN DERMATOLOGY
- **Device Type:** LUMENIS ONE
- **Catalog:** GAL140000
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

Health Professional: No

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2914019-2008-00009
Mfr Name: LUMENIS, INC.
Mfr Report No: 2914019-2008-00009

Event Date (B3): 19-Mar-2008
Report Date (B4): 15-Apr-2008
Date Mfr Rec'd (G4):

Report Date (F8):

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12):
Report Source (G3): CONSUMER

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Single Use (H5): N
Expiration Date:
Device Usage (H8):

Event Description (B5):
Mfr 22-APR-2008: IT WAS REPORTED THAT DURING A URETEROSCOPY, THE FIBER TIP DISMANTLED IN THE URETER. A STENT WAS PLACED TO DILATE THE URETER IN ORDER TO PASS THE FIBER TIP.

Concomitant Medical Products:
NA

Mfr Name: LUMENIS, LTD YOKNEAM
Address: 13 HAYETZIRA ST.
YOKNEAM INDUSTRIAL PARK
YOKNEAM, IL 20692
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
22-APR-2008: THE FIBER WAS DISPOSED OF BY THE CUSTOMER AND WAS NOT AVAILABLE FOR EVAL. A DETERMINATION OF PROBABLE CAUSE BASED ON THE EVENT DESCRIPTION IS THAT THE FIBER BROKE DUE TO MISUSE WHEN THE FIBER BEND RADIUS OR TENSILE STRENGTH WAS EXCEEDED DURING SETUP OR WHILE REMOVING FIBER FROM PACKING. ADD'L INFO REGARDING PT OUTCOME HAS BEEN REQUESTED. WHEN FURTHER EVENT INFO BECOMES AVAILABLE, A F/U MDR WILL BE FILED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SURGICAL FIBER
Device Type: LASER FIBER DELIVERY DEVICE
Device Type: 840-842
Catalog: 0641-036-01
Serial: (*confidential*)
Lot: UNK
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Health Professional: Yes
Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>22-Jan-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>01-Apr-2008</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>24-Jan-2008</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>22-Jan-2008</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td>Device Usage (H8): *</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Event Description (B5):</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>CUSTOMER REPORTED THAT A PATIENT HAD EXPERIENCED BLISTERING AND BURNS AFTER IPL TREATMENT. PATIENT IS SKIN TYPE II, AND WAS BEING TREATED FOR TAGLIATEGA, AGE SPOTS, AND ROSACIA. AESTHETICIAN HAD CALIBRATED SYSTEM PRIOR TO TREATMENT AND USED PRIOR SETTINGS. MEDICAL INTERVENTION CONSISTED OF CLOBETASOL, STEROID CREAM AND ALOE VERA. PATIENT'S FACE AND NECK HAVE NEARLY COMPLETELY HEALED; TREATMENT MARKS CONTINUE TO FADE.</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Reporter Name:</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2914019-2008-00010</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS, INC.</td>
</tr>
<tr>
<td>Date Recd (G4):</td>
<td>01-Apr-2008</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>22-Jan-2008</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010  9:17 AM</td>
</tr>
<tr>
<td>Recd:</td>
<td>845</td>
</tr>
<tr>
<td>Page:</td>
<td>1,694</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010  9:17 AM</td>
</tr>
</tbody>
</table>

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
03-JUN-2008: TREATMENT HEAD INVOLVED IS BEING RETURNED TO MANUFACTURING SITE FOR EVALUATION. WHEN REPORT IS RECEIVED, A FOLLOW-UP MDR WILL BE SUBMITTED WITH ROOT CAUSE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LUMENIS ONE
- **Device Type:** LASER, SURGICAL, FOR USE IN DERMATOLOGY
- **Device Type:** LUMENISONE
- **Catalog:** GAL140000
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: **N**

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER
- **EMAIL:** [redacted]
- **Phone:** [redacted]  
  **International:** [redacted]  
  **Fax:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2008-00019</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
<th>Date Received: 08-Apr-2008</th>
</tr>
</thead>
</table>

**Event Date (B3):** 18-Mar-2008
**Report Date (B4):** 11-Apr-2008
**Report Date (F8):**
**Date Mfr Rec'd (G4):**

**Event Report Type:** INJURY
**Event Outcome (B2):** REQUIRED INTERVENTION
**Reporter Occupation (E3):** OTHER
**Device Operator:** HEALTH PROFESSIONAL

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
**Device Age (F9):**
**Expiration Date:**
**Device Usage (H8):** I

**Event Description (B5):**
Mfr 22-APR-2008: IT WAS REPORTED THAT DURING TRANSURETHRAL URETERO-LITHOTOMY (TUL) PROCEDURE THE TIP OF A SLIMLINE FIBER WAS BROKEN AND A 5-8 MM FIBER FRAGMENT REMAINED INSIDE THE PATIENT. THE PHYSICIAN WAS UNABLE TO FIND THE DETACHED FRAGMENT AND THE PROCEDURE WAS CLOSED WITH PLACEMENT OF URETERAL STENT IN ORDER TO PASS THE FRAGMENT. IT WAS REPORTED THE FIBER WAS DAMAGED BY EXCESS FORCE AT THE SCOPE CHANNEL.

**Concomitant Medical Products:**
NA

**Mfr Name:** LUMENIS, LTD. YOKNEAM
**Address:** 13 HAYETZIRA STREET
YOKNEAM INDUSTRIAL PARK
YOKNEAM,

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
22-APR-2008: FIBER WAS RETURNED. VISUAL EVALUATION FOUND THE FIBER WAS BROKEN DUE TO MISUSE BY EXCEEDING THE BEND RADIUS OF FIBER OR EXCEEDING THE TENSILE STRENGTH. LUMENIS HAS REQUESTED INFORMATION REGARDING PATIENT OUTCOME. SHOULD ADDITIONAL EVENT INFORMATION BE PROVIDED AS REQUESTED, A FOLLOWUP MDR WILL BE FILED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SURGICAL FIBER
- **Device Type:** LASER FIBER DELIVERY DEVICE
- **Device Type:** 840, 840 SLIMLINE200
- **Catalog:** 0641-020-01
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** OTHER

**Health Professional:** Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Description (B5):
Mfr 14-NOV-2008: IT WAS REPORTED THAT PATIENT SUSTAINED 2ND DEGREE BURNS SUSTAINED AN IPL TREATMENT AND TWO OPERATORS AT USER FACILITY SUSTAINED 2ND DEGREE BURNS AFTER USING THE SYSTEMS ON THEMSELVES.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
14-NOV-2008: A LUMENIS FIELD SERVICE ENGINEER FOUND THE HEAD TO BE WITHIN FUNCTIONAL SPECIFICATIONS. FIELD SERVICE ENGINEER FURTHER REPORTED USER FACILITY HAD NOT PERFORMED REGULAR ROUTINE USER CALIBRATION OF THE HEAD IN CONTRADICTION TO PRODUCT LABELING.
**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>LUMENIS ONE</td>
</tr>
<tr>
<td>Device Type</td>
<td>LASER INSTRUMENT, SURGICAL, POWERED</td>
</tr>
<tr>
<td>Device Type</td>
<td>GAL140000</td>
</tr>
<tr>
<td>Catalog</td>
<td>GAL140000</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>)confidential</em></td>
</tr>
<tr>
<td>Lot</td>
<td></td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Address</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Email</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Phone</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
</tbody>
</table>

Health Professional: No

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 06-Oct-2008
Event Report Type: INJURY
Adverse Event (B1): Y
Problem (B1): Y
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Location (F12): REPORTER OCCUPATION: HEALTH PROFESSIONAL
Mfr Name: LUMENIS, INC.

MFR Report No: 2914019-2008-00059
Report Date (B4): 06-Nov-2008
Report Date (F8): 06-Oct-2008
Report Date (G4): 06-Oct-2008
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL
Report Source (G3): USER FACILITY

Device Age (F9): Manufacture Date (H4):
Expiration Date:
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):
Mfr 10-NOV-2008: IT WAS REPORTED THAT A PT SUSTAINED A SMALL SECOND DEGREE BURN AS A RESULT OF A HAIR REMOVAL TREATMENT TO THE BACK. PATIENT WAS REPORTED TO HAVE FULLY RECOVERED WITHOUT ANY SCARRING. NO MEDICAL INTERVENTION WAS REPORTED.

Concomitant Medical Products:

Mfr Name: LUMENIS, INC.
Address: YOKNEAM, ISRAEL

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-NOV-2008: PRELIMINARY LUMENIS FIELD SERVICE INVESTIGATION FOUND THAT THE SUBJECT DEVICE WAS WITHIN ALLOWABLE OPERATING AND FUNCTIONAL TOLERANCES. SUBJECT DEVICE WAS REQUESTED TO BE RETURNED TO THE LUMENIS MFG SITE FOR FULL FUNCTIONAL ANALYSIS. SHOULD THE DEVICE BE RETURNED, A FOLLOW UP MDR WILL BE FILLED.
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LUMENIS ONE
Device Type: LASER POWERED SURGICAL INSTRUMENT
Device Type: GAL140000
Catalog: 
Serial: (*confidential*)
Lot: 
Other ID: 
Reprocessed & Reused: N

REPORTEER INFORMATION:

Name: 
Address: (b) (6)
Health Professional: Yes

EMAIL: 
Phone: (b) (6)
International: 
Fax: 
Occupation: 100 - OTHER HEALTH CARE PROFESSIONAL
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2008-00060</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
<th>Date Received:</th>
<th>06-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Oct-2008</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Nov-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>06-Oct-2008</td>
<td>Brief Description (B5):</td>
<td>IT WAS REPORTED THAT A PT SUSTAINED A SMALL SECOND DEGREE BURN AS A RESULT OF A HAIR REMOVAL TREATMENT TO THE BACK. PATIENT WAS REPORTED TO HAVE FULLY RECOVERED WITHOUT ANY SCARRING.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

| Mfr Name: | LUMENIS, INC. |
| Address: | YOKNEAM, ISRAEL |

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7): 10-NOV-2008: PRELIMINARY LUMENIS FIELD SERVICE INVESTIGATION FOUND THAT THE SUBJECT DEVICE WAS WITHIN ALLOWABLE OPERATING AND FUNCTIONAL TOLERANCES. SUBJECT DEVICE WAS REQUESTED TO BE RETURNED TO THE LUMENIS MFG SITE FOR FULL FUNCTIONAL ANALYSIS. SHOULD THE DEVICE BE RETURNED, A FOLLOW UP MDR WILL BE FILLED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LUMENIS ONE
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:**
- **Address:**
- **Health Professional:** Yes
- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** 100 - OTHER HEALTH CARE PROFESSIONAL
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2008-00061</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Oct-2008</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>07-Nov-2008</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>10-Oct-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Mar-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>MFR 17-NOV-2008: IT WAS REPORTED THAT A PATIENT SUSTAINED A 3RD DEGREE BURN AS A RESULT OF AN IPL TREATMENT TO THE FACE. TOPICAL ANTIBIOTIC OINTMENT WAS PRESCRIBED TO AID IN RECOVERY. IT WAS FURTHER REPORTED THAT DEVICE FIRED &quot;RAPIDLY&quot; AND EXHIBITED AN ERROR CODE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS, LTD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>YOKNEAM, ISRAEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>17-NOV-2008: AFTER FULL FUNCTIONAL EVALUATION, LUMENIS SERVICE FOUND THAT THE SUBJECT DEVICE WAS WITHIN ALLOWABLE OPERATING TOLERANCES AND EXHIBITED NO DEFICIENCIES. REPORT MALFUNCTION COULD NOT BE REPLICATED DURING EVALUATION. DEVICE WAS CLEARED AND REMAINED IN USE AT USER FACILITY.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LUMENIS ONE
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** GAL140000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** No
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2914019-2009-00001</th>
<th>Mfr Name: LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 21-Sep-2006</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4): 05-Jan-2009</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8): 09-Dec-2009</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 09-Dec-2009</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Mar-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8): R</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Mfr 16-JAN-2009: IT WAS REPORTED THAT A PATIENT SUSTAINED 2ND DEGREE BURNS ON THE LEGS AFTER A HAIR REMOVAL TREATMENT WITH THE LUMENIS ONE.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products: UNK</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LUMENIS LTD. YOKNEAM</td>
<td></td>
</tr>
<tr>
<td>Address: YOKNEAM, ISRAEL</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 16-JAN-2009: SUBJECT DEVICE INVESTIGATION BY LUMENIS SERVICE OBSERVED FILTER DAMAGE DUE TO ACCUMULATION OF FOREIGN CONTAMINATES IN CONTRADICTION TO PRODUCT LABELING. THE NECESSITY OF CLEAN, DAMAGE FREE FILTERS AND IMPACT TO DEVICE PERFORMANCE AND SAFETY ARE CLEARLY EXPRESSED IN DEVICE LABELING AND TRAINING MATERIAL.</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LUMENIS ONE
- **Device Type:** LASER, INSTRUMENT, SURGICAL, POWERED
- **Device Type:** GAL110000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2914019-2009-00002
Mfr Name: LUMENIS, INC.
14-Jan-2009

Event Date (B3): 25-Jun-2008
Event Report Type: INJURY
Adverse Event (B1): Y
Problem (B1): N

Event Date (B4): 09-Jan-2009
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Report Date (B4): 09-Jan-2009
Event Location (F12):

Date Mfr Rec'd (G4): 19-Dec-2008
Report Source (G3): PATIENT

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Feb-2008
Expiration Date:

Device Usage (H8):

Event Description (B5):
Mfr 21-JAN-2009: A PT REPORTED THAT SHE SUSTAINED SCARS AFTER AN ULTRAPULSE ENCORE TREATMENT.

Concomitant Medical Products:
UNK

Mfr Name: LUMENIS LTD.
Address: YOKNEAM,
ISRAEL

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
21-JAN-2009: THE PHYSICIANS' OFFICE WAS CONTACTED AND MULTIPLE ATTEMPTS WERE MADE TO OBTAIN ADDITIONAL INFO. HOWEVER, PHYSICIANS' OFFICE DID NOT WANT TO PROVIDE ADDITIONAL INFO. SHOULD ADDITIONAL INFO BE MADE AVAILABLE, A FOLLOW UP MDR WILL BE FILED.

Recd: 852
Page: 1,708
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ULTRAPULSE ENCORE
Device Type: LASER, INSTRUMENT, SURGICAL, POWERED
Device Type: 0642-415-01
Catalog: (confidential)
Serial: (*confidential*)
Lot: 
Other ID: 

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: 
EMAIL: 
Phone: 
International: 
Fax: 

Health Professional: No

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>13-Nov-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>26-Mar-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>30-Jan-2009</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>31-Mar-2009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 03-APR-2009: IT WAS REPORTED THAT A PATIENT SUSTAINED EYE INJURIES AFTER INADVERTENTLY TOUCHING HER EYE WITH THE BLT TRIPLE ANESTHETIC GEL USED DURING THE UP ENCORE TREATMENT.

**Concomitant Medical Products:**

UNKNOWN

**Mfr Name:** LUMENIS, LTD

**Address:** YOKNEAM, ISRAEL

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

03-APR-2009: THE PATIENT INITIALLY REPORTED SHE HAD AN APPOINTMENT FOR CONSULTATION WITH AN OPHTHALMOLOGIST HOWEVER, ADDITIONAL INFORMATION WAS NOT PROVIDED DESPITE REASONABLE ATTEMPTS. NO DEVICE MALFUNCTION WAS REPORTED OR SUSPECTED. SHOULD ADDITIONAL INFORMATION BE MADE AVAILABLE, A FOLLOW UP MDR WILL BE FILED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** ULTRAPULSE ENCORE
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 0642-415-01
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]

**Health Professional:** No

**Occupation:** NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2914019-2009-00006
Mfr Name: LUMENIS, INC.

Event Date (B3): 28-Aug-2008
Report Date (B4): 19-Feb-2009
Report Date (F8): 02-Feb-2009
Date Mfr Rec'd (G4): 02-Feb-2009
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Event Description (B5):
Mfr 06-MAR-2009: IT WAS REPORTED THAT A PATIENT SUSTAINED A SMALL SPOT OF HYPERPIGMENTATION AFTER AN ULTRAPULSE ENCORE TREATMENT.

Concomitant Medical Products:
UNKNOWN

Mfr Name: LUMENIS LTD.
Address: YOKNEAM, ISRAEL
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
06-MAR-2009: A LUMENIS FIELD SERVICE ENGINEER EVALUATED THE SYSTEM AND FOUND THE CALIBRATION TO BE WITHIN ACCEPTABLE TOLERANCES. ALL OTHER OPERATING PARAMETERS WERE ALSO VERIFIED TO BE IN SPEC. NO DEVICE MALFUNCTION WAS OBSERVED. USER FACILITY REPORTED NO TEST PATCH WAS PERFORMED PRIOR TO TREATMENT AS DIRECTED IN PRODUCT LABELING. IT WAS ALSO REPORTED THAT PATIENT HAS "FULLY HEALED".
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ULTRAPULSE ENCORE
- **Device Type:** LASER, INSTRUMENT SURGICAL, POWERED
- **Device Type:** 0642-415-01
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Health Professional:** Yes
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:**
- **Fax:**
- **Occupation:** OTHER
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>28-Feb-2009</th>
</tr>
</thead>
</table>

#### Event Date (B3): 19-Jan-2009

**Event Report Type:** INJURY

**Event Date (B3):** 19-Jan-2009

**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Report Date (B4):** 23-Feb-2009

**Reporter Occupation (E3):** HEALTH PROFESSIONAL

**Device Operator:** REPORTER OCCUPATION

**Event Location (F12):** USER FACILITY

**Device Usage (H8):** R

**Event Description (B5):**

Mfr 06-MAR-2009: IT WAS REPORTED THAT 2 PATIENTS SUSTAINED MILD 2ND DEGREE BURNS AFTER AN IPL QUANTUM TREATMENT. USER FACILITY ALSO REPORTED THAT PT HAS FULLY HEALED WITH NO PERMANENT IMPAIRMENT.

**Concomitant Medical Products:**

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

06-MAR-2009: A LUMENIS FIELD SERVICE INVESTIGATION FOUND THAT THE SUBJECT DEVICE WAS WITHIN ALLOWABLE OPERATING AND FUNCTIONAL TOLERANCES. NO RELATED DEVICE MALFUNCTION WAS OBSERVED. USER FACILITY FURTHER REPORTED PATIENTS MAY HAVE HAD SUN EXPOSURE PRIOR TO TREATMENT WITHOUT DISCLOSING. TREATMENT OF SUN EXPOSED SKIN IS A CONTRA INDICATION PER PRODUCT LABELING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: IPL QUANTUM SR-208V  
Device Type: LASER INSTRUMENT SURGICAL, POWERED  
Device Type: GA3600000  
Catalog:  
Serial: (*confidential*)  
Lot:  
Other ID:  

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)  
Address: [b] (6)  
Health Professional: No  

EMAIL:  
Phone: [b] (6)  
International:  
Fax:  

Occupation: NA - NOT APPLICABLE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>18-Mar-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>2914019-2009-00010</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS, INC.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>28-Aug-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>16-Mar-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>17-Feb-2009</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Feb-2009</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-MAR-2009: A PATIENT REPORTED THAT SHE SUSTAINED HYPERPIGMENTATION AFTER AN ULTRAPULSE ENCORE TREATMENT.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS LTD.</td>
</tr>
<tr>
<td>Address:</td>
<td>YOKNEAM, ISRAEL</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: ULTRAPULSE ENCORE
Device Type: LASER, INSTRUMENT, SURGICAL, POWERED
Device Type: 0642-415-01
Catalog: 
Serial: (*confidential*)
Lot: 
Other ID: 

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
Page: 1,717
Recd: 856
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2009-00012</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-Jan-2009</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>29-Mar-2009</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>NA - NOT APPLICABLE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>02-Mar-2009</td>
<td>Device Operator:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Sep-2000</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 07-APR-2009: IT WAS REPORTED THAT 3 PATIENTS SUSTAINED 2ND DEGREE BURNS AFTER A LIGHTSHEER TREATMENT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>RH, USA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>LIVERMORE, CA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>07-APR-2009: THE LUMENIS QA EVALUATED THE SYSTEM AND FOUND THE TIP TO BE DIRTY IN CONTRADICTION TO PRODUCT LABELING. DEVICE LABELING IS CLEAR REGARDING IMPORTANCE OF DEVICE CLEANLINESS TO ENSURE OPTIMAL DEVICE PERFORMANCE.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LIGHTSHEER
- **Device Type:** LASER, INSTRUMENT, SURGICAL, POWERED
- **Device Type:** LIGHTSHEER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**

Mfr 14-APR-2009: IT WAS REPORTED BY THE USER FACILITY THAT A PATIENT CLAIMED TO HAVE RECEIVED GUILLAIN-BARRE SYNDROME AFTER AN IPL TREATMENT.

**Concomitant Medical Products:**

UNKNOWN

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

14-APR-2009: NO DEVICE MALFUNCTION SUSPECTED OR REPORTED BY USER FACILITY. REPORTED EVENT IS NOT PART OF ANY PRODUCT TRENDING.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** IPL QUANTUM
- **Device Type:** LASER, INSTRUMENT, SURGICAL, POWERED
- **Device Type:** GA3600000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

### REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **Health Professional:** Yes
- **Occupation:** 100 - OTHER HEALTH CARE PROFESSIONAL
- **EMAIL:**
- **Phone:**
- **International:** [b] (b)
- **Fax:** [b] (b)
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2914019-2009-00014</th>
<th>Mfr Name: LUMENIS, INC.</th>
<th>Date Received: 13-Apr-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Date (B3):</strong> 23-Feb-2009</td>
<td><strong>Event Report Type:</strong> INJURY</td>
<td><strong>Adverse Event (B1):</strong> Y <strong>Problem (B1):</strong> N</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong> 06-Apr-2009</td>
<td><strong>Event Outcome (B2):</strong> OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td><strong>Event Location (F12):</strong></td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td><strong>Reporter Occupation (E3):</strong> 002 - NURSE</td>
<td><strong>Report Source (G3):</strong> USER FACILITY</td>
</tr>
<tr>
<td><strong>Date Mfr Rec’d (G4):</strong> 13-Mar-2009</td>
<td><strong>Device Operator:</strong> HEALTH PROFESSIONAL</td>
<td></td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):** R

---

**Event Description (B5):**

Mfr 15-APR-2009: IT WAS REPORTED THAT 2 PATIENTS SUSTAINED 2ND DEGREE BURNS, AFTER AN IPL QUANTUM TREATMENT.

**Concomitant Medical Products:**

UNKNOWN

**Mfr Name:** LUMENIS, LTD

**Address:** YOKNEAM, ISRAEL

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

15-APR-2009: THE USER FACILITY DECLINED SERVICE BY LUMENIS, AND HAD A THIRD PARTY SERVICE THE UNIT WHICH FOUND THE UNIT WITHIN SPECS. IT WAS FURTHER REPORTED THAT BOTH PATIENTS HAD SUN EXPOSURE WHICH IS A CONTRA-INDICATION, PER PRODUCT LABELING AND PROBABLE ROOT CAUSE.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** IPL QUANTUM SR-208V
- **Device Type:** LASER, INSTRUMENT, SURGICAL, POWERED
- **Device Type:** GA3698000
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

**EMAIL:** [Redacted]

**Phone:** [Redacted]

**International:** [Redacted]

**Fax:** [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Mar-2009</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>14-Apr-2009</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>23-Mar-2009</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>2914019-2009-00015</td>
<td>Mfr Name:</td>
<td>LUMENIS, INC.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 22-APR-2009: IT WAS REPORTED A PT SUSTAINED EDEMA AND POSSIBLE GRANULATION AFTER AN ULTRAPULSE ENCORE TREATMENT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>UNK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LUMENIS, LTD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>YOKNEAM, ISRAEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>22-APR-2009: A LUMENIS FIELD SVC INVESTIGATION FOUND THAT THE SUBJECT DEVICE WAS WITHIN ALLOWABLE OPERATING AND FUNCTIONAL TOLERANCES. NO RELATED DEVICE MALFUNCTION WAS OBSERVED. EDEMA IS IDENTIFIED AS A POSSIBLE COMPLICATION AND EXPECTED SEQUELAE PER PRODUCT LABELING. ALTHOUGH EDEMA IS LISTED AS A POSSIBLE COMPLICATION FOR THE ULTRAPULSE ENCORE NO RELATED HISTORY HAS BEEN REPORTED; THEREFORE, NO SUBJECT TRENDING EXISTS.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DEVICE INFORMATION:

Brand: ULTRAPULSE ENCORE
Device Type: LASER, INSTRUMENT, SURGICAL, POWERED
Device Type: 0642-415-01
Catalog: 0642-415-01
Serial: (*confidential*)
Lot: (*)
Other ID: (*)

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health
Professional: No

EMAIL: [b] (b)
Phone: [b] (b)
International: (*)
Fax: (*)

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2914019-2009-00016</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 28-Oct-2008  
**Report Date (B4):** 08-Apr-2009  
**Report Date (F8):**  
**Date Mfr Rec’d (G4):** 26-Mar-2009  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** HEALTH PROFESSIONAL  
**Device Evaluated by Manufacturer (H3):** No  
**Device Available for Evaluation:** N  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  

13-AUG-2009: NO PT CONTACT OR USER FACILITY IDENTIFICATION WAS PROVIDED IN MAUDE REPORT. ADDITIONALLY, NO COMPLAINT OF A SIMILAR NATURE WAS REPORTED TO LUMENIS THAT COULD BE LINKED TO THIS EVENT. SHOULD MORE INFO BE PROVIDED, A F/U REPORT WILL BE FILED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LUMENIS ONE
Device Type: LASER, INSTRUMENT, SURGICAL, POWERED
Device Type: UNK
Catalog: (*confidential*)
Serial: (*confidential*)
Lot: (*confidential*)
Other ID: (*confidential*)

Reprocessed & Reused: Y
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received


Date Mfr Rec'd (G4): 13-May-2009  Event Description (B5): MFR 06-AUG-2009: IT WAS REPORTED THAT AT SOME POINT DURING A HOLAP PROCEDURE, THE SUBJECT FIBER STOPPED WORKING AND THAT A TURP WAS USED TO COMPLETE. THE SECONDARY TURP PROCEDURE WAS PERFORMED WITHOUT ANY LUMENIS DEVICE. IT WAS FURTHER REPORTED THAT DURING SAID TURP PROCEDURE, THE PATIENT CODED AND WAS STABILIZED. IT WAS ALSO REPORTED THAT THE PATIENT WAS EXPECTED TO MAKE A COMPLETE RECOVERY WITH NO SEQUELAE.

Concomitant Medical Products:
NA

Mfr Name: LUMENIS LTD. YOKNEAM
Address: 13 HAYETZIRA STREET
YOKNEAM INDUSTRIAL PARK
YOKNEAM, ID 20692
UNITED STATES

Device Available for Evaluation: N

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
06-AUG-2009: ALTHOUGH REASONABLE ATTEMPTS WERE MADE, NO ADDITIONAL EVENT INFORMATION WAS PROVIDED AND SUBJECT DEVICE WAS NOT RETURNED BY USER FACILITY. IF ADDITIONAL INFORMATION IS MADE AVAILABLE A FOLLOW-UP MDR WILL BE FILED.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** DUOTOME SIDELITE SURGICAL FIBER
- **Device Type:** LASER FIBER DELIVERY DEVICE
- **Device Type:** 840-846
- **Catalog:** 0638-801-01
- **Serial:** (*confidential*)
- **Lot:** 0079820908
- **Other ID:** 

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** 
- **Fax:** 

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2914019-2009-00035</th>
<th>Mfr Name: LUMENIS, INC.</th>
<th>Date Received: 11-Jun-2009</th>
</tr>
</thead>
</table>

**Event Date (B3):** 22-May-2009  
**Report Date (B4):** 11-Jun-2009  
**Report Date (F8):** 26-May-2009  
**Date Mfr Rec'd (G4):** 26-May-2009

**Event Report Type:** INJURY  
**Event Report Type:** INJURY  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Adverse Event (B1):** Y  
**Problem (B1):** N  
**Report Date (B4):** 11-Jun-2009  
**Report Date (F8):** 26-May-2009  
**Report Date (G4):** 26-May-2009

**Event Location (F12):** HOSPITAL  
**Report Source (G3):** USER FACILITY

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):** Manufacture Date (H4): 01-Feb-2009  
**Expiration Date:** 31-Jan-2014  
**Single Use (H5):** Y  
**Device Usage (H8):** I

**Event Description (B5):**  
Mfr 18-JUN-2009: IT WAS REPORTED THAT DURING A HOLAP PROCEDURE, THE PHYSICIAN SUSTAINED A THIRD DEGREE BURN TO HIS HAND AS A RESULT OF A FIBER BREAK. SYLVADINE WAS USED TO TREAT THE AREA WITH NO FURTHER COMPLICATIONS REPORTED.

**Concomitant Medical Products:**  
NA

**Mfr Name:** LUMENIS LTD. YOKNEAM  
**Address:** 13 HAYETZIRA ST.  
YOKNEAM INDUSTRIAL PARK  
YOKNEAM, IL 20692  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**  
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**  
18-JUN-2009: THE SUBJECT DEVICE WAS RECEIVED FROM THE USER FACILITY AND AFTER INVESTIGATION BY A LUMENIS TECHNICAL SPECIALIST, IT WAS DETERMINED THE ROOT CAUSE FOR THE REPORTED EVENT TO BE EXCESSIVE BEND FORCES APPLIED UNDER POWER IN CONTRAIDCTION TO DEVICE LABELING.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>DUOTOME SITELITE SURGICAL FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER FIBER DELIVERY DEVICE</td>
</tr>
<tr>
<td>Device Type</td>
<td>840-846</td>
</tr>
<tr>
<td>Catalog</td>
<td>0641-800-01</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>0084890209</td>
</tr>
<tr>
<td>Other ID</td>
<td>840-846</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

| Name:    | [b] (b) |
| Address: | [b] (b) |
| Health Professional: | Yes |

EMAIL: [b] (b)

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 2918486-2006-00001
Mfr Name: HOYA PHOTONICS, INC. 14-Aug-2006

Event Date (B3): 07-Jul-2006
Report Date (B4): 02-Aug-2006
Report Date (F8): 07-Jul-2006
Date Mfr Rec'd (G4): 07-Jul-2006

Event Report Type: INJURY
Event Outcome (B2): LIFE THREATENING
Report Occupation (E3): OTHER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): REPORTER OCCUPATION
Report Source (G3): USER FACILITY

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)
Device Operator: HEALTH PROFESSIONAL

Manufacture Date (H4): 01-Feb-2005
Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: HOYA CONBIO
Address: *
FREMONT, CA *
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

21-AUG-2006: THEY SUBMITTED A REPORT ON THE SITE EVALUATION OF THE SYSTEM AND INTERVIEWS WITH THE OFFICE PERSONNEL AND WITH SERVICE TECHNICIAN. THE HIGH VOLTAGE POWER SUPPLY, SCR BOARD AND THE CHARGE CAPACITOR WERE RETURNED FROM THE SYSTEM FOR FURTHER EVALUATION: THE SCR BOARD IS INTACT, THE HIGH VOLTAGE DISCHARGE RELAY AND DISCHARGE RESISTORS ARE INTACT AND THE RESISTANCE THAT WAS CONNECTED TO THE CHARGE CAPACITOR TO DISCHARGE THE CAPACITOR MEASURED 33 KILO OHMS. THIS IS CONSISTENT WITH THE DESIGN WHICH HAS 3,100 KILO OHM RESISTORS IN PARALLEL. THE HIGH VOLTAGE POWER SUPPLY WAS OPENED AND WE FOUND THAT THE BRIDGE RECTIFIER ON THE INPUT AC WAS BURNED AND ALL DIODES WERE SHORTED, WHICH WOULD NOT ALLOW THE POWER SUPPLY TO DEVELOP A HIGH VOLTAGE OUTPUT. THIS IS CONSISTENT WITH REPORT WHICH INDICATED THAT WHEN THEY TURNED ON THE SYSTEM, IT REPORTED AN ERROR 22 AND THERE WAS NO VOLTAGE DEVELOPED ON THE CHARGE CAPACITOR. IN THE REPORT, SERVICE TECHNICIAN INDICATED WHEN THE SYSTEM WOULD NOT FLASH AND WAS REPORTING AN ERROR 22, HE ALSO NOTICED A BURNING SMELL. THIS IS CONSISTENT WITH THE BURNED INPUT BRIDGE RECTIFIER IN THE POWER SUPPLY. THE CAPACITOR WAS RECEIVED IN GOOD CONDITION. THERE IS SOME EVIDENCE THAT THE THREADS ON ONE OF THE POSTS WERE DAMAGED, NOT CROSS THREADED, BUT THE POST HAD SOME ROUGH SPOTS ON THE THREADS. THIS IS CONSISTENT WITH THE OBSERVATION IN THE REPORT THAT THE NUT ON THE WIRE GOING FROM THE CHARGE CAP TO THE SCR BOARD WAS SLIGHTLY LOOSE. THIS IS THE PATH TO RAPIDLY DISCHARGE THE CAPACITOR. NOTE THE ATTACHED SPREAD SHEET ON DISCHARGE TIMES FOR THE PRIMARY DISCHARGE PATH AND THE BACKUP DISCHARGE PATH. IT WAS OBSERVED THAT YOU COULD MOVE THE WIRE ON THE POST, THAT IT WAS NOT TIGHT, BUT IT ALSO WAS NOT SLOPPY LOOSE. THE DIAMETER OF THE RING LUG ON THE WIRE THAT GOES ON THAT POST IS VERY CLOSE TO THE DIAMETER OF THE POST SO THERE IS LITTLE CHANCE THAT THE LOOSE WIRE COULD HAVE BEEN REALLY DISABLED FROM DISCHARGING THE CAPACITOR. THE BACKUP DISCHARGE RESISTOR ON THE CAPACITOR MEASURES 2.2 MEGAOHMS WHICH IS CONSISTENT WITH THE DESIGN. NONE OF THE EVIDENCE IDENTIFIES DEFECTIVE COMPONENTS, PARTS, OR DESIGN THAT WOULD CAUSE THE ACCIDENT TO HAPPEN. THE ONLY EXPLANATION THAT IS POSSIBLE IS THE POWER SUPPLY WAS ABLE TO DEPOSIT A CHARGE ON THE CAPACITOR AS IT WAS FAILING. IN ADDITION, THE LOOSE NUT ON THE CAPACITOR BROKE THE CONNECTION TO THE FAST DISCHARGE RESISTORS ON THE SCR BOARD; AS A CONSEQUENCE, THE BACK UP BLEED RESISTOR WAS DISCHARGING THE PARTIALLY CHARGED CAPACITOR WHEN SERVICE TECHNICIAN CONTACTED A HIGH VOLTAGE POINT WHEN HE WAS REMOVING THE LOW VOLTAGE CABLES FROM THE POWER SUPPLY. THE ONLY CONCLUSION IS IF HE HAD DISCHARGED THE HIGH VOLTAGE CAPACITOR AS HE HAD BEEN RECENTLY INSTRUCTED TO DO, THIS ACCIDENT WOULD NOT HAVE HAPPENED EVEN IF ONE OF THE SYSTEM SAFETY DISCHARGE CIRCUITS WAS INOPERATIVE. BECAUSE OF THE SERIOUS NATURE OF THE INCIDENT, THEY HAVE TAKEN ADDITIONAL PREVENTATIVE ACTION STEPS TO IMPRESS UPON THE SERVICE PERSONNEL THE IMPORTANCE OF FOLLOWING A SPECIFIC SAFETY REGIMEN WHEN WORKING IN AND AROUND HIGH VOLTAGE. THE SERVICE BULLETIN WILL BE INCORPORATED INTO THE SERVICE MANUAL, IN ADDITION TO BEING SENT TO THE SERVICE PERSONNEL. PREVENTATIVE ACTION: A SERVICE BULLETIN HAS BEEN GENERATED, SEE ATTACHED BULLETIN 47, WHICH HAS BEEN EMAILED TO ALL THE SERVICE ENGINEERS AND DISTRIBUTORS WORLD WIDE. THIS BULLETIN SPECIFICALLY ADDRESSES THE SAFETY PRECAUTIONS THAT MUST BE OBSERVED WHEN WORKING IN AND AROUND HIGH VOLTAGE COMPONENTS. IT ALSO STATES THE MINIMUM WAIT TIME THAT SHOULD BE OBSERVED BEFORE ATTEMPTING TO DISCHARGE THE HIGH VOLTAGE CAPACITOR TO ALLOW THE BACK UP BLEED RESISTOR TO DISCHARGE THE CAPACITOR TO MINIMIZE THE RISK IF THE CAPACITOR IS NOT FULLY DISCHARGED. THIS SERVICE BULLETIN WILL BE SENT VIA UPS WITH A RETURN RECEIPT TRACKING REQUESTED TO VERIFY THAT ALL PERSONNEL AND DISTRIBUTORS HAVE RECEIVED THE INFORMATION. THE MANUFACTURING AND ENGINEERING PERSONNEL WILL BE TRAINED IN THESE SAFETY PROCEDURES.
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** MEDLITE C6
- **Device Type:** LASER, ND: YAG
- **Device Type:** MEDLITE C6
- **Catalog:** 659-0002
- **Serial:** (*confidential*)
- **Lot:** 2/2005
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** *
- **Health Professional:** No
- **Occupation:** OTHER

**EMAIL:** (b) (6)

**Phone:** (b) (6)

**International:**

**Fax:**
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

MFR Report No: 2918486-2006-00002  Mfr Name: HOYA PHOTONICS, INC.

Event Date (B3): 03-Nov-2006  Event Report Type: INJURY  Adverse Event (B1): Y
Report Date (B4): 26-Dec-2006  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8): 27-Nov-2006  Reporter Occupation (E3): NA - NOT APPLICABLE
Date Mfr Rec'd (G4): 26-Dec-2006  Device Operator: INVALID DATA

Event Location (F12):  Report Source (G3): COMPANY REPRESENTATIVE

Product Code: (OP)-LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY AND CUTTING PUPILLA (LXS)
Device Age (F9):
Expiry Date: Single Use (H5): N
Device Usage (H8): I

Event Description (B5):
Mfr 08-JAN-2007: ACCORDING TO THE ALLEGEDLY INJURED PARTY, IN 2006, A LASER TECHNICIAN PRACTITIONER WAS PERFORMING A PROCEDURE USING A MELDITE C6 LASER AT 6 J/CM2, 1064 NM, 10HZ WITH A 4 MM SPOT SIZE WHILE COMPRESSING THE SKIN WITH A GLASS WINDOW TO FORCE THE BLOOD AWAY FROM THE TREATMENT SITE TO MINIMIZE THE FORMATION OF PURPURA. SHE REPORTS THAT DURING THE PROCEDURE, SHE NOTICED BRIGHT SPOTS THAT CAUSED HER TO BLINK. AFTER THE PROCEDURE, SHE NOTICED THAT THERE CONTINUED TO BE A "BLACK" SPOT OR SHADOW IN HER CENTRAL VISION SIMILAR TO WHAT HAPPENS AFTER YOU LOOK DIRECTLY INTO A LIGHT BULB OR THE SUN AND THEN LOOK AWAY. SHE FURTHER REPORTS THAT 3 DAYS LATER, SHE WENT TO SEE AN OPHTHALMOLOGIST WHO EXAMINED HER AND FOUND BLEEING AND REFERRED HER TO A RETINAL SPECIALIST. WE HAVE NOT YET RECEIVED HER FORMAL MEDICAL RECORDS. SIXTEEN DAYS LATER, MS. PHAM SENT AN EMAIL TO AN INDEPENDENT CONTRACTOR WORKING WITH HOYA CONBIO, INFORMING HER OF THE ADVERSE EVENT. THE INDEPENDENT CONTRACTOR REVIEWED THE EMAIL FOR THE FIRST TIME AND REPORTED THE ALLEGED INJURY TO HOYA FOR THE FIRST TIME 5 DAYS LATER.

Concomitant Medical Products:

NA

Mfr Name: HOYA CONBIO
Address: 47733 FREMONT BLVD.  FREMONT, CA 94538  UNITED STATES

Device Available for Evaluation: Y  Device Evaluated by Manufacturer (H3): No
Remedial Action (H7): REPLACE  Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
08-JAN-2007: DEVICE NOT EVALUATED AS THERE IS NO DEFECT OR PROBLEM WITH THE DEVICE. THE EVENT MAY BE RELATED TO A LACK OF EYEWEAR OR THE USE OF INCORRECT EYEWEAR. THE EYEWEAR PROVIDED WITH THE C6 LASER SYSTEM IS TO PROTECT FOR USE WITH THE 1064 AND 532 NM WAVELENGTHS. THIS EYEWEAR HAS A SLIGHT AMBER TINT. THE REPORTER REQUESTED THAT A HOYA REPRESENTATIVE SEND HER A CLEAR SET OF EYEWEAR WITHOUT THE AMBER TINT. HOYA SENT CLEAR EYEWEAR TO HER, BUT SENT EYEWEAR RATED ONLY FOR 2940 NM. UPON RECEIPT OF THE EYEWEAR, SHE DID NOT CHECK THE RATING ON THE EYEWEAR PRIOR TO USING THEM. SHE USED THEM FOR SEVERAL MONTHS PRIOR TO 11/06. SHE CLAIMS TO HAVE BEEN WEARING THIS EYEWEAR IN 2006 WHEN SHE ALLEGEDLY RECEIVED A BACK REFLECTION OFF OF THE SURFACE OF THE COMPRESSION WINDOW SHE WAS USING. THE 2940 NM EYEWEAR WAS REMOVED FROM THE TREATMENT ROOM IMMEDIATELY AFTER THE EVENT AND REPLACEMENT EYEWEAR WITH THE CORRECT PROTECTION WAS SENT TO INSTITUTE ON 12/20/06.

DEVICE INFORMATION:

- **Brand:** MEDLITE C6
- **Device Type:** LASER, Q-SWITCHED ND: YAG
- **Catalog:** 659-0020
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** NA - NOT APPLICABLE
Event Date (B3): 13-Oct-2000
Report Date (B4): 14-Nov-2000
Report Date (F8): 14-Nov-2000
Date Mfr Rec'd (G4):

Event Report Type: INJURY
Event Report Type: OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Adverse Event (B1): Y
Problem (B1): Y

Event Outcome (B2): OTHER
Event Location (F12): HOSPITAL

Reporter Occupation (E3): OTHER
Report Source (G3): CONSUMER, HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): 5 YR 1 DAYS (5 YR)
Manufacture Date (H4): 01-Jul-1995

Expiration Date: Single Use (H5): N
Device Usage (H8): R

Event Description (B5):

Concomitant Medical Products:
N.I.

Mfr Name: NIDEK CO. LTD.
Address: 34-14 MAEHAMA, HIROISHI-CHO GAMAGORI, AICHI, JAPAN

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** NIDEK DIODE LASER PHOTOCOAGULATOR
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** DC-3000
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** OTHER

Health Professional: Yes
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 2936999-2007-00531</th>
<th>Mfr Name: COVIDIEN, FORMERLY NELLCOR PURITAN BENNETT, INC.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 12-Nov-2007</th>
<th>Event Report Type: INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 19-Nov-2007</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

| Event Description (B5): Mfr 03-DEC-2007: LARYNGECTOMY PROCEDURE PERFORMED ON A FEMALE PATIENT (APPROX 160CM HEIGHT). THE LASER FLEX WAS DEFLATED FOR EXTUBATION, BUT THE CUFF KEPT A FORM LIKE A 4-TIMES-JAGGED STAR. THE VOCAL CORDS SWELLED AND THERE WAS NO CHANCE TO EXTUBATE THE PATIENT DUE TO THE ENLARGED DIAMETER OF THE CUFF. THE ONLY WAY TO EXTUBATE THE LASER FLEX WAS WITH FORCE. MD ADMITTED TO USING TOO LARGE OF TUBE. AFTER INCIDENT, PATIENT WAS REINTUBATED FOR 4 DAYS AND MOVED TO ICU. |

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name: ATHLONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: CORNMADDY, ATHLONE, IRELAND</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 03-DEC-2007: EVENT OCCURRED IN A FOREIGN COUNTRY. SAME PRODUCT IS SOLD/DISTRIBUTED IN US.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** MALLINCKRODT LASER FLEX TRACHEAL TUBE
- **Device Type:** LASER FLEX
- **Catalog:** 160-60
- **Serial:** (*confidential*)
- **Lot:** 2007070446
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>EMAIL:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td>[b] (6)</td>
<td>[b] (6)</td>
<td>[b] (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
<th>International:</th>
</tr>
</thead>
<tbody>
<tr>
<td>[b] (6)</td>
<td>[b] (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fax:</th>
</tr>
</thead>
<tbody>
<tr>
<td>[b] (6)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health Professional:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occupation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTHER</td>
</tr>
</tbody>
</table>

Recd: 867  Page: 1,741  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
2937094-1997-00016

Mfr Name: LASERSCOPE

Event Date (B3): 06-Oct-1997
Event Report Type: OTHER

Report Date (B4): 21-Oct-1997
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Report Date (F8): 21-Oct-1997
Reporter Occupation (E3): UNK - UNKNOWN

Date Mfr Rec’d (G4): 21-Oct-1997
Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-LIGHT SOURCE, ENDOSCOPE, XENON ARC (GCT)
Device Age (F9):
Manufacture Date (H4):
Expiration Date:
Device Usage (H8): U

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: LASERSCOPE
Address: 3025 ORCHARD DR.
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: N

Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7): OTHER

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
05-JAN-1998: K970157. FREQUENCY AND SEVERITY OF EVENT UNKNOWN.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** ENDOSCOPE EYE FILTER
- **Device Type:** LASER ACCESSORIES
- **Device Type:** 10-0433
- **Catalog:** 0010-0433
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** 0010-0433

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **Occupation:** UNK - UNKNOWN
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Date (B3):** 16-Feb-2001  
**Event Report Type:** OTHER  
**Adverse Event (B1):** Problem (B1): Y

**Event Location (F12):** Reporter Occupation (E3): UNK - UNKNOWN  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Report Date (B4):** 20-Feb-2001  
**Device Operator:** HEALTH PROFESSIONAL  
**Date Mfr Rec'd (G4):** 20-Feb-2001

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):** Manufacture Date (H4): 01-Jan-1997  
**Expiration Date:** Single Use (H5):  
**Device Usage (H8):** U

**Event Description (B5):**

Mfr 11-FEB-2003: LASER RENTAL COMPANY REPORTED DOCTOR (S) TREATED 10 CONSECUTIVE PTS FOR FACIAL TELANGIECTASIA NEAR OR AROUND THE PERIORBITAL AREA. FIVE PATIENTS EXPERIENCED SWELLING, REDNESS, BLISTERING, CRUSTING, DISCOLORATION, AND SCARRING. THREE PTS EXPERIENCED SWELLING WHERE THE EYES WERE COMPLETELY SWOLLEN SHUT.

**Concomitant Medical Products:**

NA

**Mfr Name: LASERSCOPE**  
**Address:** 3070 ORCHARD DR.  
SAN JOSE, CA 95134  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

Recd: 869  
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**


**DEVICE INFORMATION:**

- **Brand:** AURA
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** 0010-8112
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K951034

**Reprocessed & Reused:** N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)

Health Professional: No

Occupation: UNK - UNKNOWN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2937094-2003-00002
Mfr Name: LASERSCOPE

Report Date (B4): 12-Mar-2003
Event Date (B3): 04-Feb-2003
Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Y Problem (B1): N

Date Mfr Rec'd (G4): 12-Feb-2003
Event Location (F12): OUTPATIENT TREATMENT FACILITY
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL
Report Source (G3): HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE

MFR Report No: 2937094-2003-00002
Report Date (F8): 12-Feb-2003

Reporter Occupation (E3): 001 - PHYSICIAN
Device Usage (H8): R
Manufacture Date (H4): 01-Dec-2001
Expiration Date: Single Use (H5): N

Event Description (B5):
Mfr 17-MAR-2003: PT RECEIVED SUPERFICIAL 2ND DEGREE BURNS AND DEEP 2ND DEGREE BURNS FOLLOWING HAIR REMOVAL TREATMENT FOR THE BEARD AREA.

Concomitant Medical Products:
NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

17-MAR-2003: H.3: INITIAL INVESTIGATION REVEALED PARAMETERS USED ON PT WERE SLIGHTLY HIGHER THAN SUGGESTED TEST SPOT PARAMETERS CALLED OUT IN LASERSCOPE'S IN-SERVICE TRAINING GUIDE. PT HAS A FITZGERALD SKIN TYPE V, COARSE HAIR. THE TRAINING GUIDE STATES: "CAUTION" THE FOLLOWING TREATMENT PARAMETERS ARE THOSE REPORTED BY PHYSICIANS USING LASERSCOPE PRODUCTS EITHER IN PUBLISHED LITERATURE OR REPORTED DIRECTLY TO LASERSCOPE. ULTIMATELY, IT IS THE PHYSICIAN'S RESPONSIBILITY TO DETERMINE SAFE TREATMENT PARAMETERS THAT WILL BE USED ON A CASE BY CASE BASIS." THE FACILITY REPORTED THERE WERE NO PROBLEMS WITH THE FUNCTION OF THE LASER. LASERSCOPE'S CLINICAL EDUCATOR WAS AT THE SITE DURING THE TREATMENT. THEY DID NOT NOTICE A PROBLEM WITH THE LASER, HANDPIECE, OR THE CHILLER. LASERSCOPE PERFORMED A PREVENTIVE MAINTENANCE ON THE LASER 8 DAYS BEFORE TREATMENT OF THE PT. THE SYSTEM WAS WITHIN MFR'S SPECIFICATION. THE LASER WILL BE RETURNING FOR A FULL EVAL. A FOLLOW UP SUPPLEMENTAL MEDWATCH WILL BE SENT.

**DEVICE INFORMATION:**

- **Brand:** LYRA
- **Device Type:** LASER
- **Catalog:** 0010-1502
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K010834

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2003-00006</th>
<th>Mfr Name: LASERSCOPE</th>
<th>Date Received</th>
<th>26-Nov-2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>29-Oct-2003</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Product Code: | (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9): | Manufacture Date (H4): |
| Expiration Date: | Single Use (H5): |
| | Device Usage (H8): R |

| Event Description (B5): |

| Concomitant Medical Products: |
| NA |

| Mfr Name: LASERSCOPE |
| Address: 3070 ORCHARD DR. |
| SAN JOSE, CA 95134 |
| UNITED STATES |

| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | Yes |

| Remedial Action (H7): |
| Correction/Removal No (H9): | NA |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** GREENLIGHT PV
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** 0010-8770
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K010284

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **EMAIL:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No Information
- **Occupation:** * - INVALID DATA
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2005-00002</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
<th>Date Received</th>
<th>13-Apr-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Mar-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4):
Single Use (H5):
Device Usage (H8): U

Event Description (B5):
Mfr 19-APR-2005: LASERSCOPE CLINICIAN REPORTED PATIENT HAD UNDERGONE GREENLIGHT PVP PROCEDURE IN 2005. NO INTRAOPERATIVE BLEEDING AND CASE WAS UNEVENTFUL. PATIENT WAS PLACED IN ICU 3 DAYS LATER. X-RAYS REVEALED PATIENT HAD TOTAL OBSTRUCTION ON RIGHT SIDE OF URETER.

Concomitant Medical Products:
NA

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DR.
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9): NA
Additional Mfr Narrative (H10 & H11):

19-APR-2005: H.3 LASERSCOPE'S CLINICIAN WAS PRESENT DURING THE GREENLIGHT PVP PROCEDURE. THIS WAS THE DOCTOR'S 3RD PVP CASE OF THE DAY. PATIENT HAD PREVIOUS TURP (TRANSURETHRAL RESECTION) AND TUIP (TRANSURETHRAL INCISION OF THE PROSTATE) FOR BLADDER NECK CONTRACTURE, BUT WAS STILL HAVING VOIDING PROBLEMS. NO INTRAOPERATIVE BLEEDING ENCOUNTERED AND THE CASE WAS UNEVENTFUL. TWO DAYS LATER THE DOCTOR REPORTED PATIENT HAD NO URINE PRODUCTION. A CT SCAN SHOWED BILATERAL HYDRONEPHROSIS. THE NEXT DAY THE PATIENT WAS STARTING TO PRODUCE URINE. SCOPE SHOWED PATIENT'S BOTH URETERAL ORIFICES HAD BEEN LASED. FOLLOW UP THE FOLLOWING DAY: X-RAYS SHOWED TOTAL OBSTRUCTION OF URETER ON RIGHT SIDE, LEFT SIDE WAS OPEN. PATIENT WAS TO RETURN IN 10-14 DAYS AND DOCTOR MAY STENT THE RIGHT URETER IF NEEDED. ADDITIONAL FOLLOWUP ON 4-11-05 - DOCTOR REPORTED THAT PATIENT WAS SEEN AT THE TWO WEEK MARK AND X-RAYS SHOWED THE RIGHT URETER TO BE OPEN. THE NEPHROSTOMY TUBE WAS CLAMPED OFF FOR TWO DAYS WITHOUT PROBLEMS, AND THEN REMOVED. THE PATIENT IS DOING FINE. HIS ONLY CONCERN WAS FOR SCARRING ON THE URETERAL ORIFICES IN THE FUTURE. THERE WAS NO INDICATION THAT THE GREENLIGHT LASER OR THE ADDSTAT FIBER HAD MALFUNCTIONED, THEREFORE NO ANALYSIS WAS PERFORMED ON THE LASER. THE OUTCOME WAS UNUSUAL AND MAY HAVE BEEN DUE TO THE PATIENT'S PREVIOUS PROCEDURES, TURP AND TUIP, WHICH COULD HAVE CAUSED THE URETERS TO BE MUCH CLOSER TO THE BLADDER NECK AND/OR DIFFICULT TO SEE. IF FURTHER INFORMATION IS RECEIVED, A FOLLOW-UP MEDWATCH WILL BE SENT. LASERSCOPE'S GREENLIGHT PV SURGICAL LASER SYSTEM TRAINING MANUAL, P/N 0126-3230, REVISION F, CHAPTER 7, PG. 44 STATES THE FOLLOWING: "IT IS VERY IMPORTANT TO KEEP AN EYE ON THE AIMING/LASING BEAM AT ALL TIMES TO AVOID INADVERTENT TISSUE DAMAGE, ESPECIALLY IN THE TRIGONE AREA OF THE BLADDER FLOOR. IT IS STRONGLY EMPHASIZED THAT SPECIAL CARE CAN BE TAKEN WHEN TREATING THE BLADDER NECK, AS FORWARD SCATTER OF LASER LIGHT ONTO THE TRIGONE CAN CAUSE DELAYED POST-OPERATIVE DYSURIA, OR WORSE, DAMAGE TO THE URETERAL ORIFICES."

DEVICE INFORMATION:

- **Brand:** GREENLIGHT PV
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** 0010-9230
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K010284

Reprocessed & Reused: N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

REPORter INFORMATION:

<table>
<thead>
<tr>
<th>Name:</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>(b) (6)</td>
</tr>
</tbody>
</table>

Health Professional: Yes

EMAIL: (b) (6)

Phone: (b) (6)

International: Fax:

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2005-00004</th>
<th>Mfr Name: LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Jul-2005</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Jul-2005</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>01-Jul-2005</td>
<td>Device Operator: LAY USER/PATIENT</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4): 01-Mar-2005</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 02-AUG-2005: THE DOCTOR REPORTED THAT THE OPERATOR OF THE LASER HAD SUDDEN BILATERAL EYE PAIN AND SWELLING. THE OPERATOR WAS SEEN BY EMERGENCY ROOM PERSONNEL AND WAS TOLD THEY HAD BILATERAL CORNEAL ABRASIONS, AKIN TO &quot;WELDER'S EYES&quot; AND THAT THEY REQUIRED TIME OFF.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

Brand: GEMINI  
Device Type: LASER  
Device Type: NA  
Catalog: 0010-1090  
Serial: (*confidential*)  
Lot: NA  
Other ID: K034011

Reprocessed & Reused: N

**REPORTER INFORMATION:**

Name: [b] (b)  
Address: [b] (b)  
EMAIL: [b] (b)  
Phone: [b] (b)  
International:  
Fax:  
Health Professional: Yes  
Occupation: 001 - PHYSICIAN
### MAUDE EVENT REPORT (FOI)

#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2005-00006</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>29-Jul-2005</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>29-Jul-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>29-Jul-2005</td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>29-Jul-2005</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Mfr 30-AUG-2005:</td>
<td>THE FACILITY REPORTED THE EYE SAFETY FILTER ON THE LASER FAILED TO ACTIVATE. THE DOCTOR RECEIVED A BURN TO THEIR LEFT MACULA WITH SWELLING, BLURRED VISION AND LOSS OF DEPTH PERCEPTION.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-1989</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010  9:17 AM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**

NA

**Mfr Name:** LASERSCOPE  
**Address:** 3070 ORCHARD DR.  
SAN JOSE, CA 95134  
UNITED STATES

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

30-AUG-2005: THE DOCTOR IS BEING TREATED BY AN OPHTHALMOLOGIST. LASERSCOPE HAS BEEN UNABLE TO GET ANY FURTHER INFORMATION AS TO THE DOCTOR'S CURRENT CONDITION. LASERSCOPE'S CUSTOMER SERVICE ENGINEER VISITED SITE AND COULD NOT REPRODUCE THE CONDITION THE FACILITY STATED HAD HAPPENED, WITHOUT OVERRING THE EYE SAFETY FILTER. THE TESTS DID SHOW THERE MAY HAVE BEEN A PROBLEM WITH THE EYE SAFETY FILTERS AS IT DID NOT RECOGNIZE THE DEVICE, HOWEVER THE DOCTOR WOULD HAVE HAD TO OVERRIDE THE SYSTEM IN ORDER TO USE THE LASER. THE LASER PERFORMED PROPERLY AND ACCORDING SPECIFICATION. LASERSCOPE REPLACED THE EYE SAFETY FILTER AND THE LASER IS WORKING PROPERLY. THE EYE SAFETY FILTER WAS RETURNED AND TESTED IN-HOUSE. THIS TEST PRODUCED AN ERROR WHICH INDICATED THAT THE DEVICE WAS NOT ATTACHED AND THEREFORE HAD A POSSIBLE ELECTRICAL PROBLEM. INVESTIGATION FOUND THAT THE DOCTOR WAS NOT WEARING EYE SAFETY GLASSES. LASERSCOPE DID NOT HAVE A SERVICE CONTRACT WITH THIS FACILITY SINCE MAY 2002. A THIRD PARTY SERVICE CO WAS HANDLING ANY REPAIRS AND SERVICE. MODEL 700 SERIES OPERATOR'S MANUAL STATES THE FOLLOWING: "CAUTION: LASER LIGHT PRESENTS A SEVERE EYE HAZARD AND A POTENTIAL FOR BURNS OR FIRE. THE AIM BEAM(S) MAY BE VIEWED BY AN UNPROTECTED EYE, BUT NEVER VIEW THE SURGICAL BEAM DIRECTLY OR BY REFLECTION. AVOID EXPOSURE TO THE LASER BEAM. TAKE ALL NECESSARY PROTECTIVE MEASURES IN AREAS WHERE THE LASER IS BEING USED." "THE SURGEON AND OTHER OPERATING ROOM PERSONNEL: EACH WAVELENGTH OF LIGHT REQUIRES PROTECTION MATCHED TO THAT WAVELENGTH. SINCE THE LASER EMITS LIGHT AT 532 NM OR WITH OPTIONAL ND: YAG MODULE, 1064 NM, ONLY LASERSCOPE APPROVED EYEWEAR SHOULD BE WORN."

DEVICE INFORMATION:

- **Brand:** 704
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** 0010-0704
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** P940012-S002

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2006-00010</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>18-Aug-2006</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>18-Aug-2006</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>19-Aug-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 20-SEP-2006: THE DOCTOR CONDUCTED A PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE (PVP) PROCEDURE WITH A LASERSCOPE GREENLIGHT LASER SYSTEM ON A PATIENT WITH LOWER URINARY TRACT SYMPTOMS DUE TO BENIGN PROSTATIC HYPERPLASIA. DURING THE PROCEDURE, SIGNIFICANT BLEEDING WAS ENCOUNTERED. THE DOCTOR WAS UNABLE TO CONTROL THE BLEEDING WITH THE LASER AND CONVERTED TO A TURP. THE PATIENT RECEIVED BLOOD TRANSFUSIONS INTRA-OPERATIVELY.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Aug-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- Brand: GREENLIGHT
- Device Type: LASER
- Catalog: 0010-0070
- Serial: (*confidential*)
- Lot: NA
- Other ID: K010284

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [b] (6)
- Address: [b] (6)
- EMAIL: [b] (6)
- Phone: [b] (6)
- International: [b] (6)
- Fax: [b] (6)
- Health Professional: Yes
- Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 2937094-2007-00001
Mfr Name: LASERSCOPE

Event Date (B3): 01-Jul-2006
Report Date (B4): Omitted
Report Date (F8):
Date Mfr Rec'd (G4): 07-Dec-2006

Adverse Event (B1): Y Problem (B1): N
Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): * - INVALID DATA
Report Source (G3): PATIENT'S FATHER, FOREIGN

Mfr Name: LASERSCOPE
Event Description (B5):
Mfr 23-JAN-2007: THE PATIENT'S FATHER CONTACTED OUR CLINICAL DIRECTOR OF UROLOGY AS THEY WERE UNHAPPY WITH THE FOLLOW UP FROM THE DOCTOR WHO HAD PERFORMED THE GREENLIGHT PV PROCEDURE. THE PATIENT HAS EXPERIENCED INCONTINENCE, BURNING IN THE URETHRA, AND NEEDED A SUPRA PUBIC TUBE PUT IN TO RELIEVE A COMPLETE STRicture IN PROSTATE AREA. PAIN HAS CAUSED PATIENT TO BECOME INACTIVE.

Concomitant Medical Products: NA

Mfr Name: LASERSCOPE/AMS,
Address: 3070 ORCHARD DR. SAN JOSE, CA 95134 UNITED STATES

Device Available for Evaluation: N
Remedial Action (H7):
Correction/Removal No (H9): NA

Device Evaluated by Manufacturer (H3): No

Event Location (F12):
Report Date (F8): * - INVALID DATA
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Manufacture Date (H4):
Single Use (H5): N
Device Usage (H8): U

Recd: 876
Page: 1,761
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

23-JAN-2007: LASERSCOPE/AMS DIRECTOR OF CLINICAL UROLOGY HAS PUT THE PATIENT/PATIENT'S FATHER IN CONTACT WITH ANOTHER DOCTOR FOR HELP IN RESOLVING THE PATIENT'S PROBLEMS. INVESTIGATION FOUND THAT PATIENT'S PAIN IS ESCALATING BUT HAD NOT BEEN EVALUATED FOR POSSIBLE URINARY TRACT INFECTION; WHICH WOULD BE A POSSIBLE REASON FOR THE PAIN. INCONTINENCE IS A POSSIBLE KNOWN SIDE EFFECT; THOUGH LESS THAN 2%, AND IS LISTED IN THE GREENLIGHT PV SURGICAL LASER SYSTEM TRAINING MANUAL, P/N 0126-2320 UNDER COMPLICATIONS AND RISKS. LASERSCOPE DOES NOT KNOW THE S/N OF THE LASER THAT WAS USED ON THE PATIENT. NO EVALUATION HAS BEEN PERFORMED. THERE WAS NO MALFUNCTION OF THE LASER REPORTED. THE PATIENT/PATIENT'S FATHER DID NOT STATE THAT THERE WAS A POSSIBLE MALFUNCTION OF THE LASER. A FOLLOW UP REPORT WILL BE SENT IF LASERSCOPE/AMS LEARNS ANYTHING FURTHER CONCERNING THE PATIENT'S OUTCOME.

**DEVICE INFORMATION:**

- **Brand:** GREENLIGHT PV
- **Device Type:** LASER
- **Catalog:** 0010-9230
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K010284

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** UNK
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Health Professional:** No
- **Occupation:** * - INVALID DATA
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
26-Jan-2007

MFR Report No: 2937094-2007-00003
Mfr Name: LASERSCOPE

Event Date (B3): 28-Dec-2006
Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Y
Problem (B1): N

Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9):
Expiration Date:
Device Usage (H8): U

Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 01-FEB-2007: PHYSICIAN CONTACTED LASERSCOPE/AMS TO REPORT THAT THERE WAS LIGHT IN HER CENTER VISION DUE TO BAD GLASSES. INFORMATION REPORTED BY THE PHYSICIAN WAS THAT HER RETINA WAS RUINED.

Concomitant Medical Products:
NA

Mfr Name: LASERSCOPE/AMS
Address: *
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
01-FEB-2007: THE PHYSICIAN REPORTED TO LASERSCOPE/AMS THAT SHE HAD NOT SEEN A DOCTOR. NO MALFUNCTION OF THE LASER WAS REPORTED. CORRECT EYEWEAR, P/N 0010-0008 WAS SENT TO THE FACILITY. OPTICAL DENSITY FOR THIS EYEWEAR IS SUFFICIENT FOR USE WITH THE GEMINI LASER. OD IS 5 @ 532NM AND 5 @ 1064NM. EYEWEAR WAS SENT BACK TO LASERSCOPE/AMS FOR EVALUATION. PRELIMINARY EVALUATION HAS TAKEN PLACE: THE EYEWEAR DOES NOT EXHIBIT ANY ANOMALIES IN TERMS OF PERFORMANCE AT 532NM AND 1064NM. THEREFORE, INITIAL ASSESSMENT IS THAT THE EYEWEAR IS SAFE FOR USE ON A GEMINI LASER. FURTHER IN-DEPTH ANALYSIS WILL BE PERFORMED AND RESULTS WILL BE PRESENTED IN FOLLOW-UP MEDWATCH REPORT.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand**: GEMINI
- **Device Type**: LASER
- **Catalog**: 0010-1090
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: K034011

**Reprocessed & Reused**: N

### REPORTER INFORMATION:

- **Name**: (b)(6)
- **Address**: (b)(6)
- **Health Professional**: Yes
- **Occupation**: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Event Description (B5):**
Mfr 01-FEB-2007: FACILITY CALLED TO REPORT THAT DURING A PROCEDURE THE BRONCHOSCOPE BURNED AND PT WAS INJURED. THE DOCTOR HAD FIRED THE LASER AND STARTED TO PULL THE FIBER OUT, WHICH THEN CAUSED A FLAME IN THE PT'S CHEST.

**Concomitant Medical Products:**
NA

**Mfr Name:** LASERSCOPE/AMS
**Address:** *SAN JOSE, SD *
UNITED STATES

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** No

**Remedial Action (H7):**
**Correction/Removal No (H9):** NA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
01-FEB-2007: LASERSCOPE IS STILL GATHERING INFO ON THE INCIDENT. LASERSCOPE HAS LEFT 2 MESSAGES WITH THE RISK MGMT AT THE FACILITY. THE CALLS HAVE NOT YET BEEN RETURNED. EXTENT OF INJURY IS UNKNOWN. THERE WAS NO MALFUNCTION OF THE LASER REPORTED. LASERSCOPE'S CUSTOMER SERVICE ENGINEER VISITED THE FACILITY ON 1/26/2007 TO INSPECT THE LASER, BUT WAS DENIED ACCESS PER THEIR RISK MGMT. LASERSCOPE HAS ALSO REQUESTED THE FIBER USED BE SENT BACK FOR EVAL. THE FIBER HAS NOT BEEN SENT BACK AND IT IS UNKNOWN WHAT FIBER OR LOT NUMBER WAS USED. A FOLLOW-UP MEDWATCH REPORT WILL BE SENT IF LASERSCOPE OBTAINS ADD'L INFO.

LASERSCOPE'S 800 SERIES OPERATOR'S MANUAL, P/N 0010-1901, PAGE 2-17 STATES: ANSI ANESTHESIA RECOMMENDATIONS: THE FOLLOWING SAFETY GUIDELINES ARE RECOMMENDED BY ANSI Z136.3-1988, SECTIONS 7.5.2.1 AND 7.6: "USE NON-FLAMMABLE LASER-SAFE ENDOTRACHEAL TUBES."

DEVICE INFORMATION:

Brand: 813
Device Type: LASER
Catalog: 0010-2703
Serial: (*confidential*)
Lot: NA
Other ID: K970948

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax:

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2007-00006</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
<th>Date Received: 29-Mar-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Mar-2007</td>
<td>Event Report Type:</td>
<td>DEATH</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2):</td>
<td>DEATH</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>01-Mar-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4): 01-Sep-2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Single Use (H5): N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Device Usage (H8): R</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Mfr 04-APR-2007: CUSTOMER REPORTED TO AMS PERSONNEL THAT FOLLOWING A BPH TREATMENT WITH THE GREENLIGHT HPS LASER SYSTEM, THE PATIENT'S BLADDER HAD PERFORATED AND WAS IN ICU. THE PATIENT COULD NOT BE EXTUBATED FOLLOWING THE PROCEDURE (FROM ANESTHESIA) DUE TO THE AMOUNT OF FLUID IN HIS ABDOMEN FROM THE IRRIGATION.

**Concomitant Medical Products:**
NA

**Mfr Name:** AMS INNOVATION CENTER
**Address:** 3070 ORCHARD DR.
SAN JOSE, CA 95134
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):** NA

DEVELOPMENT INFORMATION:

**Brand:** GREENLIGHT HPS
**Device Type:** LASER
**Catalog:** 0010-0070
**Serial:** (*confidential*)
**Lot:** NA
**Other ID:** K010284
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2007-00008</th>
<th>Mfr Name:</th>
<th>AMS INNOVATIVE CENTER-SAN JOSE</th>
<th>Date Received</th>
<th>07-Dec-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>05-Nov-2007</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>08-Nov-2007</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-Nov-2007</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Expiration Date:</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 19-FEB-2008: THE DOCTOR REPORTED A COMPLICATION DURING THE GREENLIGHT PVP (PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE) PROCEDURE FOR BPH. THE PT HAD FLUID ABSORPTION THAT ENDED WITH AN ACUTE RENAL FAILURE.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>AMERICAN MEDICAL SYSTEMS, INNOVATIVE CENTER -SILICON VALLEY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>SAN JOSE, CA 95134</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010  9:17 AM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

19-FEB-2008: IT IS UNKNOWN IF THE LASER SYSTEM USED WAS A GREENLIGHT PV OR A GREENLIGHT HPS. AMS HAS MADE ATTEMPTS TO CONTACT THE DR FOR MORE INFO. AT THIS TIME, THERE HAS BEEN NO RESPONSE. IT IS UNKNOWN IF THE PT HAD ANY PRE-EXISTING CONDITIONS. RENAL FAILURE IS VERY RARE TO THE PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE (PVP) Procedure. It is generally caused by excess fluid absorption, which then disrupts the kidney function and results in sodium levels in the body being upset. Managing the fluid imbalance and restarting normal kidney function (perhaps with interim dialysis) would be normal treatment. Solutions other than saline irrigant would cause fluid to be absorbed more rapidly. There was no report of any laser malfunction. "RENAL INSUFFICIENCY" is listed under precautions in the Greenlight PV operator manual. (SECTION 2.4). A follow-up report will be submitted if any additional info is obtained.

DEVICE INFORMATION:

Brand: GREENLIGHT PV
Device Type: LASER
Device Type: NA
Catalog: 0010-9230
Serial: (*confidential*)
Lot: NA
Other ID: K010284

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] [b]
Address:

Email: [b] [b]
Phone:
International: UNK - -
Fax:

Health Professional: Yes

Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2008-00004</th>
<th>Mfr Name:</th>
<th>AMS INNOVATIVE CENTER-SAN JOSE</th>
<th>Date Received</th>
<th>16-Sep-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>07-Aug-2008</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>08-Aug-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>08-Aug-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: AMERICAN MEDICAL SYSTEMS, INNOVATION CENTER- SILICON VALLEY
Address: SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT HPS
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** 0010-0070
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K010284

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 29-Oct-2008

MFR Report No: 2937094-2008-00005

Mfr Name: AMS INNOVATIVE CENTER-SAN JOSE

Event Date (B3): 29-Oct-2008
Event Report Type: OTHER

Report Date (B4): 29-Oct-2008
Event Outcome (B2): HOSPITALIZATION

Report Date (F8): 29-Oct-2008
Reporter Occupation (E3): 100 - OTHER HEALTH CARE PROFESSIONAL

Event Location (F12):

Date Mfr Rec'd (G4): 29-Oct-2008
Device Operator: USER FACILITY, EMPLOYEE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Single Use (H5): N
Expiration Date:
Device Usage (H8): R

Event Description (B5):
Mfr 04-MAY-2009: AN EMPLOYEE FROM THE FACILITY REPORTED THAT AS HE WAS UNPLUGGING THE GREENLIGHT HPS CONSOLE, AFTER SWITCHING THE CIRCUIT BREAKER OFF, HE WAS BURNED BY THE PLUG. THE EMPLOYEE WAS EVALUATED IN THE ER AT THE FACILITY. IT WAS REPORTED, THERE WERE BLACK MARKS ON HIS FINGERS AND THAT HE HAD LOST FEELING FROM HIS FINGERS TO HIS ELBOW.

Concomitant Medical Products:
NA

Mfr Name: AMERICAN MEDICAL SYSTEMS
Address: INNOVATION CENTER
SILICON VALLEY
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Recd: 882 Page: 1,775
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

04-May-2009: FOLLOW UP WITH THE RISK MGR AT THE FACILITY REVEALED THAT THE EMPLOYEE HAD BEEN ADMITTED TO THE HOSPITAL. NO FURTHER INFO WAS GIVEN TO AMS AS TO THE EMPLOYEE'S CONDITION EXCEPT THAT HE HAD BEEN RELEASED FROM THE HOSPITAL A FEW DAYS LATER. THE RISK MGR STATED THAT THEY HAD FILED A MEDWATCH REPORT. IT WAS ALSO REPORTED TO AMS THAT THE RECEPTACLE IN THE OR WAS TESTED AND FOUND WORKING PROPERLY. THE FACILITY REQUESTED A 3RD PARTY TEST THE LASER WHICH WAS PERFORMED ON (B) (6) 2008. AMS REQUESTED THAT OUR CUSTOMER SERVICE ENGINEER BE AT THE SITE AT THE TIME OF THE TESTING. THIS WAS NOT GRANTED. THE 3RD PARTY REPORT WAS GIVEN TO AMS. THE REPORT STATED THAT A CONTINUITY TEST WAS PERFORMED ON THE POWER CORD WIRES AND THEY CHECKED OUT FINE. THE FACILITY REQUESTED THE LASER REMAIN SINCE THERE WAS NO PROBLEM FOUND WITH IT BY THE 3RD PARTY.


Recd: 882  Page: 1,776  Date Last Updated: 11/2/2010 9:17 AM
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** GREENLIGHT HPS
- **Device Type:** LASER
- **Device Type:** NA
- **Catalog:** 0010-0070
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** K010284

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** 
- **Address:** (b) (b) (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (b)
- **Phone:** (b) (b)
- **International:**
- **Fax:**
- **Occupation:** 100 - OTHER HEALTH CARE PROFESSIONAL

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2937094-2009-00002</th>
<th>Mfr Name:</th>
<th>AMS INNOVATIVE CENTER-SAN JOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>15-Jun-2009</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Jun-2009</td>
<td>Event Date (B5):</td>
<td>15-Jun-2009</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Jun-2009</td>
<td>Event Outcome (B2):</td>
<td>HOSPITALIZATION</td>
</tr>
<tr>
<td>Mfr 24-JUL-2009: DESCRIPTION EVENT IS TAKEN IN-PART FROM FACILITY'S (B)(6) MEDWATCH REPORT. (B)(4). PT WAS ADMITTED TO THE HOSPITAL WITH THREE-MONTH HISTORY OF PERSISTENT PNEUMONIA. CT SCAN SHOWED CALCIFIED MASS OBSTRUCTING THE RIGHT MIDDLE LOBE TAKEOFF INTRALUMINALLY. A SURGICAL PROCEDURE WAS SCHEDULED FOR DIRECT LARYNGOSCOPY, BRONCHOSCOPY AND BIOPSY OF MASS WITH KTP LASER. PT WAS INITIALLY INTUBATED AND A FLEXIBLE ADULT FIBER OPTIC BRONCHOSCOPE WAS PLACED THROUGH ETT. BIOPSIES WERE OBTAINED. THE KTP LASER WAS USED TO CONTROL BLEEDING. PT VENTILATED WITH 21% FI02, THEN INCREASED TO 100%. THE SURGEON WAS UNABLE TO REMOVE THE MASS. A RIGID BRONCHOSCOPE WAS THEN PLACED AND ATTEMPTS TO REMOVE MASS WAS UNSUCCESSFUL. THE PRIMARY SURGEON USED THE KTP TO DEMONSTRATE TO THE GENERAL SURGEON THE HARDNESS OF THE MASS. THE LIGHT OF THE BRONCHOSCOPE WENT OFF AND LASER PUT IN STANDBY. A SMALL AMOUNT OF SMOKE WAS NOTED IN THE ETT. IT APPEARED ONE SIDE OF THE SCOPE HAD BEEN MELTED. EXAMINATION FOUND MELTED PLASTIC VERSES VAPORIZED PLASTIC FROM THE END OF THE FLEXIBLE SCOPE. PT TRANSFERRED TO INTENSIVE CARE.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td>Event Outcome (B2):</td>
<td>HOSPITALIZATION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Jun-2009</td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>USER FACILITY, COMPANY REPRESENTATIVE</td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>17-Jun-2009</td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 24-JUL-2009: DESCRIPTION EVENT IS TAKEN IN-PART FROM FACILITY'S (B)(6) MEDWATCH REPORT. (B)(4). PT WAS ADMITTED TO THE HOSPITAL WITH THREE-MONTH HISTORY OF PERSISTENT PNEUMONIA. CT SCAN SHOWED CALCIFIED MASS OBSTRUCTING THE RIGHT MIDDLE LOBE TAKEOFF INTRALUMINALLY. A SURGICAL PROCEDURE WAS SCHEDULED FOR DIRECT LARYNGOSCOPY, BRONCHOSCOPY AND BIOPSY OF MASS WITH KTP LASER. PT WAS INITIALLY INTUBATED AND A FLEXIBLE ADULT FIBER OPTIC BRONCHOSCOPE WAS PLACED THROUGH ETT. BIOPSIES WERE OBTAINED. THE KTP LASER WAS USED TO CONTROL BLEEDING. PT VENTILATED WITH 21% FI02, THEN INCREASED TO 100%. THE SURGEON WAS UNABLE TO REMOVE THE MASS. A RIGID BRONCHOSCOPE WAS THEN PLACED AND ATTEMPTS TO REMOVE MASS WAS UNSUCCESSFUL. THE PRIMARY SURGEON USED THE KTP TO DEMONSTRATE TO THE GENERAL SURGEON THE HARDNESS OF THE MASS. THE LIGHT OF THE BRONCHOSCOPE WENT OFF AND LASER PUT IN STANDBY. A SMALL AMOUNT OF SMOKE WAS NOTED IN THE ETT. IT APPEARED ONE SIDE OF THE SCOPE HAD BEEN MELTED. EXAMINATION FOUND MELTED PLASTIC VERSES VAPORIZED PLASTIC FROM THE END OF THE FLEXIBLE SCOPE. PT TRANSFERRED TO INTENSIVE CARE.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
24-JUL-2009: LASER EVALUATED BY AMS. FIBER NOT YET EVALUATED. (B)(6) HEALTH CTR CONTRACTED THE LASER FROM (B)(6). A COPY OF THE MEDWATCH REPORT WAS SENT TO AMS FROM (B)(6) HEALTH CTR. AMS CONTACTED THE RISK MANAGER AT THE (B)(6) HEALTH CTR. INJURY WAS TO THE PT'S AIRWAY BUT EXTENT OF THAT INJURY WAS UNK, BUT QUESTIONABLE DEBRIS WAS REMAINING. (B)(4) THE PT WAS INTUBATED FOR 24 HOURS. THE MEDWATCH REPORT FROM THE FACILITY STATES THE SCOPE THAT WAS USED WAS BF-P40, FROM OLYMPUS AMERICA, INC. THE FIBER OPTIC USED IN THIS CASE IS REPORTEDLY AN ENDOSTAT FIBER, 600 MICRON. THIS HAS NOT BEEN CONFIRMED AS THE FACILITY NO LONGER HAD THE ORIGINAL PACKAGING. AMS HAS REQUESTED THE FIBER BE SENT BACK FOR EVAL. THIS FIBER HAS NOT YET BEEN RETURNED. AMS CUSTOMER SERVICE ENGINEER VISITED THE (B)(6) HOSP AND PERFORMED IN EVAL ON THE AURA XP LASER. THE LASER WAS FOUND WITHIN SPECIFICATION. NO PROBLEMS WERE FOUND WITH THE LASER THAT WOULD HAVE CAUSED THE INCIDENT.

**DEVICE INFORMATION:**

- **Brand:** AURA KP
- **Device Type:** LASER
- **Catalog:** 010-8118
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:** K951034

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** 100 - OTHER HEALTH CARE PROFESSIONAL

**Reprocessed & Reused:** N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2939653-2004-00003</th>
<th>Mfr Name:</th>
<th>IRIDEX CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>08-Jul-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>04-Aug-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>04-Aug-2004</td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>08-Jul-2004</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Oct-2003</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
</tbody>
</table>

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HEALTH PROFESSIONAL, USER FACILITY
Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Event Description (B5):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.


Concomitant Medical Products:

**Mfr Name:** IRIDEX CORP.

Recd: 884 Page: 1,781 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Address:  *
          MOUNTAIN VIEW, CA *
          UNITED STATES

Device Available for Evaluation:  Y
Device Evaluated by Manufacturer (H3):  Yes

Remedial Action (H7):  REPAIR
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
09-AUG-2004: ADD'L EASYFIT SLAS: 30898-Z30/EASYFIT ZEISS 30; 30898-Z3S/EASYFIT ZEISS 30 & SPIT MIRROR; 31044/EASYFIT ZEISS 120; 31045/EASYFIT ZEISS 130. ADD'L SYMPHONY SLAS: 31122-02/3-FIBER, CSO; 31122-04/3-FIBER, ZEISS 30.

DEVICE INFORMATION:

Brand:  IRIS MEDICAL SLIT LAMP ADAPTER
Device Type:  LASER DELIVERY DEVICE
Device Type:  30898-CSO
Catalog:  30898-CSO
Serial:  (*confidential*)
Lot:  NA
Other ID:  NA

Reprocessed & Reused:  N

REPORTER INFORMATION:

Name:  
Address:  
Health Professional:  Yes

EMAIL:  
Phone:  
International:  
Fax:  
Occupation:  OTHER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 12-Mar-2006
Report Date (B4): 03-May-2006
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Event Description (B5):
Mfr 08-MAY-2006: A MONTH PRIOR TO THE EVENT THE PT WAS TREATED FOR REFLUX OF THE GREAT SAPHENOUS VEIN USING ENDOVENOUS LASER ABLATION. A REUSABLE OPTICAL FIBER WAS USED FOR THE TREATMENT. AT THE FOLLOW-UP EXAMINATION, ULTRASOUND INSPECTION INDICATED A FOREIGN OBJECT IN THE GREAT SAPHENOUS VEIN DISTAL TO THE ACCESS SITE. A 2 CM. PIECE OF OPTICAL FIBER WAS IDENTIFIED AND REMOVED BY PHLEBOTOMY USING A SMALL NEEDLE. NO INFLAMMATION OR INFECTION WAS NOTED AND THE PT MADE AN UNREMARKABLE RECOVERY. THE OPTICAL FIBER USED IN THE PROCEDURE HAD BEEN DISCARDED AND WAS UNAVAILABLE FOR EXAMINATION. THE FIBER HAD BEEN REUSED APPROX FIVE TIMES ACCORDING TO MFR'S RECOMMENDATIONS.

Concomitant Medical Products:

Mfr Name: COOLTOUCH, INC.
Address: *
ROSEVILLE, CA *
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
08-MAY-2006: K040921.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** MODEL 1600R
- **Device Type:** LASER INSTRUMENT, SURGICAL, POWERED
- **Device Type:** 1600R
- **Catalog:** 7420-0017
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (b)
- **Address:** (b) (b)
- **EMAIL:**
- **Phone:** (b) (b)
- **International:**
- **Fax:**

Health Professional: Yes

Occupation: 112 - PHYSICIAN ASSISTANT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 09-Oct-1996

MFR Report No: 2952590-1996-00001

Mfr Name: TISSUE TECHNOLOGIES, INC.

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4): 01-Feb-1996

Expiration Date: Single Use (H5): N

Device Usage (H8): U

Event Date (B3): 09-Sep-1996

Report Date (B4): 08-Oct-1996

Date Mfr Rec’d (G4): 09-Sep-1996

Event Report Type: *

Event Outcome (B2): REQUIRED INTERVENTION

Reporter Occupation (E3): 001 - PHYSICIAN

Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y

Problem (B1): N

Event Location (F12): INVALID DATA

Report Source (G3): HEALTH PROFESSIONAL

Event Description (B5):

Concomitant Medical Products:

Mfr Name: TISSUE TECHNOLOGIES, INC.
Address: 4432 ANAHEIM NE
ALBUQUERQUE, NM 87113
UNITED STATES

Device Available for Evaluation: *

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
16-DEC-1996: THE PHYSICIAN PERFORMED TWO PROCEDURES SIMULTANEOUSLY. THE RESULT WAS MILD NECROSIS OF TISSUE AS A RESULT OF THE SURGICAL AND LASER PROCEDURES BEING PERFORMED AT THE SAME TIME. THE LASER WAS EVALUATED WITHIN 24 HOURS OF RECEIVING KNOWLEDGE OF THE PROBLEM. THE LASER WAS PERFORMING CORRECTLY. IT HAS BEEN DETERMINED THAT THIS INJURY WAS A RESULT OF PHYSICIAN'S ERROR. ON 9/10/96 CO'S REP RECEIVED A SPECIAL REQUEST TO VISIT A DR. DR SUSPECTED THAT HE WAS HAVING TROUBLE WITH HIS LASER, AND CO'S REP WAS TOLD THAT THIS WAS A "STICKY POLITICAL SITUATION." ALL CO'S REP WAS TO DO WAS TAKE THE VITAL STATISTICS FROM THE LASER SOFTWARE AND GET READINGS OF THE OUTPUT AT SEVERAL DIFFERENT LEVELS. MD SAID THAT HIS NURSES SAID THAT IT SEEMED THE WOMEN WERE STAYING RED LONGER WITH THIS NEW LASER SINCE THE UPGRADE, WHICH TOOK PLACE ON 7/29/96. WHEN CO'S REP TURNED ON THE LASER HE NOTICED THAT IT DID NOT REQUIRE A WARM UP, THIS INDICATED THAT THE LASER HAD BEEN TURNED ON THAT DAY AND HAD BEEN ALLOWED TO RUN THROUGH ITS WARM-UP PHASE. WHEN REP RETRIEVED THE LASER VITALS, HE FOUND THEM TO BE JUST AS HE HAD LEFT THEM. THE READINGS OF THE OUTPUT FROM THE HAND PIECE ALSO SEEMED TO BE WELL WITHIN TOLERANCES. AS HE WAS FINISHING UP WITH THE LASER THE REP NOTICED THAT A WOMAN WAS BEING WALKED OUT OF A RECOVERY ROOM WHO APPEARED TO HAVE JUST HAD A LASER RESURFACING. NOTHING APPEARED TO BE OUT OF THE ORDINARY.

DEVICE INFORMATION:

- **Brand:** TRU-PULSE CO2 LASER
- **Device Type:** LASER
- **Device Type:** TRU-PULSE
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [b] (6)
- **Email:** [b] (6)
- **Phone:** [b] (6)
- **International:** 
- **Fax:** 
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>2953684-2002-00001</th>
<th>Mfr Name:</th>
<th>COHERENT STAR</th>
<th>Date Received</th>
<th>11-Jan-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Sep-2001</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
<td>OUTPATIENT TREATMENT FACILITY</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>14-Dec-2001</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
</tbody>
</table>

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 01-Jun-2000
Expiration Date: 

Device Usage (H8): U

Event Description (B5):
Mfr 17-JAN-2002: THE FACILITY REPORTED A PATIENT HAD DEVELOPED BLISTERS AND HYPERPIGMENTATION FOLLOWING THE THIRD TREATMENT. TREATMENT WAS FOR HAIR REMOVAL ON THE LEGS. LUMENIS HAS BEEN UNABLE TO CONFIRM SERIOUSNESS OF INJURY.

Concomitant Medical Products:
NA

Mfr Name: LUMENIS, INC.
Address: 2400 CONDENSA STREET
SANTA CLARA, CA 95051
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
## MAUDE EVENT REPORT (FOI)

### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Additional Mfr Narrative (H10 & H11):

17-JAN-2002: H.3 - THE LIGHTSHEER SYSTEM WAS EVALUATED BY THE SERVICE DEPARTMENT AT LUMENIS, PLEASANTON, CA. THE FOLLOWING SYSTEM TESTS WERE CONDUCTED TO VERIFY COMPLIANCE TO RELEASED SPECIFICATIONS: ENERGY METER READINGS, BEAM PROFILE, THERMAL TEST, EPI TEMPERATURE MEASURED, CALIBRATION AND FINAL TEST. ALL COMPLETED TESTS AND EVALUATIONS INDICATE THE SYSTEM PERFORMED WITHIN MANUFACTURING SPECIFICATIONS. LUMENIS COULD NOT CONFIRM SERIOUSNESS OF EVENT DUE TO POSSIBLE LAWSUIT. LASER PARAMETERS WERE WITHIN NORMAL RANGE. THE BLISTERING AND PIGMENTATION CHANGE IS MOST LIKELY DUE TO THE PATIENT'S PARTICULAR SKIN PHYSIOLOGY. THE LIGHTSHEER DIODE LASER SYSTEM MANUAL, P/N 10-03498-00.AA, STATES UNDER COMPLICATIONS AND SIDE EFFECTS: "OTHER SIDE EFFECTS MAY INCLUDE HYPOPIGMENTATION AND HYPERPIGMENTATION. SIDE EFFECTS OF TREATMENT ARE FLUENCE-DEPENDENT AND SKIN TYPE DEPENDENT. APPROXIMATELY 20% OF PATIENTS DEVELOPED TRANSIENT PIGMENTATION CHANGES WHICH USUALLY RESOLVED IN 1-3 MONTHS, BUT IN SOME CASES LASTED UP TO 12 MONTHS. NO SCARRING OR PERMANENT PIGMENTARY CHANGE WAS OBSERVED IN ANY PATIENT."

### DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>LIGHTSHEER SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Reprocessed &amp; Reused</td>
<td>N/A</td>
</tr>
<tr>
<td>Catalog</td>
<td>50-02717-00</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID</td>
<td>K973324</td>
</tr>
</tbody>
</table>

### REPORTER INFORMATION:

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] (6)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>Yes</td>
</tr>
<tr>
<td>Occupation</td>
<td>002 - NURSE</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>26-Nov-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>MFR Report No:</td>
<td>3005350457-2005-00001</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>OMNIGUIDE, INC.</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>28-Oct-2005</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>23-Nov-2005</td>
</tr>
<tr>
<td>Report Date (B8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>28-Oct-2005</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>01-Oct-2005</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>25-Oct-2006</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NOT KNOWN</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>OMNIGUIDE, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>CAMBRIDGE, MA</td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>PATIENT MONITORING</td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
</tbody>
</table>

Recd: 888 Page: 1,789 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**

06-DEC-2005: DURING THE PROCEDURE PERFORMED IN 2005 IN WOMEN HOSPITAL, DEVICE WORKED PROPERLY WITHIN ITS SPECIFICATION AND ALLOWED TO SUCCESSFULLY FINISH THE PROCEDURE (REMOVAL OF MALIGNANT BRONCHIAL LESION). THE ADVERSE EVENT HAPPENED AFTER THE SURGERY. THERE IS NO DIRECT CONFIRMATION FROM THE PHYSICIAN THAT THE USE OF THE DEVICE IN SURGERY CAUSED THE ADVERSE EVENT. THE FOLLOWING INFORMATION WAS RECEIVED FROM DR IN 2005; "DR DO NOT THINK THAT THEY WILL EVER KNOWN WHAT CAUSED HIS TEMPORARY STROKE. IT COULD BE AN AIR EMBOLUS BUT IS COULD ALSO BE A FACTOR ASSOCIATED WITH HIS METASTATIC CARCINOID DISEASE AND CARCINOID SYNDROME OR FRANKLY UNRELATED TO ANYTHING ABOVE. EVEN IF HE HAD A GAS EMBOLUS IT COULD POTENTIALLY BE DUE TO EITHER THE DEVICE OR INADEVETERN INJECTION OF AIR (UNKNOWN) OR OTHER UNDETERMINED CAUSES."

**DEVICE INFORMATION:**

- **Brand:** OMNIGUIDE BEAMPATH CO2 MARK I LASER BEAM DELIV
- **Device Type:** LASER POWERED SURGICAL INSTRUMENT (GEX)
- **Device Type:** 3-0099-001-00-00
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** LA030831AG-P1
- **Other ID:** NA

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** CHIEF
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received 3005350457-2007-00001

Mfr Name: OMNIGUIDE, INC.

Event Date (B3): 15-May-2007
Report Date (B4): 14-Jun-2007
Report Date (F8): 15-May-2007
Date Mfr Rec'd (G4): 15-May-2007

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): REPORTER OCCUPATION
Report Source (G3): USER FACILITY

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 28-Mar-2007
Expiration Date: 28-Mar-2008
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

Mfr Name: OMNIGUIDE, INC.
Address: 1 KENDALL SQUARE, BLDG 100
CAMBRIDGE, MA 02139
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-JUN-2007:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNIGUIDE BP 100 CO2 LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** BP 100
- **Serial:** (*confidential*)
- **Lot:** LA070307AB-P1
- **Other ID:**

  - Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

**Repd: 889  Page: 1,792**
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>3005350457-2008-00001</th>
<th>Mfr Name:</th>
<th>OMNIGUIDE, INC.</th>
</tr>
</thead>
</table>

Event Date (B3): 14-Dec-2007
Report Date (B4): 11-Jan-2008
Report Date (F8): 14-Dec-2007
Date Mfr Rec'd (G4): 14-Dec-2007

Event Report Type: DEATH
Event Outcome (B2): DEATH
Reporter Occupation (E3): HEALTH PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): DEATH
Problem (B1): N
Event Location (F12): COMPANY REPRESENTATIVE

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 04-Oct-2008
Expiration Date: 31-Oct-2008
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>OMNIGUIDE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>1 KENDALL SQUARE, BLDG 100</td>
</tr>
<tr>
<td></td>
<td>CAMBRIDGE, MA 02139</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-JAN-2008:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: BEAMPATH 150
Device Type: LASER WAVEGUIDE FIBER
Device Type: BP 150
Catalog: NA
Serial: (*confidential*)
Lot: LA071004AI-P1
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
Health Professional: No

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 3005350457-2008-00002
Mfr Name: OMNIGUIDE, INC. 11-Mar-2008

Event Date (B3): 11-Feb-2008
Event Report Type: INJURY
Adverse Event (B1): Y
Problem (B1): N
Event Outcome (B2): LIFE THREATENING
Event Location (F12):

Date Mfr Rec'd (G4): 11-Feb-2008
Device Operator: HEALTH PROFESSIONAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 17-MAR-2008: DURING LARYNGEAL AIRWAY SURGERY, AN AIRWAY FIRE OCCURRED.

Concomitant Medical Products:

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: OMNIGUIDE LP 150
Device Type: LASER WAVEGUIDE FIBER
Device Type: LP 150
Catalog: LP 150
Serial: (*confidential*)
Lot: NA
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

EMAIL: 
Phone: 
International: 
Fax: 

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>3005350457-2008-00003</th>
<th>Mfr Name:</th>
<th>OMNIGUIDE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Jan-2008</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Apr-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>21-Mar-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Device not Returned to Manufacturer</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td>Y</td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>24-APR-2008:</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
</tbody>
</table>

Mfr Name: OMNIGUIDE, INC.
Address: CAMBRIDGE, MA
UNITED STATES
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
 Brand: OMNIGUIDE LIGHTPATH 150
 Device Type: LASER WAVEGUIDE FIBER
 Device Type: LP 150
 Catalog: LP 150
 Serial: (*confidential*)
 Lot: NA
 Other ID:
 Reprocessed & Reused: N

REPORTER INFORMATION:
 Name: [Redacted]
 Address: [Redacted]
 EMAIL: [Redacted]
 Phone: (617) 638-5600
 International: 001 - PHYSICIAN
 Fax: [Redacted]

Health Professional: Yes
Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 10-Aug-2008
Report Date (B4): 15-Sep-2008
Report Date (F8):
Date Mfr Rec'd (G4): 15-Sep-2008

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (B4): 15-Sep-2008
Event Location (F12):

Product Code: (OP)-KNIFE (HNO)
Device Age (F9):
Expiration Date:

Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Mfr 06-OCT-2008: THE INTRALASE FS LASER WAS USED TO CREATE A BILATERAL CORNEAL FLAP(S) FOR LASIK SURGERY IN 2008. ONE DAY POSTOPERATIVELY THE FOLLOWING DAY, THE PATIENT PRESENTED WITH STAGE 1+ BILATERAL DIFFUSE LAMELLAR KERATITIS (DLK) IN BOTH (OU) EYES. A FLAP LIFT AND RINSE WAS PERFORMED OU THE NEXT DAY, A SECOND FLAP LIFT AND RINSE ON THE LEFT (OS) EYE FOUR DAYS LATER. DUE TO STAGE 2 DLK, THE PATIENT WAS PRESCRIBED TOPICAL STEROIDS. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POSTOPERATIVE BCVA IS 20/20 OU. THE PATIENT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

Concomitant Medical Products:

Mfr Name: AMO MANUFACTURING USA, LLC.
Address: IRVINE, CA 92618
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Date Last Updated: 11/2/2010 9:17 AM

Page: 1,799

Recd: 893

Date Received: 30-Sep-2008
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 3006695864-2008-00022
Mfr Name: AMO MANUFACTURING USA LLC

Event Date (B3): 10-Aug-2008
Report Date (B4): 15-Sep-2008
Report Date (F8):
Date Mfr Rec'd (G4): 15-Sep-2008

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION

Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12):
Report Source (G3):

Product Code: (OP)-KNIFE (HNO)
Device Age (F9):
Expiration Date:

Manufacture Date (H4): 01-Jan-2007
Single Use (H5): N
Device Usage (H8): R

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Event Description (B5):

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

Brand: INTRALASE FS LASER
Device Type: LASER KERATOME
Device Type: 20003
Catalog: 20003
Serial: (*confidential*)
Lot: NA
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
Email: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax: [b] (6)

Health Professional: Yes

Occupation: 001 - PHYSICIAN
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>3006695864-2008-00026</th>
<th>Mfr Name:</th>
<th>AMO MANUFACTURING USA LLC</th>
<th>11-Nov-2008</th>
</tr>
</thead>
</table>

**Event Date (B3):** 04-Sep-2008  
**Report Date (B4):** 04-Sep-2008  
**Report Date (F8):**  
**Date Mfr Rec’d (G4):** 04-Sep-2008

**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Adverse Event (B1):** Y  
**Problem (B1):** N

**Event Location (F12):**  
**Report Source (G3):** HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Operator:** HEALTH PROFESSIONAL

**Event Description (B5):**

**Concomitant Medical Products:**  
NA

**Mfr Name:** AMO MANUFACTURING USA, LLC.  
**Address:** IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**  

Recd: 895  
Page: 1,803  
Date Last Updated: 11/2/2010 9:17 AM

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

**Occupation:** 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>3006695864-2009-00002</th>
<th>Mfr Name:</th>
<th>AMO MANUFACTURING USA LLC</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>20-Nov-2008</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>20-Nov-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>20-Nov-2008</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adverse Event (B1):</th>
<th>Y</th>
<th>Problem (B1):</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Product Code: | (OP)-LASER, OPHTHALMIC (HQF) |
| Device Age (F9): | |
| Expiration Date: | |
| Manufacture Date (H4): | 01-Jun-2007 |
| Single Use (H5): | N |
| Device Usage (H8): | R |

Event Description (B5):


Concomitant Medical Products:

| Mfr Name: | AMO MANUFACTURING USA, LLC. |
| Address: | IRVINE, CA 92618 |
| UNITED STATES |

Concomitant Medical Products:

INTACS INTRASTROMAL CORNEAL RINGS (ICRS)

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

23-FEB-2009: AN INTRALASE CLINICAL DEVELOPMENT SPECIALIST (CDS) VISITED THE SITE AS FOLLOW UP TO THE REPORTED EVENT. THE TECH AT THE SITE REPORTED THAT SHE HAD PROGRAMMED THE LASER SETTINGS FOR BOTH (OU) EYES INSTEAD OF A LEFT (OS) EYE ONLY. WHILE ON SITE, CDS CHECKED THE PERFORMANCE OF THE LASER AND FOUND IT PERFORMED AS INTENDED, AND MET SPECS.
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20003
- **Catalog:** 20003
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 001 - PHYSICIAN

Health Professional: Yes
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 3006695864-2009-00003</th>
<th>Mfr Name: AMO MANUFACTURING USA LLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 12-Dec-2008</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4): 21-Jan-2009</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 001 - PHYSICIAN</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4): 21-Jan-2009</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td></td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td></td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td></td>
<td>Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY, COMPANY REPRESENTATIVE</td>
</tr>
<tr>
<td>Product Code: (OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4): 01-Jan-2008</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): N</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8): R</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Mfr 23-FEB-2009: THE INTRALASE FS LASER WAS USED TO CREATE A BILATERAL CORNEAL FLAP(S) FOR LASIK SURGERY IN 2008. ONE DAY POSTOPERATIVELY (THE NEXT DAY), THE PATIENT PRESENTED WITH STAGE 1+ DIFFUSE LAMELLAR KERATITIS (DLK) ON BOTH (OU) EYES. A FLAP LIFT AND RINSE WAS PERFORMED ONE DAY PRIOR. PATIENT WAS TREATED WITH TOPICAL AND ORAL STEROIDS. THE PATIENT'S PREOPERATIVE BEST CORRECTED VISUAL ACUITY (BCVA) WAS 20/20 OU. POST OPERATIVELY, BCVA WAS 20/20 OU. THE PATIENT RESPONDED TO TREATMENT AND DLK HAS RESOLVED. THE ASSOCIATION BETWEEN THE EVENT AND THE DEVICE IS UNKNOWN.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name: AMO MANUFACTURING USA LLC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: IRVINE, CA 92618</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** INTRALASE FS LASER
- **Device Type:** LASER KERATOME
- **Device Type:** 20005
- **Catalog:** 20005
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:**

  Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

  Health Professional: Yes

  Occupation: 001 - PHYSICIAN
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Distributor Report No: 33467-1992-00004  Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 28-Oct-1992  Event Report Type: INJURY
Report Date (F8): 04-Nov-1992  Reporter Occupation (E3): 999 - UNKNOWN
Report Date (F8): 04-Nov-1992  Device Operator: INVALID DATA

Event Description (B5):

DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: INVALID DATA. INVALID DATA - REGARDING MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

INVALID DATA - REGARDING WHETHER EVENT PRESENTS IMMINENT HAZARD. INVALID DATA - WHETHER DEVICE USED AS LABELED/INTENDED.

INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: INVALID DATA. CORRECTIVE ACTIONS: NO DATA. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Mfr Name: TRIMEDYNE, INC.
Address:

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
17-DEC-1992:

DEVICE INFORMATION:

Brand: BARD UROLASE RIGHT ANGLE LASER FIBER
Device Type: LASER FIBER
Catalog: 350000
Serial: (*confidential*)
Lot:
Other ID: 021992110005

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:

EMAIL:
Phone: (b) (6)
International:
Fax:

Health Professional: Unknown

Occupation: 999 - UNKNOWN

Recd: 898 Page: 1,810 Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 33467-1993-00007
Mfr Name: TRIMEDYNE, INC.

Event Date (B3): 15-Oct-1993
Report Date (B4): 26-Oct-1993
Report Date (F8): 26-Oct-1993
Date Mfr Rec'd (G4): 
Product Code: (CV)-FIBEROPTIC (LWX)
Device Operator: 999 - UNKNOWN

Event Description (B5):
Importer 13-JAN-1994: IT WAS REPORTED THAT DURING A LASER PROCEDURE, THE FIBER TIP SEPERATED AT THE AREA WHERE THE TIP IS CRIMPED TO THE FIBER. THE EVENT OCCURRED ON THE THIRD SIXTY-SECOND LASER APPLICATION AT 60 WATTS. THE TIP WAS RETREIVED USING GRASPING FORCEPS THROUGH THE PREVIOUSLY PLACED SCOPE AS DESCRIBED IN THE PRODUCT LABELING. THE PROCEDURE WAS COMPLETED WITH A SECOND FIBER AND NO FURTHER COMPLICATION WERE REPORTED. IT WAS ALSO REPORTED THAT TWO LASER FIBERS FROM A COMPETITOR WAS USED PRIOR TO THE USE OF THE UROLASE FIBERS WITH UNSUCCESSFUL RESULTS.

INVALID DATA - REGARDING SINGLE USE LABELING OF DEVICE. PATIENT MEDICAL STATUS PRIOR TO EVENT: UNKNOWN. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

INVALID DATA - REGARDING EVALUATION BY USER AFTER EVENT. METHOD OF EVALUATION: INVALID DATA. RESULTS OF EVALUATION: INVALID DATA. CONCLUSION: INVALID DATA. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: YES. CORRECTIVE ACTIONS: NONE OR UNKNOWN. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:

Mfr Name: TRIMEDYNE, INC.
Address: ,
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-JAN-1994:

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>UROLASE RIGHT ANGLE LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type:</td>
<td>LASER FIBER</td>
</tr>
<tr>
<td>Catalog:</td>
<td>350000</td>
</tr>
<tr>
<td>Serial:</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot:</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Other ID:</td>
<td>021993100126</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

REPORTER INFORMATION:

| Name:                  |                                  |
| Address:               | [REDACTED]                       |
| HEALTH PROFESSIONAL:   | Unknown                          |

| EMAIL:                 | [REDACTED]                       |
| Phone:                 | [REDACTED]                       |
| International:         | [REDACTED]                       |
| Fax:                   |                                  |

Occupation: 999 - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3): | 26-Oct-1993 | Event Report Type: | INJURY | Adverse Event (B1): | Y |
| Report Date (F8): | 29-Oct-1993 | Reporter Occupation (E3): | 999 - UNKNOWN | Event Location (F12): | HOSPITAL |

**Event Description (B5):**


DEVICE LABELED FOR SINGLE USE. PATIENT MEDICAL STATUS PRIOR TO EVENT: UNKNOWN. THERE WAS NOT MULTIPLE PATIENT INVOLVEMENT.

INVALID DATA - ON DEVICE SERVICE/MAINTENANCE. NO DATA - REGARDING DATE LAST SERVICED. SERVICE PROVIDED BY: INVALID DATA. INVALID DATA - SERVICE RECORDS AVAILABILITY.

NO IMMINENT HAZARD TO PUBLIC HEALTH CLAIMED. DEVICE USED AS LABELED/INTENDED.

DEVICE WAS EVALUATED AFTER THE EVENT. METHOD OF EVALUATION: NONE OR UNKNOWN. RESULTS OF EVALUATION: NONE OR UNKNOWN. CONCLUSION: NONE OR UNKNOWN. CERTAINTY OF DEVICE AS CAUSE OF OR CONTRIBUTOR TO EVENT: YES. CORRECTIVE ACTIONS: NONE OR UNKNOWN. INVALID DATA - ON DEVICE DESTROYED/DISPOSED OF STATUS.

Concomitant Medical Products:

| Mfr Name: | TRIMEDYNE, INC. |
| Address: | |

Device Available for Evaluation: * No Answer
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
29-SEP-1994:

DEVICE INFORMATION:

- **Brand:** BARD UROLASE RIGHT ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** 350000
- **Serial:** (*confidential*)
- **Lot:** 7592
- **Other ID:** 021993100191

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** Unknown
- **Occupation:** 999 - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>6000002-2006-00724</th>
<th>Mfr Name:</th>
<th>BAXTER HEALTHCARE CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>09-Nov-2006</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>09-Nov-2006</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Event Date (B5):</td>
<td>09-Nov-2006</td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Event Date (B5):</td>
<td>09-Nov-2006</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>09-Nov-2006</td>
<td>Mfr Name:</td>
<td>BAXTER HEALTHCARE CORP.</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>09-Nov-2006</td>
<td>Mfr Name:</td>
<td>BAXTER HEALTHCARE CORP.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>01-Aug-2006</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Feb-2007</td>
<td>Single Use (H5):</td>
<td>Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Mfr 21-DEC-2006: IT WAS REPORTED THAT THE LASER BURNED A VERY SMALL HOLE IN THE LEFT ATRIUM. IT WAS STATED THAT THE PHYSICIAN REPAIRED THE ATRIUM WITH 4-0 PROLENE. IT WAS INDICATED THAT THE COLOR OF THE LESIONS VARIED WHEREBY TWO LESIONS WERE &quot;CHARRED&quot; AND ONE DID HAVE FULL THICKNESS AND CREATED A HOLE IN THE ATRIUM. FOLLOW-UP INDICATED THAT THE PT WAS STABLE AND DOING WELL WITHOUT COMPLICATIONS.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>EDWARDS LIFESCIENCES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>ONE EDWARDS WAY</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>IRVINE, CA 92614</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
21-DEC-2006: THE DEVICE WAS EXAMINED PRIOR TO DECONTAMINATION, AND THE DEVICE SHOWED NO SIGNS OF THERMAL DAMAGE ON THE SPINE OR CATHETER WHEN EXAMINED UNDER THE MICROSCOPE AT 30X WHILE ASSEMBLED AND DISASSEMBLED. THERE WAS A SEVERE KINK IN THE BLUE TUBING (JACKETED CABLE), AT THE PROXIMAL END OF THE HANDLE. POST DECONTAMINATION, THE DEVICE WAS EXAMINED AND FOUND TO HAVE A FIBER GAP OF 0.41MM TO 0.44MM. THE GOLD WAS FOUND TO BE IN GOOD CONDITION. THERE IS NO THERMAL DAMAGE TO THE AREA AROUND THE FIBER FACE. THERE ARE WHAT APPEAR TO BE PINCH MARKS ON THE CATHETER, LOCATED AT AND BETWEEN THE 6.5 AND 7.25 MARKERS. THERE ALSO APPEARS TO BE THERMAL DAMAGE TO THE OUTSIDE SURFACE OF THE CATHETER BETWEEN THE SAME AREAS AS THE PINCH MARKS. THE DAMAGE APPEARS TO HAVE OCCURRED FROM THE OUTSIDE INWARD. THE DEVICE WAS TESTED IN THE RETURNED POSITION (STRAIGHT) AND ALSO PLACED IN A 4.7CM BEND. THE TESTING WAS PERFORMED IN ALL (1-7) INDEX POSITIONS IN THE STRAIGHT AND BENT POSITIONS. THE DEVICE PASSED ALL TEST "LASES".

DEVICE INFORMATION:

- Brand: OPTIWAVE 980
- Device Type: LASER SURGICAL INSTRUMENT
- Device Type: 180360
- Catalog: NA
- Serial: (*confidential*)
- Lot: SV6H0744
- Other ID: NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [b] (b) [b] (b)
- Address: [b] (b) [b] (b)
- Health Professional: Yes
- EMAIL: [b] (b) [b] (b)
- Phone: [b] (b) [b] (b)
- International
- Fax: [b] (b) [b] (b)

Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Distributor Report No: 8010121-1995-00001</th>
<th>Mfr Name: LASER INDUSTRIES LTD.</th>
<th>Date Received: 22-Sep-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 01-Aug-1995</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 22-Sep-1995</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 22-Sep-1995</td>
<td>Reporter Occupation (E3): 114 - RESPIRATORY THERAPIST</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Event Location (F12): AMBULATORY SURGICAL FACILITY</td>
<td></td>
</tr>
<tr>
<td>Product Code: (AN)-YAG (LLO)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Code (F9):</td>
<td>Manufacturer Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5): Importer 12-OCT-1995: THE RESPIRATORY THERAPIST REPORTED THAT DURING A BRONCHOSCOPY PROCEDURE BEING PERFORMED ON AN OUTPATIENT BASIS ON A 45 YR OLD MALE WITH A SURGICAL LASER, THE TIP OF A LASER FIBER BROKE. THE PT EXPERIENCED NO ADVERSE REACTION AS A RESULT OF THE EVENT &amp; WAS DISCHARGED FROM THE FACILITY ON THE SAME DATE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LASER INDUSTRIES, LTD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: ATIDIM SCIENCE INDUSTRIAL PARK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEL ANIV, ISRAEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 12-OCT-1995:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DUAL EFFECT BARE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 600 MICRON DUAL EFFECT FIBER
- **Catalog:** AA2214000
- **Serial:** (*confidential*)
- **Lot:** 25389
- **Other ID:**

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Distributor Report No: 8010121-1995-00002
Mfr Name: LASER INDUSTRIES LTD.

Event Date (B3): 01-Aug-1995
Report Date (B4): 22-Sep-1995
Report Date (F8): 22-Sep-1995

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 114 - RESPIRATORY THERAPIST
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): AMBULATORY SURGICAL FACILITY
Report Source (G3):

Product Code: (AN)-YAG (LLO)
Device Age (F9):
Expiration Date:

Event Description (B5):
Import 12-OCT-1995: THE RESPIRATORY THERAPIST REPORTED THAT DURING A BRONCHOSCOPY PROCEDURE BEING PERFORMED ON AN OUTPATIENT BASIS (PT STATISTICS UNKNOWN) WITH A SURGICAL LASER, A TIP OF A LASER FIBER ALLEGEDLY BROKE. THE HEALTHCARE PROFESSIONAL WHO GAVE THIS REPORT, INDICATED THAT IT WAS RECEIVED AS HEARSAY INFO. THE DEVICE WAS DISCARDED BY THE USER FACILITY & THE PT DID NOT EXPERIENCE ANY ADVERSE CONSEQUENCES AS A RESULT OF THE EVENT.

Concomitant Medical Products:

Mfr Name: LASER INDUSTRIES, LTD
Address: ATIDIM SCIENCE INDUSTRIAL PARK
TEL AVIV,
ISRAEL

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-OCT-1995:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DUAL EFFECT BARE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 600 MICRON DUAL EFFECT FIBER
- **Catalog:** AA2214000
- **Serial:** (*confidential*)
- **Lot:** 25389
- **Other ID:**

**Reprocessed & Reused:** N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 8010121-1998-00001
Mfr Name: SHARPLAN LASERS, INC.

Event Date (B3): 15-Jan-1998
Report Date (B4): Omitted
Report Date (F8): Omitted
Date Mfr Rec'd (G4): 26-Feb-1998

Event Report Type: INJURY
Event Report Type: INJURY

Adverse Event (B1): Problem (B1): N
Event Location (F12): Report Source (G3): HEALTH PROFESSIONAL, USER FACILITY

Date Mfr Rec'd (G4): 06-Mar-1998

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5): Y
Device Usage (H8): U

Event Description (B5):
Unk:

Concomitant Medical Products:

Device Available for Evaluation:
Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
: USER FACILITY WAS CONTACTED BY TELEPHONE ON 3/2/98. HOSPITAL POLICY WOULD NOT PERMIT THEM TO RELEASE THE DEVICE SO THAT IT COULD BE PROPERLY EVALUATED. BASED UPON THE RISK MANAGER'S DESCRIPTION OF THIS FIBER, ALONG WITH TWO OTHER FIBERS WHICH WERE USED EARLIER IN THE PROCEDURE, THE MFR HAS CONCLUDED THAT THIS EVENT WAS CAUSED BY USER ERROR. THE FIBER WAS LABELED AND RECOMMENDED FOR FREE BEAM USE ONLY IN A LIQUID ENVIRONMENT. IF TISSUE ACCUMULATED ON THE DISTAL TIP, AND THE FIBER WAS NOT BEING COOLED, THE CONDITIONS COULD EXIST FOR AN AIRWAY FIRE.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

   Brand: *

   Device Type:

   Catalog:

      Serial: (*confidential*)

      Lot:

   Other ID:

   Reprocessed & Reused: N/A

REPORTER INFORMATION:

   Name: 

   Address: 

   EMAIL: 

   Phone: 

   International: 

   Fax: 

   Health Professional: No Answer

   Occupation: -
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 8020889-1999-00001</th>
<th>Mfr Name: MALLINCKRODT MEDICAL</th>
<th>10-Jan-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 09-Dec-1998</td>
<td>Event Report Type: MALFUNCTION</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4): 10-Dec-1998</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8): 10-Dec-1998</td>
<td>Reporter Occupation (E3): UNK - UNKNOWN</td>
<td>Report Source (G3): FOREIGN, HEALTH PROFESSIONAL, USER FACILITY</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4): 10-Dec-1998</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product Code: (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)
Device Age (F9): 0 YR 150 DAYS (5 MO)
Expiration Date: 31-Jul-2003

Manufacture Date (H4): 01-Jul-1998
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 20-JAN-1999: PILOT LINE FEEDING ACCESS TO CUFFS HAD A SUBSTANTIAL LEAK WHICH WAS DISCOVERED DURING TESTING PRIOR TO INTUBATION.

Concomitant Medical Products:
NA

Mfr Name: MALLINCKRODT
Address: CORNAMADDY
ATHLONE CO. WESTMEATH, IRELAND

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Recd: 905
Page: 1,823
Date Last Updated: 11/2/2010 9:17 AM
CDRH MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):


DEVICE INFORMATION:

Brand: LASER-FLEX TRACHEAL TUBE
Device Type: LASER-FLEX TRACHEAL TUBE 5.0MM
Device Type: NA
Catalog: 86394
Serial: (*confidential*)
Lot: 1998-07 1576
Other ID: 160-50

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
EMAIL: [b] (6)
Phone: [b] (6)
International:
Fax:
Health Professional: Unknown
Occupation: UNK - UNKNOWN
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Sep-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MFR Report No:</strong></td>
<td>8020889-1999-00013</td>
</tr>
<tr>
<td><strong>Mfr Name:</strong></td>
<td>MALLINCKRODT MEDICAL</td>
</tr>
<tr>
<td><strong>Event Date (B3):</strong></td>
<td>02-Aug-1999</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong></td>
<td>02-Aug-1999</td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td>12-Aug-1999</td>
</tr>
<tr>
<td><strong>Date Mfr Rec'd (G4):</strong></td>
<td>12-Aug-1999</td>
</tr>
<tr>
<td><strong>Event Report Type:</strong></td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td><strong>Event Outcome (B2):</strong></td>
<td>OTHER</td>
</tr>
<tr>
<td><strong>Adverse Event (B1):</strong></td>
<td>Y</td>
</tr>
<tr>
<td><strong>Event Location (F12):</strong></td>
<td>HOSPITAL</td>
</tr>
<tr>
<td><strong>Report Source (G3):</strong></td>
<td>FOREIGN, HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td><strong>Product Code:</strong></td>
<td>(AN)-TUBE, TRACHEAL (W/NO CONNECTOR) (BTR)</td>
</tr>
<tr>
<td><strong>Device Age (F9):</strong></td>
<td>1 YR - 65 DAYS (10 MO)</td>
</tr>
<tr>
<td><strong>Expiration Date:</strong></td>
<td>31-Oct-2003</td>
</tr>
<tr>
<td><strong>Device Operator:</strong></td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td><strong>Device Evaluated by Manufacturer (H3):</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Remedial Action (H7):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Correction/Removal No (H9):</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Additional Mfr Narrative (H10 &amp; H11):</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Unk :

**Concomitant Medical Products:**

NA

**Mfr Name:** MALLINCKRODT

**Address:** CORNAMADDY

ATHLONE CO. WESTMEATH,

IRELAND

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** :
MAUDE EVENT REPORT (FOI)

SORTED BY

02-Nov-2010

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER - FLEX TRACHEAL TUBE
- **Device Type:** LASER - FLEX TRACHEAL TUBE 6.0MM
- **Device Type:** NA
- **Catalog:** 86398
- **Serial:** (*confidential*)
- **Lot:** 1998 10 2767
- **Other ID:** 160-60
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:** (b) (6)
- **Fax:** (b) (6)
- **Health Professional:** Yes
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MFR Report No:** 8020889-1999-00023  
**Mfr Name:** MALLINCKRODT MEDICAL  
**Report Date (G4):** 27-Oct-1999

**Event Date (B3):** 14-Oct-1999  
**Report Date (B4):** 14-Oct-1999  
**Report Date (F8):** 27-Oct-1999  
**Date Mfr Rec'd (G4):** 27-Oct-1999

**Event Report Type:** MALFUNCTION  
**Event Report Type:** MALFUNCTION  
**Event Location (F12):** HOSPITAL

**Product Code:** (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)  
**Device Age (F9):** 1 YR 115 DAYS (16 MO)  
**Expiration Date:** 30-Jun-2003

**Device Operator:** HEALTH PROFESSIONAL  
**Device Evaluated by Manufacturer (H3):** Yes

**Event Description (B5):**  
Mfr 18-JAN-2000: CAUGHT ON FIRE IN PT USING CO2 LASER.

**Concomitant Medical Products:**  
UNK

**Mfr Name:** MALLINCKRODT MEDICAL  
**Address:** CORNAMADDY  
ATHLONE CO. WESTMEATH,  
IRELAND

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**
**Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

- **Brand:** LASER-FLEX TRACHEAL TUBE
- **Device Type:** LASER-FLEX TRACHEAL TUBE 6.0MM
- **Catalog:** 86398
- **Serial:** (*confidential*)
- **Lot:** 1998-06 1479
- **Other ID:** 160-60

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (6)
- **Address:** [b] (6)
- **Email:** [b] (6)
- **Phone:** [b] (6)
- **International:** [b] (6)
- **Fax:**

- **Health Professional:** No Information
- **Occupation:** UNK - UNKNOWN

Recd: 907  Page: 1,828  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

Date Received: 25-Feb-2000

<table>
<thead>
<tr>
<th>MFR Report No: 8020889-2000-00003</th>
<th>Mfr Name: MALLINCKRODT MEDICAL</th>
</tr>
</thead>
</table>

Event Date (B3): 23-Dec-1999
Report Date (B4): 28-Jan-2000
Report Date (F8): 31-Jan-2000
Date Mfr Rec'd (G4): 31-Jan-2000

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (B4): 28-Jan-2000
Event Location (F12): HOSPITAL
Report Source (G3): FOREIGN, CONSUMER, HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Product Code: (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)
Device Age (F9): Manufacture Date (H4): Single Use (H5): Y Device Usage (H8): I
Expiration Date:

Event Description (B5):

Concomitant Medical Products:
UNK

Mfr Name: MALLINCKRODT MEDICAL
Address: CORNAMADDY
ATHLONE, CO. WESTMEATH, IRELAND

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
29-FEB-2000: INFO RECORDED IN SECTION F COMPLETED BY MFR. H.3: SAMPLE WAS NOT RETURNED TO MFR FOR EVAL. THE ATTACHED EVAL SUMMARY WAS CARRIED OUT BASED ON BATCH PAPERWORK REVIEW (PRELIMINARY RESPONSE). THE EVAL OF THIS COMPLAINT IS CURRENTLY BEING COMPLETED BY AN INDEPENDENT ASSESSOR. PRODUCT COMPLAINT ANALYSIS REPORT: CAUSE: EVAL OF THIS COMPLAINT IS CURRENTLY BEING COMPLETED BY AN INDEPENDENT ASSESSOR. FROM THE PRELIMINARY INVESTIGATION CARRIED OUT, INDEPENDENT ASSESSOR HAS COMMENTED THAT THE PLASTIC PARTS OF THE TUBE ARE TOO BURNED AND DESTROYED TO DETERMINE WHAT THE CUFF HAD BEEN ORIGINALLY FILLED WITH. ASSESSOR ALSO FEELS THAT IT MAY BE IMPOSSIBLE TO TELL IF ANY MINERAL TRACES INSIDE THE CUFF ARE 'REMAINS' OF THE ORIGINAL FILLING OR 'REMAINS' OF THE BURN. SUMMARY OF ANALYSIS: MEDICAL THERE WAS A PT INVOLVED. CONFIRMED/ NON-CONFIRMED: PRELIMINARY RESPONSE - COMPLAINT BEING ANALYZED BY INDEPENDENT EXPERT. CORRECTIVE ACTION/COMMENT: CURRENTLY CO. IS TRYING TO LOCATE ADD'L SAMPLES OF THIS BATCH FOR FURTHER EVAL. IF CO. CAN OBTAIN SAMPLE, INDEPENDENT ASSESSOR WILL TRY TO SIMULATE THE INCIDENT IN QUESTION AND REPORT BACK ON THE FINDINGS.

DEVICE INFORMATION:

Brand: LASER-FLEX TRACHEAL TUBE
Device Type: LASER-FLEX TRACHEAL TUBE 6.0MM
Device Type: NA
Catalog: 86398
Serial: (*confidential*)
Lot: ML 07060
Other ID: 160-60

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)
EMAIL: (UNK)
Phone: (UNK)
International: 
Fax: 

Health Professional: Yes
Occupation: 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>MFR Report No: 8020889-2000-00043</th>
<th>Mfr Name: MALLINCKRODT MEDICAL</th>
<th>Event Date (B3): 28-Jul-2000</th>
<th>Event Report Type: MALFUNCTION</th>
<th>Adverse Event (B1): Y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date Mfr Rec'd (G4): 28-Jul-2000</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>2 YR 80 DAYS (27 MO)</td>
<td>Manufacture Date (H4): 01-Apr-1998</td>
<td>Single Use (H5): Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>30-Apr-2003</td>
<td></td>
<td>Device Usage (H8): I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: MALLINCKRODT MEDICAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: CORNAMADDY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Athlone, Co. Westmeath, Ireland</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17-AUG-2000: INFO RECORDED IN SECTION F COMPLETED BY MFR. H.3. DEVICE HAS NOT BEEN EVALUATED BY MFR TO DATE. A FOLLOW-UP REPORT WILL BE SENT WHEN EVAL HAS BEEN COMPLETED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER-FLEX TRACHEAL TUBE
Device Type: LASER-FLEX TRACHEAL TUBE 5.0MM
Device Type: NA
Catalog: 86394
Serial: (*confidential*)
Lot: 1998-04 0293
Other ID: 160-50

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: Yes
EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

MFR Report No: 8020889-2000-00070
Mfr Name: MALLINCKRODT MEDICAL

Event Date (B3): 10-Nov-2000
Report Date (B4): 29-Nov-2000
Report Date (F8): 29-Nov-2000
Date Mfr Rec'd (G4): 29-Nov-2000

Event Report Type: MALFUNCTION
Event Outcome (B2):
Report Date (F8): 001 - PHYSICIAN
Report Source (G3): HEALTH PROFESSIONAL

Device Operator: HEALTH PROFESSIONAL

Product Code: (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)
Device Age (F9): 1 YR 25 DAYS (13 MO)
Expiration Date: 31-Oct-2004
Manufacture Date (H4): 01-Oct-1999
Single Use (H5): Y
Device Usage (H8): I

Event Description (B5):
Mfr 29-DEC-2000: AIR LEAKAGE FROM PILOT BALLOON. TORN PILOT BALLOON.

Concomitant Medical Products:
NA

Mfr Name: MALLINCKRODT MEDICAL
Address: CORNAMADDY
ATHLONE
CO. WESTMEATH,
IRELAND

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
29-DEC-2000: INFO RECORDED IN SECTION F COMPLETED BY MFR. H.3: DEVICE HAS NOT BEEN EVALUATED BY MFR TO DATE. WHEN EVAL IS COMPLETED A FOLLOW-UP REPORT WILL BE SUBMITTED.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER FLEX TRACHEAL TUBE
- **Device Type:** LASER-FLEX TRACHEAL TUBE WITH CUFF 6.0MM
- **Device Type:** NA
- **Catalog:** 86398
- **Serial:** (*confidential*)
- **Lot:** 1999-10 7758
- **Other ID:** 160-60
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM

Event Date (B3): 11-Jan-2001  
Report Date (B4): 15-Jan-2001  
Report Date (F8): 15-Jan-2001  
Date Mfr Rec'd (G4): 15-Jan-2001  

Event Report Type: MALFUNCTION  
Event Outcome (B2):  
Reporter Occupation (E3): 001 - PHYSICIAN  
Device Operator: HEALTH PROFESSIONAL  

Product Code: (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)  
Device Age (F9):  
Expiration Date:  
Device Usage (H8): I  

Event Description (B5):  
Mfr 14-FEB-2001: DIFFICULT WATER INFLATION FROM THE VALVE.  
Concomitant Medical Products:  
NA  

Mfr Name: MALLINCKRODT MEDICAL  
Address: CORNAMADDY  
ATHLONE, CO. WESTMEATH,  
IRELAND  

Device Available for Evaluation: R  
Device Evaluated by Manufacturer (H3): Yes  
Remedial Action (H7):  
Correction/Removal No (H9):
14-FEB-2001: INFORMATION RECORDED IN SECTION F COMPLETED BY MANUFACTURER. H.6. SLIGHT BLOCKAGE AT INFLATION LINE TO TUBE CONNECTION. CAUSE: ONE SAMPLE RETURNED WITHOUT IT’S PERTAINING PACKAGING FOR ANALYSIS. BOTH CUFFS WERE INFLATED. THE DISTAL CUFF INFLATED WITHOUT ANY PROBLEM. THERE WAS RESTRICTION IN INFLATING THE PROXIMAL CUFF. THE PROXIMAL PILOT WAS SNIPPED OFF AND RESASSEMBLED WITH A NEW PILOT. A RESTRICTION WAS STILL FOUND WHEN INFLATED. THIS WOULD INDICATE THAT THE SLIGHT BLOCKAGE OCCURRED AT THE TAIL OPERATION DUE TO OPERATOR ERROR. SUMMARY OF ANALYSIS: QUALITY: THERE WAS NO PT INVOLVED. CONFIRMED: THE RETURNED UNIT DISPLAYED THE REPORTED DEFECT. JUSTIFIED: THIS UNIT WAS NOT MFG ACCORDING TO PROCEDURE. CORRECTIVE ACTION/COMMENT: THE SEVERITY OF THE DEFECT AND THE IMPORTANCE OF THE TAILING OPERATION WERE HIGHLIGHTED TO ALL THE RELEVANT OPERATORS. THE COMPLAINT SAMPLE WAS HIGHLIGHTED TO OPERATORS ON THIS CELL. TAILING AUDITS ARE CARRIED OUT ON A QUARTERLY BASIS TO ENSURE NO METHOD DEVIATIONS. QUARTERLY BASIS TO ENSURE NO METHOD DEVIATIONS. THE TAILING PROCESS IS CAREFULLY MONITORED ON AN ON-GOING BASIS BY PRODUCTION AND QUALITY ASSURANCE PERSONNEL. THE OPERATORS ON THIS CELL WILL BE RE-AUDITED TO ENSURE NO METHOD DEVIATION. ALL ENDOTRACHEAL PRODUCT UNDERGO A FOUR (4) HOUR INFLATE/DEFLATE TEST PRIOR TO RELEASE AND IT IS AT THIS POINT THAT ANY DEFECTS ARE REMOVED FROM THE ORDER HOWEVER THIS UNIT ESCAPED DETECTION DUE TO OPERATOR ERROR. CO FEELS THAT THIS IS AN ISOLATED INCIDENCE AS CO HAS BEEN MFG LASER FLEX SINCE 1997 AND HAVE NOT RECEIVED ANY COMPLAINTS OF THIS NATURE WITH THIS PRODUCT. CO APOLOGIZES FOR ANY INCONVENIENCE CAUSES.

DEVICE INFORMATION:
Brand: LASER-FLEX TACHEAL TUBE
Device Type: LASER-FLEX TACHEAL TUBE 5.5MM
Serial: (*confidential*)
Lot: UNK
Other ID: 160-55

REPORTER INFORMATION:
Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]
Occupation: 001 - PHYSICIAN

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 8020889-2001-00029
Mfr Name: MALLINCKRODT MEDICAL
Event Date (B3): 12-Apr-2001
Event Report Type: MALFUNCTION
Adverse Event (B1): Problem (B1): Y

Report Date (B4): 24-Apr-2001
Event Outcome (B2): Report Date (F8): 002 - NURSE

Report Date (F8): 11-May-2001
Report Source (G3): HEALTH PROFESSIONAL

Date Mfr Rec’d (G4): 11-May-2001
Device Operator: HEALTH PROFESSIONAL

Product Code: (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)

Device Age (F9):
Expiration Date:
Single Use (H5): Y
Device Usage (H8):

Event Description (B5):
Mfr 31-MAY-2001: ENDOTRACHEAL LASER-FLEX TUBE INSERTED INTO PATIENT FOR TONSIL WHEN METHYLENE BLUE INFLATED IN PROXIMAL END TUBE - RUPTURED - BLUE ALL OVER PATIENT. THE ITEM WAS TESTED BY ANAESTHESIS BEFORE INSERTION.

Concomitant Medical Products:
UNK

Mfr Name: MALLINCKRODT MEDICAL
Address: CORNAMADDY
ATHLONE, CO. WESTMEATH, IRELAND

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
31-MAY-2001: EVALUATION SUMMARY: NOT ATTACHED AS COMPLAINT SAMPLE AND/OR LOT NO. WAS NOT PROVIDED AND THEREFORE DEVICE COULD NOT BE EVALUATED. CURRENT CONDITION OF PATIENT IS STABLE. NO PATIENT CODE FOR 'STABLE'.

Date Last Updated: 11/2/2010 9:17 AM Recd: 912 Page: 1,837
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: LASER-FLEX TRACHEAL TUBE.
- **Device Type**: LASER-FLEX TRACHEAL TUBE 6.0MM.
- **Device Type**: NA
- **Catalog**: 86398
- **Serial**: (*confidential*)
- **Lot**: UNK
- **Other ID**: 160-60
- **Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: [redacted]
- **Address**: [redacted]
- **EMAIL**: [redacted]
- **Phone**: [redacted]
- **International**: [redacted]
- **Fax**: [redacted]
- **Health Professional**: Yes
- **Occupation**: 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM
## MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>8020889-2005-00009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>MALLINCKRODT MEDICAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>11-May-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>26-May-2005</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>27-May-2005</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Report Type:** MALFUNCTION

**Event Outcome (B2):**

**Event Location (F12):** HOSPITAL

**Device Operator:** HEALTH PROFESSIONAL

**Report Source (G3):** FOREIGN, HEALTH PROFESSIONAL, USER FACILITY

**Product Code:** (AN)-TUBE, TRACHEAL (W/O CONNECTOR) (BTR)

**Device Age (F9):** 1 YR 0 DAYS (1 YR)

**Expiration Date:** 31-May-2009

**Manufacture Date (H4):** 01-May-2004

**Single Use (H5):** Y

**Device Usage (H8):** I

**Event Description (B5):**

Mfr 10-AUG-2006: THE SHARP AND STIFF ENDOTRACHEAL TUBE CAUSED LACERATION WOUND, DURING INTUBATION IN THE PHARYNX AND LARYNGEAL INLET LEADING TO GRANULOMA FORMATION POST OPERATIVELY. RE-INTUBATION WAS NOT NECESSARY.

**Concomitant Medical Products:**

NA

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
10-AUG-2006: ACTUAL DEVICE RETURNED FOR EVALUATION. AS LOT NO. WAS PROVIDED FOR THIS REPORT, BATCH PAPERWORK AND RETAIN SAMPLE WERE REVIEWED AND CONFIRMS THAT THIS ORDER WAS MANUFACTURED TO MEET ALL BLUEPRINT SPECIFICATIONS AND QUALITY REQUIREMENTS BEFORE FINAL RELEASE. THERE IS EVIDENCE TO SUGGEST THAT THE REPORTED DEFECT OCCURRED IN-HOUSE. EVALUATION: THE BATCH PAPERWORK FOR LOT NUMBER 2004051186 WAS REVIEWED AND CONFIRMS THAT THE LOT WAS MANUFACTURED TO MEET ALL OF THE BLUEPRINT SPECIFICATION AND QUALITY REQUIREMENTS. THE RETAIN SAMPLE RETURNED FOR EVALUATION CONTAINED IN A PLASTIC BAG, ALSO RETRUNED WAS THE ORIGINAL UNIT CARTON. VISUAL EXAMINATION OF THE RETURNED UNIT SHOWS THAT THERE IS BLUE COLOURING ON THE PROXIMAL PILOT BALLOON AND ON THE PROXIMAL CUFF, WHICH IS NOT PART OF OUR MANUFACTURING PROCESS. FURTHER EXAMINATION SHOWS THAT THERE IS A SHARP PIECE OF BONDING AGENT ON THE DISTAL CUFF SHOULDER. A DEVIATION OCCURRED DURING THE GLUEING OPERATION AND SHOULD HAVE BEEN DETECTED DURING THE INSPECTION STAGE OF THE PROCESS. THERE IS EVIDENCE TO SUGGEST THAT THE REPORTED DEFECT OCCURRED IN HOUSE. CORRECTIVE ACTION/COMMENTS: WE ARE SORRY THAT YOU EXPERIENCED A PROBLEM WITH OUR CUFFED LASER FLEX PRODUCT. ALL OUR CUFFED LASER FLEX PRODUCT UNDERGOES A FOUR-HOUR INFLATE/DEFLATE TEST PRIOR TO RELEASE, IT IS AT THIS POINT THAT ALL DEFECTS ARE REMOVED. THE COMPLAINT SAMPLE HAS BEEN HIGHLIGHTED TO ALL OF THE RELEVANT PERSONNEL AND THE SERIOUSNESS OF THIS COMPLAINT STRESSED TO ALL CONCERNED. THE TRAINING DEPARTMENT WILL CARRY OUT A METHOD AUDIT ON ALL OF THE GLUE, INFLATE AND DEFLATE OPERATORS ON THIS PROCESS CELL.

DEVICE INFORMATION:
- **Brand:** LASER-FLEX TRACHEAL TUBE 5.5MM
- **Device Type:** LASER-FLEX TRACHEAL TUBE CUFFED 5.5MM
- **Device Type:** NA
- **Catalog:** 86395
- **Serial:** (*confidential*)
- **Lot:** 2004051186
- **Other ID:** 160-55

Reprocessed & Reused: N

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Employer:** [redacted]
- **Position:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** (b) (6)
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 25-May-2007

**Event Date (B3):** 19-Apr-2007
**Report Date (B4):** 25-Apr-2007
**Report Date (F8):** 25-Apr-2007
**Date Mfr Rec'd (G4):** 26-Apr-2007

**Event Report Type:** MALFUNCTION

**Adverse Event (B1):** Problem (B1): Y
**Event Location (F12):** HOSPITAL
**Report Source (G3):** FOREIGN, CONSUMER, HEALTH PROFESSIONAL

**Product Code:** (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)

**Device Available for Evaluation:** Y

**Concomitant Medical Products:** NA

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Device not Returned to Manufacturer

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

**Event Description (B5):**

Mfr 13-JUN-2007: AFTER INTUBATION AND BEFORE THE PROCEDURE WAS STARTED, THE PATIENT WENT INTO RESPIRATORY DISTRESS; HYPERCAPNIA; DESATURATION AND BRADYKINESIA; INJECTION OF ADRENALIN; PATIENT OK AFTER WAKING; PATIENT HAD TO BE KEPT IN HOSPITAL UNDER SURVEILLANCE INSTEAD OF OUTPATIENT SURGERY; A HERNIA WAS DETECTED ON THE DEVICE.

**Mfr Name:** MALLINCKRODT MEDICAL
**Address:** CO. WESTMEATH
CORNMADDY,ATHLONE,,
IRELAND

**Remedial Action (H7):**

**Correction/Removal No (H9):** NA

**Additional Mfr Narrative (H10 & H11):**

13-JUN-2007: ACTUAL DEVICE HAS NOT BEEN RETURNED TO THE MANUFACTURER TO DATE. IF A SAMPLE BECOMES AVAILABLE FOR EVALUATION A COMPREHENSIVE EVALUATION WILL BE COMPLETED AND A FOLLOW-UP REPORT WILL BE SUBMITTED. THE PATIENT WAS REPORTED TO HAVE EXPERIENCED HYPERCAPNIA & BRADYKINESIA, HOWEVER, THERE IS NO PATIENT RELATED TERMS AVAILABLE IN PART 1, SUBPART A FOR THESE REPORTED CONDITIONS.

**Recd:** 914  **Page:** 1,841  **Date Last Updated:** 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER-FLEX TRACHEAL TUBE 5.0MM
- **Device Type:** LASER-FLEX TRACHEAL TUBE CUFFED 5.0
- **Device Type:** NA
- **Catalog:** 86394
- **Serial:** (*confidential*)
- **Lot:** 2002062228
- **Other ID:** 160-50
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No Answer
- **Occupation:** UNK - UNKNOWN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>21-May-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>RUSCH GMBH</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Sep-2001</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(AN)-TUBE, TRACHEAL (W/ WO CONNECTOR) (BTR)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>I</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>WILLY RUSCH AG</td>
</tr>
<tr>
<td>Address:</td>
<td>WILLY RUSCH STRASSE 4-10 KERNEN, GERMANY</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>26-OCT-2001: PRODUCT DISCARDED BY CUSTOMER.</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: RUSCH  
Device Type: LASERTRACHEAL TUBE  
Device Type: NA  
Catalog: 102004070  
Serial: (*confidential*)  
Lot: 99/11/1  
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]  
Address: [redacted]  
Health Professional: Yes  
Email: [redacted]  
Phone: [redacted]  
International: [redacted]  
Fax: [redacted]  
Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>21-May-2001</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
<th>Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>05-Oct-2001</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>24-Sep-2001</td>
<td>Device Operator:</td>
<td>LAY USER/PATIENT</td>
<td>Event Location (F12):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Report Source (G3):</td>
<td>USER FACILITY</td>
<td></td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>9610520-2001-01747</td>
<td>Mfr Name:</td>
<td>RUSCH GMBH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: WILLY RUSCH AG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: WILLY-RUSCH STRASSE 4-10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KERNEN, GERMANY</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>10-OCT-2001: EVALUATION ANTICIPATED BUT NOT YET BEGUN.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: RUSCH
Device Type: LASERTRACHEAL TUBE
Device Type: NA
Catalog: 102004070
Serial: (*confidential*)
Lot: 99/11/1
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No: 9611812-2007-00003</th>
<th>Mfr Name: DORNIER MEDTECH LASER GMBH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received:</td>
<td></td>
</tr>
</tbody>
</table>

| Event Date (B3): 18-Oct-2006       | Event Report Type: MALFUNCTION         |
| Report Date (B4): 13-Jul-2007      | Event Outcome (B2):                    |
| Report Date (F8): 13-Jul-2007      | Reporter Occupation (E3): NA - NOT APPLICABLE |
| Date Mfr Rec'd (G4): 18-Oct-2006   | Device Operator: HEALTH PROFESSIONAL   |

| Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
| Device Age (F9):                                           |
| Expiration Date:                                          |
| Device Usage (H8): R                                      |

Event Description (B5):

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH GMBH
Address: WESSLING,
         GERMANY

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DORNIER DIODE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** K2010260
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** 0191/0806
- **Other ID:**

- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:**
- **Address:**
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** No
- **Occupation:** NA - NOT APPLICABLE

Recd: 917  Page: 1,848  Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>MFR Report No:</th>
<th>9611812-2007-00004</th>
<th>Mfr Name:</th>
<th>DORNIER MEDTECH LASER GMBH</th>
<th>Date Received: 13-Jul-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>12-Dec-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Mfr 27-JUL-2007: CUSTOMER STATED THAT A FIBER BROKE WHEN REMOVING FROM PACKAGE.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH GMBH
Address: WESSLING, GERMANY

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
27-JUL-2007:
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DORNIER DIODE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** K1008084
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** UNKNOWN
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>23-Feb-2007</th>
<th>Event Report Type:甘</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>13-Jul-2007</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>18-Oct-2006</td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**

**Expiration Date:**

**Device Usage (H8):** R

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** Yes

**Adverse Event (B1):** Problem (B1): Y

**Event Description (B5):**


**Concomitant Medical Products:**

**Device Evaluated by Manufacturer (H3):** Yes

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

27-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: DORNIER DIODE LASER FIBER
- Device Type: LASER FIBER
- Device Type: K2010260
- Catalog: (*confidential*)
- Serial: (*confidential*)
- Lot: 0273 / 1106
- Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:
- Name: [Redacted]
- Address: [Redacted]
- Health Professional: Yes
- Occupation: 002 - NURSE
- EMAIL: [Redacted]
- Phone: [Redacted]
- International: [Redacted]
- Fax: [Redacted]

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 9617149-2004-00002
Date Mfr Rec'd (G4): 21-Apr-2004
Report Date (B4): 10-May-2004
Date Mfr Rec'd (G4): 17-May-2004

Event Date (B3): 07-Apr-2004
Event Report Type: INJURY
Event Date (B3): 07-Apr-2004
Event Outcome (B2): REQUIRED INTERVENTION

Report Date (F8): 10-May-2004
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):

Concomitant Medical Products:
NI

Mfr Name: DIOMED, LTD.
Address: CAMBRIDGE RESEARCH PARK
          WATERBEACH, CAMBRIDGE,
          UNITED KINGDOM

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): Device not Returned to Manufacturer

Remedial Action (H7):
Correction/Removal No (H9): 11/2/2010  9:17 AM
DEVICE INFORMATION:

- **Brand:** EVLT KIT
- **Device Type:** LASER FIBER
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** 002921
- **Other ID:** NA

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

| MFR Report No: | 9681384-1997-00059 | Mfr Name: | MMJ S.A. DE C.V. | Date Received: | 27-May-1997 |
| Event Date (B3): | 10-Mar-1997 | Event Report Type: | OTHER | Adverse Event (B1): | Problem (B1): Y |
| Date Mfr Rec’d (G4): | 23-Apr-1997 | Device Operator: | HEALTH PROFESSIONAL |
| Product Code: | (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR) | Manufacture Date (H4): | 01-Jan-1996 |
| Device Age (F9): | 1 YR 0 DAYS (1 YR) | Single Use (H5): | Y |
| Expiration Date: | 01-Jan-2001 | Device Usage (H8): | U |

Event Description (B5):
Mfr 04-JUN-1997: THE HOSPITAL REPORTED THAT CUFF LEAKED DURING OPERATION.

Concomitant Medical Products:
NA

Mfr Name: MALLINCKRODT MEDICAL, INC.
Address:
HOOK RD
ARGYLE, NY 12809
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes

Remedial Action (H7):
Correction/Removal No (H9): NA

Additional Mfr Narrative (H10 & H11):
04-JUN-1997: SECTION H6, CODE 68: THE MICROSCOPIC EVALUATION REVEALED A SMALL EMBEDDED PARTICLE WHICH MAY HAVE WEAKENED THE OF THE CUFF. INFORMATION Recorderd in SECTION F COMPLETED BY THE MANUFACTURER. INFORMATION WAS NOT PROVIDED TO THE MANUFACTURER ON A MEDWATCH FORM.
CDRH MAUDE EVENT REPORT (FOI) 02-Nov-2010

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER FLEX TRACHEAL TUBE
Device Type: LASER RESISTANT ENDOTRACHEAL TUBE, CUFFED, 6.0
Device Type: NA
Catalog: 86398
Serial: (*confidential*)
Lot: ML06480
Other ID: NA
Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax:

Occupation: 109 - PHARMACIST
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>29-Apr-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>29-May-1997</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>29-Apr-1997</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL, USER FACILITY</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>MALLINCKRODT MEDICAL</td>
</tr>
<tr>
<td>MFR Report No:</td>
<td>9681384-1997-00064</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>MFR 09-JUN-1997: THE HOSPITAL REPORTED THAT IT WAS DIFFICULT TO REMOVE THE ET. SOME TRAUMA TO PATIENT BECAUSE EXTUBATION TOOK 10 TO 15 MINUTES LONGER THAN USUAL. DID NOT CAUSE FURTHER COMPLICATIONS.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5): Y</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>U</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>Yes</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td>NA</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>09-JUN-1997: INFORMATION RECORDED IN SECTION F COMPLETED BY THE MANUFACTURER. INFORMATION WAS NOT PROVIDED TO THE MANUFACTURER ON A MEDWATCH FORM.</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER FLEX TRACHEAL TUBE, 5.5MM
- **Device Type:** LASER RESISTANT ENDOTRACHEAL TUBE, CUFFED, 5.5MM
- **Catalog:** 86398
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Health Professional:** Yes
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Phone:** [Redacted]
- **EMAIL:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 29-Apr-1998
Event Report Type: OTHER
Adverse Event (B1): Problem (B1): Y
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Event Location (F12): HOSPITAL
Date Mfr Rec'd (G4): 29-Apr-1998
Product Code: (AN)-TUBE, TRACHEAL (W/WO CONNECTOR) (BTR)
Device Age (F9): 4 YR -182 DAYS (3.5 YR)
Manufacture Date (H4): 01-Nov-1994
Expiration Date: Single Use (H5): Y
Device Usage (H8): U
Event Description (B5):
Mfr 08-JUN-1998: FACILITY REPORTED "BALLOON LEAKED, DR HAD TO REMOVE IT AND USE ANOTHER ONE., O.K. DURING RE-TEST."

Concomitant Medical Products:

Mfr Name: MMJ SA DE CV
Address: AV. HENEQUEN #1181
CD. JUAREZ, CHIH., MEXICO
Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): Yes
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
08-JUN-1998: NOTE: INFO IN SECTION F COMPLETED BY THE MFR. INFO WAS NOT PROVIDED ON A MEDWATCH FORM.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: LASER FLEX
- Device Type: LASER FLEX
- Device Type: NA
- Catalog: 86398
- Serial: (*confidential*)
- Lot: ML05880
- Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [b] (b)
- Address: [b] (b)
- EMAIL: [b] (b)
- Phone: [b] (b)
- International: [b] (b)
- Fax: [b] (b)
- Occupation: OTHER

Health Professional: No
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1001954</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
<th>Date Received</th>
<th>12-May-1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Mar-1994</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>20-Apr-1994</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 13-MAY-1994: DURING LASER TURP, SMOKE WAS OBSERVED COMING FROM LASER SCOPE. THE PHYSICIAN COMPLAINED OF SMALL BURN TO THUMB. NO ADVERSE AFFECT TO PT. UPON COMPLETION OF CASE, THE LASER DEVICE WOULDN'T COME OUT OF LASER SCOPE AND WAND (FIBER) MELTED INTO SCOPE. DEVICE WAS SENT TO MFR.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>ANOTHER CO'S OBTURATOR LB 150</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LASERSCOPE</td>
<td>Address:</td>
<td>SAN JOSE, CA 95134</td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>*</td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>13-MAY-1994:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: KTP/YAG LASER
- **Device Type**: LASER
- **Catalog**: 19051171, 10-2071
- **Serial**: (*confidential*)
- **Lot**: 
- **Other ID**: 

**Reprocessed & Reused**: N/A

REPORTER INFORMATION:

- **Name**: (b) (6)
- **Address**: (b) (6)

- **Health Professional**: Yes
- **Occupation**: 002 - NURSE
- **EMAIL**: 
- **Phone**: 
- **International**: 
- **Fax**: 
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1002725</th>
<th>Mfr Name: LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>24-Jun-1994</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Event Date (B4):</td>
<td>30-Jun-1994</td>
<td>Adverse Event (B1): Problem (B1): Y</td>
</tr>
<tr>
<td>Event Date (F8):</td>
<td></td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 07-JUL-1994: DURING THE FIRST MINUTE OF USE THE LASER FIBER BURNED THROUGH AT THE HANDPIECE. THE TIP OF THE FIBER WAS BURNED. THERE WAS NO HARM TO THE PT DUE TO IMMEDIATE MEDICAL INTERVENTION.

**Concomitant Medical Products:**

- Mfr Name: LASERSCOPE
- Address: SAN JOSE, CA 95134 UNITED STATES
- Device Available for Evaluation: R
- Device Evaluated by Manufacturer (H3): No Answer
- Remedial Action (H7): 
- Correction/Removal No (H9): 
- Additional Mfr Narrative (H10 & H11): 07-JUL-1994:

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER YAG ADD
Device Type: LASER YAG ADD
Device Type: 1064
Catalog: 10-2701
Serial: (*confidential*)
Lot: 10-2701-414

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>21-Jun-1994</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>22-Jun-1994</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Device Operator:</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>WHILE USING LASER DURING LAPAROSCOPIC PROCEDURE, A TWO INCH PIECE OF THE FIBER BURNED OFF AND FELL NEAR THE PT'S STOMACH. RPTR WAS ABLE TO RETRIEVE THE STRAY PORTION AND REMOVE IT FROM INSIDE THE PT.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>HERAEUS LASERSONICS, INC.</td>
</tr>
<tr>
<td>Address:</td>
<td>MILPITAS, CA 95035</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>07-JUL-1994</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER FIBER
Device Type: LASER FIBER
Catalog: 0016-5601-90
Serial: (*confidential*)
Lot: 301778

Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: No Information

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]

Occupation: NI - NO INFORMATION
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1003299

<table>
<thead>
<tr>
<th>Event Date (B3): 22-Jun-1994</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 01-Sep-1994</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:

Mfr Name: SURGICAL LASER TECHNOLOGIES, INC.
Address: OAKS, PA 19456
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-SEP-1994:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: YAG LASER PROBE
Device Type: LASER PROBE
Device Type: MTRL 3
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b]
Address: [b] [b]

Health Professional: Yes

EMAIL: 
Phone: 
International: 
Fax: 

Occupation: 401 - BIOMEDICAL ENGINEER
CDRH MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1003301</th>
<th>Mfr Name:</th>
<th>C.R. BARD, INC.</th>
<th>Date Received</th>
<th>12-Sep-1994</th>
</tr>
</thead>
</table>

**Event Date (B3):** 26-Aug-1994  
**Report Date (B4):** 31-Aug-1994  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Event Description (B5):** Volun 13-SEP-1994: DURING LASER ABLATION OF THE PROSTATE, THE LASER FIBER CAME APART (TIP BROKE OFF.) THE TIP INITIALLY WAS IN THE PROSTATE, BUT WAS SUCCESSFULLY IRRIGATED AT. THERE WAS NO HARM TO THE PT.  
**Concomitant Medical Products:**  

**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:** 01-Mar-1997  
**Single Use (H5):**  
**Device Usage (H8):**  
**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 13-SEP-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: UROLASE
Device Type: LASER FIBER
Catalog: 350000
Serial: (*confidential*)
Lot: 03BDT010
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International: Fax:

Occupation: 500 - RISK MANAGER
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1003670</th>
<th>Mfr Name:</th>
<th>HGM MEDICAL LASER SYSTEMS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Sep-1994</td>
<td>Event Report Type: INJURY</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>27-Sep-1994</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(OP)-LASER, OPHTHALMIC (HQF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 14-OCT-1994: DURING PROCEDURE SURGEON STATED THE LASER WASN'T WORKING. LASER PROBE HAD BEEN TESTED AND WORKED PRIOR TO BEGINNING OF PROCEDURE. IN EXAMINATION IT WAS NOTED THE LASER PROBE WAS BROKEN IN HALF. THERE WAS NO EVIDENCE ON OBSERVATION OF THE DRAPE BEING BURNED OR MELTED. THE PROBE WAS CHANGED AND THE CASE PROCEEDED.

**Concomitant Medical Products:**

**Mfr Name:** HGM MEDICAL LASER SYSTEMS, INC.

**Address:** SALT LAKE CITY, UT 84104

UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
14-OCT-1994:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: GHERINI-KAUFMANN ENDO OTO PROBE
Device Type: LASER ENERY DELIVERY PROBE
Device Type: FLP050-G01-U-S
Catalog: (*confidential*)
Serial: (*confidential*)
Lot: 00494F50A-01
Other ID:

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1005003</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
<th>Date Received</th>
<th>Event Date (B3): 17-Jan-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 06-FEB-1995: LASER WAS BEING USED ON PROSTATE. SURGEON INDICATED THAT LASER WAS STILL FIRING WHEN HE TOOK HIS FOOT OFF THE PEDAL. EMERGENCY SHUT-OFF USED. NO INJURY TO THE PT.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>TRIMEDYNE, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>IRVINE, CA 92714</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>06-FEB-1995:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- Brand: ND YAG LASER
- Device Type: LASER FOR PROSTATE ABLATION
- Device Type: 1000
- Catalog:
- Serial: (*confidential*)
- Lot:
- Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- Name: (b) (6)
- Address: (b) (b)
- EMAIL:
- Phone:
- International:
- Fax:
- Health Professional: Yes
- Occupation: 500 - RISK MANAGER
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1005117</th>
<th>Mfr Name:</th>
<th>MARLO SURGICAL TECHNOLOGY</th>
<th>Date Received:</th>
<th>13-Feb-1995</th>
</tr>
</thead>
</table>

**Event Date (B3):** 28-Oct-1994  
**Report Date (B4):** 06-Feb-1995  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Report Type:** INJURY  
**Event Outcome (B2):** HOSPITALIZATION  
**Report Source (G3):** HEALTH PROFESSIONAL  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Device Available for Evaluation:** Y  
**Device Usage (H8):** Single Use  
**Manufacture Date (H4):**  
**Expiration Date:**  
**Adverse Event (B1):** Y  
**Problem (B1):** Y  
**Event Location (F12):** HOSPITAL  
**Report Date (F8):**  
**Event Description (B5):**  
Volun 14-FEB-1995: PT UNDERGOING LAPAROSCOPY WITH LASER. SURGEON SAW A SMALL PIECE OF LASER FIBER BREAK OFF INTO PELVIC CAVITY. UNABLE TO RETRIEVE. PROCEDURE CHANGED TO OPEN LAPAROTOMY. UNABLE TO RETRIEVE FIBER.  
**Concomitant Medical Products:**  

**Mfr Name:** MARLOW SURGICAL TECHNOLOGIES  
**Address:** WILLOUGHBY, OH 44094 UNITED STATES  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
14-FEB-1995:  

---

Recd: 931  
Page: 1,875  
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER FIBER DEFLECTOR
- **Device Type:** LASER FIBER DEFLECTOR
- **Device Type:** ML0590
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1005517</th>
<th>Mfr Name:</th>
<th>SURGITEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Feb-1995</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 21-MAR-1995: DURING LASER ABLATION OF THE PROSTATE, FIBER WAS IN USE FOR ABOUT 5 MINUTES BEFORE THERE WAS A FLASH OF LIGHT. LASER PLACED ON STAND BY. SEVERED TIP OF FIBER NOTED IN BLADDER ALONG WITH 3 BLACK PIECES FROM SHAFT OF FIBER. ALL PIECES RETRIEVED WITHOUT HARM OR INJURY TO PT. PROCEDURE COMPLETED WITH A NEW FIBER.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>SURGITEK, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>RACINE, WI 53404</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>21-MAR-1995:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ULTRAGOLD UROLOGIC RIGHT-ANGLE LASER FIBER
- **Device Type:** LASER FIBER
- **Device Type:** 8000
- **Catalog:** 8000
- **Serial:** (*confidential*)
- **Lot:** 11478
- **Other ID:**

  Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

  EMAIL: [REDACTED]
  Phone: [REDACTED]
  International: [REDACTED]
  Fax: [REDACTED]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1006892</th>
<th>Mfr Name:</th>
<th>CANDELA LASER CORP.</th>
<th>Date Received: 11-Sep-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>30-Aug-1995</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 12-SEP-1995: DURING A LASER LITHOTRIPSY OF A BLADDER STONE, THE LASER STOPPED WORKING WITH INTERLOCK WORKING WITH INTERLOCK LIGHT ON. THE CO. STATED THE LASER MAY HAVE OVERHEATED DUE TO MULTILE USES. THE OPERATOR MANUAL DOES NOT ADDRESS THE MAXIMUM NUMBER OF TIMES THE LASER MAY BE FIRED.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>12-SEP-1995:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** MDL PULSE DYE LASER
- **Device Type:** LASER
- **Device Type:** MDL2000
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

**EMAIL:**
**Phone:**
**International:**
**Fax:**
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1007533</th>
<th>Mfr Name:</th>
<th>BOSTON SCIENTIFIC CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Oct-1995</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 03-NOV-1995: PRONG FROM LASER BASKET BROKE OFF IN PT'S URETER. ALL PARTS RECOVERED. NO RECORDED OR OBSERVED PT INJURY.

**Concomitant Medical Products:**

- **Mfr Name:** BOSTON SCIENTIFIC CORP
- **Address:** SCIENTIFIC PLACE
  NATICK, MA 01760
  UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer
**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 03-NOV-1995.
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SEGURA-DRETLER BASKET 4 WIRE
Device Type: LASER BASKET

Catalog: 320-104
Serial: (*confidential*)
Lot: 553895
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b] [b] [b]
Address: [b] [b] [b] [b]

Health Professional: Yes

EMAIL: [b] [b] [b] [b]
Phone: [b] [b] [b] [b]
International: Fax:

Occupation: OTHER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1007743</th>
<th>Mfr Name:</th>
<th>BOSTON SCIENTIFIC CORP.</th>
<th>Date Received:</th>
<th>21-Nov-1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Nov-1995</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 24-NOV-1995: DURING LASER LITHOTRIPSY, THE WIRE BASKET, WITH STONE ENTRAPPED, APPEARED TO MALFUNCTION WHEN LASER FIBER WAS INTRODUCED. ATTEMPTS WERE MADE TO REMOVE THE LASER, BUT SEEMED TO BIND IN BASKET, AND THE DISTAL GOLDEN TIP FRAGMENTED AND FELL OFF. THESE WERE REMOVED AND THE STONE AND GOLDENTIP WERE FRAGMENTED WHEN 2ND LASER ENERGY WAS APPLIED DIRECTLY THROUGH URETEROSCOPE.

**Concomitant Medical Products:**

Mfr Name: BOSTON SCIENTIFIC CORP.
Address: 480 PLEASANT ST
WATERTOWN, MA 02172
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
24-NOV-1995:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>MICROVASIVE SEQURA BASKET MICRON LASER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Catalog</td>
<td>320-104</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>523459</td>
</tr>
<tr>
<td>Other ID</td>
<td></td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>(b) (b)</td>
</tr>
<tr>
<td>EMAIL</td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax</td>
<td></td>
</tr>
<tr>
<td>Health</td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>No</td>
</tr>
<tr>
<td>Occupation</td>
<td>500 - RISK MANAGER</td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
Event Date (B3): 26-Oct-1995
Report Date (B4): 16-Jan-1996
Report Date (F8):
Date Mfr Rec'd (G4):
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: HEALTH PROFESSIONAL
Event Description (B5):
Volun 19-JAN-1996: APPROX 20 MINUTES AFTER PROCEDURE, RAISED BLISTERS APPEARED IN ALL 53 PLACES WHERE LASER HAD BEEN APPLIED. BURNS WERE 1/2" X 1 1/2" IN SIZE, CONSISTENT WITH SIZE OF OPENING ON MACHINE. RPTR WAS TREATED AT AN OUTPATIENT BURN CENTER. SHE HAS SOME SCARRING. SEVERAL CAPILLARIES HAVE RUPTURED AND NOW APPEAR AS SOLID RED AREAS. RPTR STATES PHOTOGRAPHS OF HER LEGS WERE TAKEN PRIOR TO PROCEDURE BUT A SAMPLE AREA WAS NOT TREATED TO DETERMINE IF BURNS WOULD OCCUR. RPTR HAS OLIVE SKIN. RPTR STATES TREATING PHYSICIAN HAS BROCHURES FROM CO WHICH HE DOES NOT FEEL SHOULD BE GIVEN OUT DUE TO THE INACCURATE INFO CONTAINED IN THE BROCHURES. ACCORDING TO PHYSICIAN 97% OF ALL PTS RECEIVING NON-SURGICAL LASER TREATMENT FOR BROKEN CAPILLARIES REPORT NO SIDE EFFECTS. ALSO STATES LASER "FOLLOWS" RED AND SHE MAY NOT HAVE BEEN AN APPROPRIATE CANDIDATE FOR PROCEDURE DUE TO OLIVE SKIN.
Concomitant Medical Products:

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
19-JAN-1996:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LASER DERM V.L.
- **Device Type:** LASER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N/A

REPORTEER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:**
- **Fax:**

Date Last Updated: 11/2/2010 9:17 AM

Recd: 936  Page: 1,886
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1008213</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>SURGICAL LASER TECHNOLOGIES, INC.</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 27-Dec-1995  
**Report Date (B4):** 03-Jan-1996  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Event Location (F12):** HOSPITAL  
**Event Description (B5):** Volun 02-FEB-1996: WHILE PERFORMING LASER LAPAROSCOPY IT WAS NOTICED THAT TIP OF ROUNDED LASER PROBE HAD BROKEN OFF. STERILE FIELD AND SURROUNDING AREA SEARCHED. UNABLE TO LOCATE LASER TIP. THE MD IS AWARE. THE PROBE TIP CRYSTAL IS NOT X-RAY DETECTIBLE, NOT EVEN SURE IF IT VAPORIZED.  
**Concomitant Medical Products:**  

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Device Evaluated for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>02-FEB-1996:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** ROUNDED LASER PROBE
- **Device Type:** LASER PROBE
- **Catalog:** *(confidential*)
- **Serial:** *(confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** *(b)(6)*
- **Address:** *(b)(6)*
- ** EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1008332</th>
<th>Mfr Name: STRYKER CORP.</th>
<th>Date Received</th>
<th>14-Feb-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Jan-1996</td>
<td>Event Report Type: *</td>
<td>Adverse Event (B1): Y</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Feb-1996</td>
<td>Event Outcome (B2):</td>
<td>Event Location (F12): HOSPITAL</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 0HP - HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(AN)-YAG (LLO)</td>
<td></td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Corrective Action No (H9):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Volun 20-FEB-1996: POSSIBLE PRODUCT PROBLEM; DURING ARTHROSCOPY, A SMALL PIECE OF METAL WAS SEEN. RPTR QUESTIONS IF IT BREAKS OFF FROM KNEE SHAVER. 3 POSSIBLE BOXES WITH 3 (PACKAGING NOT SAVED). 1. 95096352, 2. 96015012, 3. 93126682.

Concomitant Medical Products:

Mfr Name: STRYKER ENDOSCOPY DIV. STRYKER CORP.
Address: SAN JOSE, CA 95134 UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 20-FEB-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** ARTHROSCOPE
- **Device Type:** ARTHROSCOPE
- **Catalog:** 275-756-000
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1008574</th>
<th>Mfr Name: HERAEUS SURGICAL, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>07-Feb-1996</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Feb-1996</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Unk :</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: HERAEUS SURGICAL, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 575 COTTONWOOD DR MILPITAS, CA 95035 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): :</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** YAG LASER FIBER, SINGLE, 5FR, 600 UM CORE
- **Device Type:** LASER FIBER
- **Catalog:** 956D
- **Serial:** (*confidential*)
- **Lot:** 045G6
- **Other ID:** 0016-8318-81

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

EMAIL: (b) (6)
Phone: (b) (6)
International: (b) (6)
Fax: (b) (6)
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1008692
Mfr Name: UNKNOWN

| Event Date (B3): 19-Mar-1996 | Event Report Type: MALFUNCTION |
| Report Date (F8): | Reporter Occupation (E3): OTHER |
| Date Mfr Rec'd (G4): | Device Operator: HEALTH PROFESSIONAL |

Date Received: 21-Mar-1996

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3):

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Volun 26-MAR-1996: YAG LASER FIBER BROKE OFF INSIDE BLADDER. RETRIEVED WITH NO NEGATIVE OUTCOME.

Concomitant Medical Products:

Mfr Name: STEIN TECHNOLOGY, INC.
Address: 1809-E CROSSBEAM DR
CHARLOTTE, NC 28219
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
26-MAR-1996:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LASER OPTI LINK
- **Device Type:** LASER FIBER OPTIC
- **Catalog:** LOL 9307
- **Serial:** (*confidential*)
- **Lot:** 40
- **Other ID:**

  Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** (b) (6)
- **Address:** (b) (b)

  Health Professional: Yes

  EMAIL: (b) (b)
  Phone: (b) (b)
  International: (b) (b)
  Fax: (b) (b)

  Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>14-May-1996</td>
<td>Event Report Type: MALFUNCTION</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4)</td>
<td>15-May-1996</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Dec-1999</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td>Volun 05-JUN-1996: GLASS/PLASTIC PORTION OF DISTAL TIP LOOSENED FROM TIP AND WAS NOTED IN THE KNEE AS SEEN ON TV MONITOR BY SURGEON. THIS WAS SUCTIONED INTO SPECIMEN CATCHER AND RETRIEVED BY CIRCULATING NURSE.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: TRIMEDYNE, INC.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 2801 BARRANCA RD IRVINE, CA 92714 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>05-JUN-1996</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** OMNI TIP SIDEFIRE TIP
- **Device Type:** LASER SWITCHABLE TIP 90 DEGREE
- **Device Type:** 20479-HP
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** 11431
- **Other ID:**

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 25-May-1996
Event Date (B3): 15-May-1996
Adverse Event (B1): Y
Problem (B1): N

Event Report Type: *
Event Outcome (B2): 002 - NURSE
Event Location (F12): HOSPITAL

Mfr Name: HERAEUS LASERSONICS, INC.

Voluntary Report No: MW1009242
Report Date (B4): 25-May-1996
Report Date (F8): 002 - NURSE
Report Date (F8): 06-Jun-1996

Voluntary Report No: MW1009242
Report Date (B4): 25-May-1996
Report Date (F8): 002 - NURSE
Report Date (F8): 06-Jun-1996

Date Mfr Rec'd (G4): 25-May-1996
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Volun 14-JUN-1996: PT RECEIVED SUPERFICIAL BURN TO LIP DURING ORAL SURGERY. DEVICE EVALUATED BY HOSP BIOMED AND MFR AND NO PROBLEMS FOUND. HOSP INVESTIGATING POSSIBLE USER ERROR.

Concomitant Medical Products:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
14-JUN-1996:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASER
- **Device Type:** LASER
- **Catalog:** 
- **Serial:** (*confidential*)
- **Lot:** 
- **Other ID:** 

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

EMAIL: 
Phone: 
International: 
Fax: 

Date Last Updated: 11/2/2010  9:17 AM
Recd: 942  Page: 1,898
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Dec-1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Date Received:</td>
<td>26-Jun-1997</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Voluntary Report No:</td>
<td>MW1011590</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 30-JUN-1997: DR. IS USING A NON-APPROVED LASER MACHINE.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>UNK</td>
</tr>
<tr>
<td>Address:</td>
<td>UNK</td>
</tr>
<tr>
<td>UNK, UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>30-JUN-1997:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: PRK EXCIMER LASER
Device Type: LASER MACHINE
Device Type: UNK
Catalog: UNK
Serial: (*confidential*)
Lot: UNK
Other ID: UNK

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1011608</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
<th>Date Received</th>
<th>02-Jul-1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Apr-1997</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>02-Jul-1997</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 03-JUL-1997: DR IS USING A NON-APPROVED LASER.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>UNK</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>UNK, UNKNOWN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>03-JUL-1997:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EXCIMER LASER
- **Device Type:** LASER MACHINE
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

**Reprocessed & Reused:** N/A
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1011726</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>01-May-1997</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 21-JUL-1997: DR IS USING A NON-APPROVED LASER MACHINE.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>UNK</td>
</tr>
<tr>
<td>Address:</td>
<td>UNK</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>21-JUL-1997:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** EXCIMER LASER
- **Device Type:** LASER MACHINE
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1011734</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received:</td>
<td>02-Nov-2010</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Event Date (B3): | 01-Jan-1997 | Event Report Type: | INJURY |
| Event Date (B4): | 18-Jul-1997 | Event Outcome (B2): |        |
| Report Date (F8): |            | Reporter Occupation (E3): | 305 - PATIENT |
| Date Mfr Rec'd (G4): |            | Device Operator: | HEALTH PROFESSIONAL |
| Product Code: | (OP)-LASER, OPHTHALMIC (HQF) | Manuf Date (H4): |        |
| Expiration Date: | | Single Use (H5): |        |
| Device Usage (H8): | |        | |

**Event Description (B5):**
Volun 21-JUL-1997: PT HAD SURGERY WITH THE LASER SYSTEM. PT NOW IS EXPERIENCING VISION PROBLEMS IN WHICH THERE IS CLOUDINESS IN LIGHT AND CLEAR IN DARK AREAS.

**Concomitant Medical Products:**
NA

**Mfr Name:** UNK
**Address:** UNK, UNKNOWN

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 21-JUL-1997:
CDRH
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LASER SYSTEM
- **Device Type:** LASER SYSTEM
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Fax:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Occupation:** 305 - PATIENT
- **EMAIL:** [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1013076</th>
<th>Mfr Name:</th>
<th>THERMOLASE CORP.</th>
<th>Date Received</th>
<th>19-Feb-1998</th>
</tr>
</thead>
</table>

**Event Date (B3):** 28-Feb-1997  
**Report Date (B4):** 19-Feb-1998  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):** UNKNOWN  
**Report Source (G3):** HEALTH PROFESSIONAL  

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** HEALTH PROFESSIONAL  
**Device Usage (H8):**  

**Event Description (B5):**  
Volun 04-MAR-1998: LASER ADVERTISED AS HAIR REMOVAL DEVICE WITH "LASTING RESULTS." RPTR PURCHASED THREE TREATMENTS (TO REMOVE FACIAL HAIR) WHICH WERE PERFORMED BY PHYSICIAN/STAFF. TREATMENT CONSISTED OF WAXING FOLLOWED BY USE OF LASER. ALL HAIR GREW BACK WITHIN 4 WEEKS AFTER EACH TREATMENT.  

**Concomitant Medical Products:**  

**Mfr Name:** THERMOLASE CORP.  
**Address:** 10455 PACIFIC CENTER CT.  
SAN DIEGO, CA 92121  
UNITED STATES  

**Device Available for Evaluation:** *  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
04-MAR-1998:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SOFTLIGHT LASER
Device Type: LASER ADVERTISED FOR HAIR REMOVAL
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: PATENTS 5226907; 5423728
Other ID: FDA # K950019

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (b)
Address: [b] (b)

EMAIL: [b] (b)
Phone: [b] (b)
International: [b] (b)
Fax: [b] (b)

Health Professional: No

Occupation: 305 - PATIENT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name:</th>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW1013295</td>
<td>CERAMOPTEC, INC.</td>
<td>Unk :</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3): 18-Feb-1998</th>
<th>Event Report Type: MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 19-Feb-1998</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

| Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX) |
|-------------|----------------|
| Device Age (F9): | |
| Expiration Date: | |

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unk :</td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

Mfr Name: CERAMOPTEC, INC.
Address: 515 SHAKER RD.
EAST LONGMEADOW, MA 01028
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: CERAMOPIC
Device Type: LASER FIBER

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

Health Professional: Yes

Occupation: 002 - NURSE
The output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product contributed to the event.

**Voluntary Report No:** MW1013886  
**Mfr Name:** NIDEK, INC.

**Event Date (B3):** 01-Jan-1996  
**Report Date (B4):** 19-May-1998  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** INJURY  
**Event Report Type:** REQUIRED INTERVENTION  
**Adverse Event (B1):** N  
**Problem (B1):** N  

**Event Location (F12):** UNKNOWN  
**Report Source (G3):** HEALTH PROFESSIONAL

**Product Code:** (OP)-LASER, OPHTHALMIC (HQF)  
**Device Operator:** HEALTH PROFESSIONAL  
**Reporter Occupation (E3):** INVALID DATA

**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 03-JUN-1998

**Event Description (B5):**  
Volun 03-JUN-1998: RPTR REC'D LASER TREATMENT TO STOP "LEAKAGE" IN THEIR RIGHT EYE. ON WATCHING AN EYE SURGERY ON TV ONE DAY, IT WAS SAID THAT BEING TREATED BY LASER, A CERTAIN MODEL COULD NOT BE CALIBRATED PROPERLY UNLESS THEY HAD BEEN APPROVED BY FDA, "NEEDLESS TO SAY MY RIGHT EYE HAS BEEN BLINDED."

**Concomitant Medical Products:**  
**Mfr Name:** NIDEK, INC.  
**Address:** 47651 WESTINGHOUSE DR.  
FREMONT, CA 94539  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer:** No Answer
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: NIDEK-AMO
Device Type: LASER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *
Address: *

EMAIL:
Phone: (*)
International:
Fax:

Health Professional: No Information

Occupation: * - INVALID DATA
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1014001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>HGM MEDICAL LASER SYSTEMS, INC.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>15-Jun-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>16-Jun-1998</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(OP)-LASER, OPHTHALMIC (HQF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>001 - PHYSICIAN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volun 18-JUN-1998: DURING THE USE OF AN ARGON LASER, A BIG, RED FLASH BACK OF LASER LIGHT OCCURRED INTO PHYSICIANS EYES. PHYSICIAN HAS PAIN IN HER EYES FROM THIS INCIDENT.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concomitant Medical Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mfr Name: HGM MEDICAL LASER SYSTEMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: 3959 WEST 1820 SOUTH</td>
</tr>
<tr>
<td>SALT LAKE CITY, UT 84108</td>
</tr>
<tr>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Y</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Device Evaluated by Manufacturer (H3):</th>
<th>No Answer</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Correction/Removal No (H9):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Mfr Narrative (H10 &amp; H11):</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-JUN-1998:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: HGM ARGON LASER
- **Device Type**: LASER
- **Device Type**: SURGICA K 5
- **Catalog**: NA
- **Serial**: (*confidential*)
- **Lot**: NA
- **Other ID**: NA

**Reprocessed & Reused**: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1014092</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Jun-1998</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 06-JUL-1998: NEW LASER COHERENT HOLMIUM CORD. WHEN SURGEON STEPPED ON FOOT PEDAL, LASER CORD BROKE AND STARTED ON FIRE. HOLE MELTED IN PT DRAPE; ONLY ON CORD HOLDER OF DRAPE. FIRE ON CORD WAS PUT OUT AND REMOVED FROM THE FIELD. NO KINKS OR BENDS IN CORD WERE NOTED; NO INSTRUMENT WAS HOLDING THE CORD TO CAUSE BREAKAGE. NO INJURY TO PT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>COHERENT, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>3270 W. BAYSHORE RD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PALO ALTO, CA 94303</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>06-JUL-1998:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** INFRATOME 30 DEGREE
- **Device Type:** LASER CORD
- **Device Type:** 0624-084-30
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 021298
- **Other ID:** 2003-02-12

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1014146
Mfr Name: LUMENIS, INC.

Date Received: 07-Jul-1998

Event Date (B3): 08-May-1998
Report Date (B4): 09-Jun-1998
Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: HEALTH PROFESSIONAL
Event Location (F12): HOSPITAL
Report Source (G3): HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 10-JUL-1998: ARGON LASER HIGH TEMP CODE 239. CASE DELAYED APPROX 20 MINS WHILE MACHINE COOLED DOWN.

Concomitant Medical Products:

Mfr Name: COHERENT INC.
Address: 3270 WEST BAY SHORE RD.
PALO ALTO, CA 94303
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 10-JUL-1998:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** ARGON LASER
- **Device Type:** LASER
- **Device Type:** UPM ULTIMA 2000
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** CE 20927
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** *(b) (6)*
- **Address:** *(b) (6)*
- **Health Professional:** Yes
- **EMAIL:** *(b) (6)*
- **Phone:** *(b) (6)*
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1014863</th>
<th>Mfr Name: CANDELA CORP.</th>
<th>Date Received: 28-Oct-1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B5):</td>
<td></td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
<td>Event Location (F12): AMBULATORY SURGICAL FACILITY</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 03-NOV-1998: USER FIBER BROKE DURING PROCEDURE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: CANDELA CORP.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 530 BOSTON POST RD. WAYLAND, MA 01778 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>03-NOV-1998;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: RADIOGOLD RADIOPAQUE LASER FIBER
Device Type: LASER FIBER
Catalog: 8075-26-1300
Serial: (*confidential*)
Lot: NA
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]
Health Professional: Yes

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1017041
Mfr Name: UNKNOWN

Event Date (B3): 04-Jan-1999
Report Date (B4): 25-Aug-1999
Report Date (F8): 
Date Mfr Rec'd (G4): 

Event Report Type: INJURY
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Reporter Occupation (E3): 305 - PATIENT
Device Operator: INVALID DATA

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): NO INFORMATION
Report Source (G3): INVALID DATA

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): 

Manufacture Date (H4): 
Single Use (H5): 

Event Description (B5):
Volun 31-AUG-1999: HAD LASIK SURGERY WHICH LED TO EXTREME NIGHT VISION PROBLEMS AND THE INABILITY TO DRIVE A CAR AT NIGHT WITHOUT MEDICATION. (PILOCARPINE). THERE IS VERY BAD GHOSTING AND ESPECIALLY STARBURSTS IN ALL DIM LIGHT SITUATIONS. RPTR'S PRESCRIPTION WAS -3.5 AND -1.25 AND PUPIL SIZE IS ABOUT 7MM.

Concomitant Medical Products:

Mfr Name: UNK
Address: UNK
UNK, UNKNOWN

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
31-AUG-1999:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LASER
Device Type: LASER
Device Type: UNK
Catalog: UNK
Serial: (*confidential*)
Lot: UNK
Other ID: UNK

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] [b] [b] [b] [b]
Address: [b] [b] [b] [b] [b]
UNK

Health Professional: No

EMAIL: [b] [b] [b] [b]
Phone: [b] [b] [b] [b]
International: 
Fax: 

Occupation: 305 - PATIENT
Event Description (B5):
Volun 07-SEP-1999: RPTR HAS HAD POOR RESULTS WITH THESE SYSTEMS. WHEN SHE CONSULTED THE MFR, SHE WAS ADVISED TO INCREASE THE HEAT SETTING AND THE NUMBER OF PASSES PER APPLICATION, WELL BEYOND THE FDA APPROVED LIMIT. THE RECOMMENDATION WAS ALSO CLEARLY ABOVE THE RECOMMENDED SETTINGS IN THE OPERATOR'S MANUAL. THE RPTR IS CONCERNED THAT OTHERS MAY TAKE THIS ADVICE AND IT WILL RESULT IN AN INJURY. SHE WAS ALSO CONCERNED THAT THE CO WOULD EVEN MAKE SUCH A RECOMMENDATION.

Concomitant Medical Products:
NA

Mfr Name: ESC MEDICAL SYSTEMS, INC.
Address: 250 FIRST AVE.
          NEEDHAM, MA 02494
          UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
07-SEP-1999:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VASCULIGHT
Device Type: LASER VARICOSITY REMOVAL SYSTEM
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1017434
Mfr Name: UNKNOWN
Event Date (B3): 23-Apr-1999
Report Date (B4): 29-Oct-1999
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 305 - PATIENT
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y
Event Location (F12): UNKNOWN
Report Source (G3):

Product Code: (OP)-LASER, OPHTHALMIC (HQF)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 02-NOV-1999: REPORTER HAD LASIK SURGERY ON BOTH EYES AND VISION HAS DECREASED INSTEAD OF IMPROVING. VISION BEFORE WAS 20/50-2, AND NOW IS 20/100 WITH NO NIGHT VISION. THIS WAS ATTRIBUTED TO RETINOPATHY OF PREMATURITY PER PROCEDURE PERFORMING SURGEON. REPORTER HAD EVALUATION OF RETINA PRIOR TO AND AFTER PROCEDURE. HE WAS GIVEN THE "OK" TO GO AHEAD WITH THE PROCEDURE. REPORTER NOT SURE IF DEVICE MALFUNCTIONED OR IT WAS PROCEDURAL ERROR.

Concomitant Medical Products:
NA

Mfr Name: UNK
Address: UNK
UNK,
UNKNOWN

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-NOV-1999:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** LASIK EYE SURGERY SYSTEM
- **Device Type:** LASER REFRACTIVE EYE SURGERY SYSTEM
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:**  
- **Address:**  
- **Email:**  
- **Phone:**  
- **International:**  
- **Fax:**  
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
Voluntary Report No: MW1017495  Mfr Name: HGM, INC.

Event Date (B3): 27-Oct-1999  Event Report Type: MALFUNCTION
Report Date (B4): 03-Nov-1999  Event Outcome (B2):
Report Date (F8): 03-Nov-1999  Event Location (F12): HOSPITAL

Report Date (B4): 03-Nov-1999  Event Outcome (B2):

Date Mfr Rec'd (G4): 08-Nov-1999  Reporter Occupation (E3): 401 - BIOMEDICAL ENGINEER

Product Code: (HE)-FIBRINOGEN STANDARD (GFX)

Device Operator: OTHER  Report Source (G3):

Device Age (F9): Single Use (H5):
Expiration Date:  
Device Usage (H8):  

Event Description (B5):
Volun 10-NOV-1999: EQUIPMENT HAD BEEN AWAITING INSTALLATION BY HGM, SINCE EARLY SEPTEMBER 1999. THE CO WAS UNABLE TO COMPLETE THE INSTALL, "DUE TO PERSONNEL PROBLEMS". AFTER REPEATED REQUESTS WERE MADE A REP WAS DISPATCHED AND HE ATTEMPTED TO OPERATE THE LASER. THE UNIT'S CIRCUIT BREAKER TRIPPED AND WOULD NOT RESET. WHEN THE CASE WAS OPENED, NO OBVIOUS FAULT WAS SEEN SO POWER WAS RETURNED AND AN ARC WAS SEEN TO RISE FROM THE POWER SUPPLY, ACCOMPANIED BY A LOUD POP. A WIRE WAS FOUND TO HAVE INSULATION DAMAGE DUE TO CONTACT WITH A METAL CASE. THIS WAS REPAIRED, BUT THE SYSTEM STILL WOULD NOT WORK. THE HGM REP SAID THE PROBLEM WAS DUE TO SOME "LEAKY" CAPACITORS THAT "SHOULD NEVER HAVE BEEN IN THE PRODUCTION AREA, AS THEY WERE KNOWN TO BE BAD..." REPORTER IS STILL WAITING.

Concomitant Medical Products:

Mfr Name: HGM, INC.
Address: 3959 WEST 1820 SOUTH
SALT LAKE CITY, UT 84104
UNITED STATES

Device Available for Evaluation: R  Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11):
10-NOV-1999:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** HGM PCC-EDO 2.5W
- **Device Type:** LASER
- **Device Type:** PC-EDO 2.5W NON-SMART
- **Catalog:** OLS01B2B01D
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 401 - BIOMEDICAL ENGINEER

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1017497
Mfr Name: INDIGO MEDICAL, INC.

Event Date (B3): 26-Oct-1999
Report Date (B4): 04-Nov-1999
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3):

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 01-Mar-2004
Single Use (H5): Device Usage (H8):

Event Description (B5):
Volun 10-NOV-1999: PRODUCT PROBLEM OCCURRED DURING AN INDIGO LASER OF THE PROSTATE PROCEDURE. FIRST FIBER FAILURE. WARNING ON LASER SCREEN SHOWED BLACK BODY. ANOTHER FIBER WAS OPENED, IT FAILED ALSO. SECOND FIBER'S WARNING SHOWED FIBER FAULT.

Concomitant Medical Products:

Mfr Name: INDIGO MEDICAL, INC.
Address: 6465 CREEK RD.
CINCINNATI, OH 45242
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-NOV-1999:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** 1CM, TEMPERATURE-SENSING DIFFUSER-TIP
- **Device Type:** LASER FIBER
- **Device Type:** LF 001
- **Catalog:** LF 001
- **Serial:** (*confidential*)
- **Lot:** M4E08E
- **Other ID:** *

- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1018372</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>12-Jan-2000</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>25-Feb-2000</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 14-MAR-2000: DURING PROCEDURE IT WAS NOTED THAT THE TIP OF THE LASER FIBER WAS BROKEN.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>LASER SCOPE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>3052 ORCHARD DR. SAN JOSE, CA 95134 UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>14-MAR-2000:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASER SCOPE (LASER SENIC)
- **Device Type:** LASER TIP (CONE)
- **Device Type:** 5221
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 824610
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]

- **Health Professional:** Yes
- **Occupation:** 002 - NURSE

**EMAIL:** [Redacted]
**Phone:** [Redacted]
**International:** [Redacted]
**Fax:** [Redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1018478</th>
<th>Mfr Name:</th>
<th>VISX, INCORPORATED</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>14-Jul-98</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B4):</td>
<td>19-Mar-00</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Event Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>306 - PATIENT FAMILY MEMBER OR FRIEND</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 28-MAR-2000: LASIK VISION CORRECTION SURGERY. PT HEALTHY AND EYES HEALTHY. NO ASTIGMATISM (OR MINOR) AND MINIMAL MYOPIA. PT DID NOT NOTICE THE LASER BEING CALIBRATED PRIOR TO SURGERY. MAY NOT HAVE BEEN DONE. COMPUTER PRINT OUT SHOWS DISCREPANCY IN THE PULSES ACTUALLY DELIVERED VS HZ PER SECOND. BOTH EYES HAD NUMEROUS SUBCONJUNCTIVAL HEMORRHAGES WHICH MAY BE DUE TO ANESTHESIA AND MICROKERATOME. EYES PAINFUL, RED, TIRED. VISION IMBALANCE BETWEEN EYES IS NOW 3 DIOPTERS. INCREASED ASTIGMATISM. MUST WEAR GLASSES CONSTANTLY. CONTACT LENS WEAR IS POOR TO NOT POSSIBLE. HAVE FLOATERS IN EYES NOW - POSSIBLY SUCTION PRESSURE OF KERATOME RING. VISION IS MUCH WORSE SINCE SURGERY. PERMANENT TEMPORAL SCLERAL VEINS AND PINGUECULA.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>VISX, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>3400 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051 UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation: Y**

**Device Evaluated by Manufacturer (H3): No Answer**

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

28-MAR-2000:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VISX EXCIMERLASER STAR
- **Device Type:** LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Voluntary Report No:** MW1018563  
**Mfr Name:** UNKNOWN

**Event Date (B3):** 29-Jul-1999  
**Report Date (B4):** 31-Mar-2000  
**Report Date (F8):** 03-Apr-2000

**Event Report Type:** INJURY  
**Event Report Type:** INJURY

**Adverse Event (B1):** Y  
**Problem (B1):** N

**Event Location (F12):** UNKNOWN  
**Event Location (F12):** UNKNOWN

**Device Operator:** HEALTH PROFESSIONAL  
**Device Operator:** HEALTH PROFESSIONAL

**Event Description (B5):**  
Volun 06-APR-2000: LASIK EYE SURGERY ON BOTH EYES IN 1999, WHICH RESULTED IN PERMANENTLY BLURRED VISION NOT CORRECTABLE WITH GLASSES. DAMAGED EYES, DAMAGED LIFE.

**Concomitant Medical Products:**

**Mfr Name:** UNK  
**Address:** UNK  
UNK,  
UNKNOWN

**Device Available for Evaluation:** *  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 06-APR-2000:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASIK
- **Device Type:** LASER FOR LASIK EYE SURGERY
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **Email:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**

Health Professional: No

Occupation: 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3): 27-Sep-1999</th>
<th>Event Report Type: INJURY</th>
<th>Adverse Event (B1): Y</th>
<th>Problem (B1): N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 08-Apr-2000</td>
<td>Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE</td>
<td>Event Location (F12): UNKNOWN</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td>Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: VISX, INCORPORATED</td>
<td>Device Age (F9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 13-APR-2000: RPTR HAD LASIK EYE SURGERY. FOREIGN MATERIAL WAS DEPOSITED INTO EYE DURING THE SURGERY, WHICH RESULTED IN A MASSIVE INFLAMMATION AND SEVERE HYPEROPIC SHIFT BECAUSE ENZYMES FROM THE INFLAMMATION DIGESTED CORNEAL TISSUE. A SECOND PROCEDURE WAS DONE WITH THE VISX STAR S2 LASER, AND SIGNIFICANT IRREGULAR ASTIGMATISM WAS INDUCED BY THE LASER.

**Concomitant Medical Products:**

1999/10/01 AFFECTED EYE. 10/1999 TO 01/2000

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 13-APR-2000:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VISX
Device Type: LASER
Device Type: STAR S2
Catalog: UNK
Serial: (*confidential*)
Lot: UNK
Other ID: UNK

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [REDACTED]
Address: [REDACTED]

Health Professional: No

EMAIL: [REDACTED]
Phone: [REDACTED]
International: [REDACTED]
Fax: [REDACTED]

Occupation: 305 - PATIENT
Event Date (B3): 29-Oct-1999
Report Date (B4): 13-May-2000
Report Date (F8):
Date Mfr Rec'd (G4):

Voluntary Report No: MW1018894
Mfr Name: UNKNOWN

Event Report Type: INJURY
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE

Report Date (B4): 13-May-2000
Event Report Type: INJURY
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE

Event Description (B5):
Volun 19-MAY-2000: RPTR HAD LASIK EYE SURGERY TO CORRECT VISION. ALTHOUGH IT DID CORRECT VISION FOR SEEING LONG DISTANCES, IT LEFT RPTR WITH A DISABILITY WITH NIGHT DRIVING. ALL RPTR CAN SEE AT NIGHT IS A HAZING EFFECT WITH EVERY HEADLIGHT THEY LOOK AT. IT CAUSES RPTR TO NOT SEE ALL OF THE VEHICLES THEY NEED TO SEE, AND RPTR IS AT A POINT WHERE IT IS VERY DANGEROUS FOR THEM TO DRIVE AT NIGHT. EVEN WHEN RPTR GOES INTO DIFFERENT PLACES THE LIGHTING MAKES IT HARD FOR THEM TO FOCUS ON LOTS OF DIFFERENT OBJECTS. RPTR IS AT A POINT THAT THEY HAVE TOTAL NIGHT BLINDNESS.

Concomitant Medical Products:

Mfr Name: UNK
Address: UNK
UNK,
UNKNOWN

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 19-MAY-2000:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** UNK
- **Device Type:** LASER SURGERY DEVICE
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT

EMAIL: [redacted]

Phone: [redacted]

International: [redacted]

Fax: [redacted]
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1019084
Date Received: 07-Jun-2000

Mfr Name: LUMENIS, INC.
Event Date (B3): 12-May-2000
Report Date (B4): 23-May-2000
Report Date (F8): 
Date Mfr Rec'd (G4): 
Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: HEALTH PROFESSIONAL
Adverse Event (B1): Problem (B1): N
Event Location (F12): HOSPITAL
Report Source (G3): 
Report Date (F8): 

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8): 

Event Description (B5):
Volun 12-JUN-2000: LASER FAILURE RESULTING IN INABILITY TO TURN MACHINE ON. SURGEON UNABLE TO COMPLETE SURGERY CAUSING A 4 HR DELAY. VISUAL PROGNOSIS VERY UNCERTAIN AND GUARDED DUE TO DELAY DURING SURGERY.

Concomitant Medical Products:

Mfr Name: COHERENT, INC.
Address: 2400 CONDENSA ST.
SANTA CLARA, CA 95051
UNITED STATES

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-JUN-2000:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: COHERENT NOVUS 2000- ARGON UNIT
Device Type: LASER UNIT
Device Type: NOVUS 2000
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: BMET # CH 20216
Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:
Health Professional: Yes

EMAIL:
Phone: (b) (b)
International:
Fax:

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

| Event Date (B3) | 06-Jun-2000 |
| Event Report Type | * |
| Report Date (B4) | 08-Jun-2000 |
| Report Date (F8) | |
| Event Report Type | |
| Event Location (F12) | AMBULATORY SURGICAL FACILITY |
| Event Outcome (B2) | |
| Reporter Occupation (E3) | 002 - NURSE |
| Report Date (F8) | |
| Reporter Occupation (E3) | |
| Event Description (B5) | Volun 14-JUN-2000: TIP OF LASER FIBER BROKE OFF WHEN DOING A LASER TURBINOPLASTY. WHEN THE FIBER, WHICH WAS SECURED TO SUCTION TUBING WAS REMOVED FROM THE HOSE IT WAS NOTED TO HAVE THE TIP OF THE FIBER MISSING. THE LASER USED WAS A HOLMIUN. THE SETTINGS WERE 1.2 JOULES, ENERGY WAS 14, WATTS OF 16.8. THE TIP OF THE FIBER WAS NOT LOCATED. NO INJURIES REPORTED AT THIS TIME. |
| Concomitant Medical Products: | |
| Mfr Name: | CERAMOPTEC, INC. |
| Address: | 515 SHAKER RD. EAST LONGMEADOW, MA 01028 UNITED STATES |
| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | No Answer |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 14-JUN-2000: |

Date Last Updated: 11/2/2010 9:17 AM

Recd: 965 Page: 1,943
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** CERAMOPTEC
- **Device Type:** LASER FIBER SMA 400 UM BASE FIBER ASSY
- **Device Type:** HBFSF 363-403
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** A9-0291
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name:</th>
<th>NIDEK, INC.</th>
<th>Date Received</th>
<th>10-Jun-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Mar-1999</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>10-Jun-2000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 16-JUN-2000: POST LASIK EYE SURGERY PROBLEMS. PT'S VISION AT NIGHT AND IN ARTIFICIAL LIGHT SITUATIONS IS IMPAIRED. GHOSTING AND HALOS MAKE DRIVING VERY DIFFICULT. ARTIFICIAL LIGHTING IN INTERIOR SPACES CREATES SIMILAR PROBLEMS.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: NIDEK, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 47651 WESTINGHOUSE DR.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FREMONT, CA 94539</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16-JUN-2000:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** NYDAK LASER
- **Device Type:** LASER FOR CORRECTIVE EYE SURGERY
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>03-Jul-2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>02-Oct-2000</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 05-OCT-2000: PT WENT TO LOCAL "AESTHETIC LASER" CENTER FOR HAIR REMOVAL ON FACE. WAS TREATED WITH "YAG" LASER MANUFACTURED BY ALTUS CORP. TREATMENT ADMINISTERED BY NURSE AT CLINIC. ONE TREATMENT. SUFFERED INTENSE PAIN, BLISTERING, OPEN WOUNDS, PIGMENTATION ALTERATION, PERMANENT FACIAL SCARRING AND DISFIGUREMENT.

**Concomitant Medical Products:**

2000/07/03 INJURY EVENT MULTIPLE SUBSEQUENT TREATMENT FOR

**Mfr Name:** ALTUS MEDICAL CO.

**Address:**

821 COWAN RD.

BURLINGTON, CA 94010

UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

05-OCT-2000:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: YAG COOL GLIDE LASER
- Device Type: LASER
- Device Type: UNK
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: (b) (b)
- Address: (b) (b)
- Health Professional: No
- EMAIL: (b) (b)
- Phone: (b) (b)
- International: 
- Fax: 
- Occupation: 305 - PATIENT

Date Last Updated: 11/2/2010  9:17 AM Recd: 967 Page: 1,948
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1020177</th>
<th>Mfr Name:</th>
<th>CARDIOGENES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Sep-2000</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(CV)-SYSTEM, LASER, TRANSMYOCARDIAL REVASCULARIZATION (MNO)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 20-OCT-2000: LASER USED DURING HEART PROCEDURE. LASER FAILED TO FIRE. AFTER SEVERAL UNSUCCESSFUL ATTEMPTS, A LASER WAS BORROWED FROM ANOTHER HOSP. PROCEDURE WAS COMPLETED WITHOUT ANY APPARENT INJURY.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ECLIPSE SURGICAL TECH INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>1049 KIEL COURT</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SUNNYVALE, CA 94089</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>20-OCT-2000:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

Device Information:
- Brand: ECLIPSE
- Device Type: LASER
- Catalog: 20203
- Serial: (*confidential*)
- Lot: *
- Other ID: *
- Reprocessed & Reused: N/A

Reporter Information:
- Name: [Redacted]
- Address: [Redacted]
- Health Professional: Yes
- Occupation: 500 - RISK MANAGER

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1020621</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>CARDIOGENES</td>
</tr>
</tbody>
</table>

**Event Date (B3):** 07-Dec-2000  
**Report Date (B4):** 08-Dec-2000  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Event Location (F12):** HOSPITAL  
**Reporter Occupation (E3):** 500 - RISK MANAGER  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:** Single Use (H5):  
**Device Usage (H8):**  

**Event Description (B5):**  
Volun 20-DEC-2000: THE PT WAS UNDERGOING A TRANSMYOCARDIAL LASER REvascularization of ANTERIOLATERAL and INFERIOR LEFT VENTRICULAR WALL USING A HOLMIUM LAG LASER. THE SINGLE USE FIBER THAT WAS BEING USED BROKE. NO ONE WAS INJURED.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>ECLIPSE SURGICAL TECHNOLOGIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>1049 KIEL COURT</td>
</tr>
<tr>
<td></td>
<td>SUNNYVALE, CA 94089</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
20-DEC-2000:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SOLOGRIP III HANDPIECE DELIVERY SYSTEM
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: TA-03124-50
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [Redacted]
Address: [Redacted]
Health Professional: Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>30-Jul-1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>02-Feb-2001</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5): Volun 08-FEB-2001: RPTR HAD THE LASIX EYE SURGERY AND IT HAS CAUSED MAJOR VISION PROBLEMS. RPTR HAS WRINKLES IN CORNEA, DECENTRATION IN RIGHT EYE AND THE ABLATION ZONES ARE TOO SMALL IN COMPARISON TO PUPIL DIAMETER. THIS CAUSES GHOST IMAGES, HALOS AROUND LIGHTS AND A LOSS OF CONTRAST SENSITIVITY. FOR EXAMPLE, AT NIGHT TIME WHEN RPTR LOOKS AT A GREEN TRAFFIC LIGHT, THEY SEE TWO TO THREE OF THEM BECAUSE OF THE GHOSTING. RPTR'S DR IGNORED SITUATION.</td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>NOT SURE</td>
</tr>
<tr>
<td>Address:</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>08-FEB-2001:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASIK LASER DEVICE NOT SURE OF THE BRAND
- **Device Type:** LASER FOR EYE CORRECTION
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [redacted] [redacted]
- **Address:** [redacted] [redacted]
- **Email:** [redacted] [redacted]
- **Phone:** [redacted] [redacted]
- **International:** [redacted] [redacted]
- **Fax:** [redacted] [redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1021132</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>15-Dec-2000</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>22-Feb-2001</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 27-FEB-2001: SINCE THE LASER SURGERY, PT'S EYES ARE INFLAMED, RED, AND PAINFUL. PT CONTINUES TO TAPE MEDICATION SUCH AS ANTI-INFLAMMATORY DRUGS BUT IS EXPERIENCING NO RELIEF.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Mfr Name: | UNK |
| Address:  | UNK, UNKNOWN |
| Device Available for Evaluation: | * |
| Device Evaluated by Manufacturer (H3): | No Answer |
| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 27-FEB-2001: |

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASIK LASER
- **Device Type:** LASER
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
MW1021465
Mfr Name: VISX, INCORPORATED

Event Date (B3): 27-Jul-1999
Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Problem (B1): N

Report Date (B4): 26-Mar-2001
Reporter Occupation (E3): NI - NO INFORMATION

Device Operator: INVALID DATA

Event Location (F12): UNKNOWN
Report Source (G3): INVALID DATA

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 30-MAR-2001:

Additional Mfr Narrative (H10 & H11):

Volun 30-MAR-2001: PERMANENT DOUBLE/BLURRY VISION AS A RESULT OF LASER REFRACTIVE SURGERY. LASER USED = VISX. PROCEDURE - LASIK. VISION NOT CORRECTABLE WITH GLASSES OR CONTACTS.

Concomitant Medical Products:

Mfr Name: *
Address: *
*, UNKNOWN

Device Available for Evaluation: *

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 30-MAR-2001:

Additional Mfr Narrative (H10 & H11):

30-MAR-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VISX
Device Type: LASER SURGERY
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: *
Address: *

EMAIL: Phone: (*)
International:
Fax:

Health Professional: No Information

Occupation: NI - NO INFORMATION
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1021466  Mfr Name: VISX, INCORPORATED

Date Received: 27-Mar-2001

Event Date (B3): 25-Jan-2001  Event Report Type: INJURY
Report Date (B4): 21-Mar-2001  Adverse Event (B1): Y
Report Date (F8): Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Date Mfr Rec'd (G4): Reporter Occupation (E3): 305 - PATIENT
Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Volun 30-MAR-2001: LASIK SURGERY CAUSED ONGOING VISION PROBLEMS - GLARE, HALOS, VISUAL DISTORTIONS OF LIGHT IN DIM LIGHT. ONGOING BURNING OF EYES. ONGOING BLURRY VISION.

Concomitant Medical Products:

Mfr Name: *
Address: *
*, UNKNOWN

Device Available for Evaluation: *

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
30-MAR-2001:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VISX 2
- **Device Type:** LASER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1022032  Mfr Name: SPECTRANETICS CORP.

Event Date (B3): 25-May-2001  Event Report Type: DEATH
Report Date (B4): 30-May-2001  Event Outcome (B2): DEATH
Report Date (F8):              Reporter Occupation (E3): 001 - PHYSICIAN
Date Mfr Rec'd (G4):          Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):
Volun 01-JUN-2001: DEATH DUE TO IRREPARABLE DAMAGE TO MAJOR VESSELS CAUSED BY PROPER USE OF THE SPECTRANETICS LASER SHEATH FOR REMOVAL OF CHRONIC ICD LEAD.

Concomitant Medical Products:
SPECTRANETICS LLD (LEAD LOCKING DEVICE).

Mfr Name: SPECTRANETICS
Address: 96 TALAMINE COURT
          COLORADO SPRINGS, CO 80907
          UNITED STATES

Device Available for Evaluation: N  Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
01-JUN-2001:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SPECTRANETICS
- **Device Type:** LASER SHEATH FOR CHRONIC LEAD REMOVAL
- **Catalog:** 500-013
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** 16F SIZE

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1022200</th>
<th>Mfr Name:</th>
<th>SHARPLAN LASERS, INC.</th>
<th>Date Received: 18-Jun-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>14-Jun-2001</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>100 - OTHER HEALTH CARE PROFESSIONAL</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Concomitant Medical Products:

Mfr Name: SHARPLAN LASERS
Address: 250 FIRST AVE, STE 300
ALLENDALE, NJ 07401
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-JUN-2001:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: LASER
- Device Type: LASER
- Device Type: 1041
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Health Professional: Yes
- Occupation: 100 - OTHER HEALTH CARE PROFESSIONAL

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax: [redacted]
<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1022230</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>06-Oct-1999</td>
<td>Event Report Type:</td>
<td>OTHER</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Operator: Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Event Description (B5):</td>
<td>Volun 27-JUN-2001: HAD CO2 LASER DONE ON FACE. NOW HAVE PERMANENT LINES AROUND MOUTH AND DOWN CHIN. ALSO HAVE PIGMENTATION CHANGES.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mfr Name:</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Address:</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>UNKNOWN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Available for Evaluation:</td>
<td>Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>27-JUN-2001:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: CO2 LASER 200 MM HP SILK TOUCH MODE
Device Type: LASER
Device Type:
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (b)

Health Professional: Yes

EMAIL: (b) (6)
Phone: (b) (6)
International:
Fax:

Occupation: 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1022456
Mfr Name: LASERSCOPE

Event Date (B3): 01-Oct-1999
Event Report Type: MALFUNCTION

Report Date (B4): 24-Jul-2001
Report Date (F8):

Date Mfr Rec'd (G4):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:

Event Description (B5):
Volun 26-JUL-2001: RPTR WAS TOLD DEVICE WAS FDA APPROVED FOR HAIR REMOVAL AND VEIN REMOVAL BUT RPTR DOES NOT BELIEVE THAT IS THE CASE. RPTR HAD A PROBLEM WITH AIMING BEAM NOT FUNCTIONING. WAS TOLD DEVICE COULD BE USED IN THAT CONDITION. DEVICE IS MARKETED FOR UNAPPROVED FDA INDICATION. THE SCREEN SAYS THAT DEVICE NEEDS SVC BUT MFR HAS NOT SERVICED DEVICE AS INDICATED. RPTR HAS HAD ONGOING PROBLEMS.

Concomitant Medical Products:

Mfr Name: LASERSCOPE
Address: *
  *
  *
  UNKNOWN

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
26-JUL-2001:
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASERSCOPE LYRA
- **Device Type:** LASER
- **Device Type:** UNK
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **EMAIL:**
- **Phone:** [b] (b)
- **International:**
- **Fax:**
- **Health Professional:** Yes
- **Occupation:** 001 - PHYSICIAN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1023189</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>13-Dec-1999</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>01-Jan-2001</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>INVALID DATA</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 25-OCT-2001: DR DID LASER RESURFACING ON RPTR'S FACE, MOSTLY TO REMOVE CREVICES BELOW LIPS LEFT AFTER SHE HAD REMOVED A SCAR FROM THERE MONTHS BEFORE. SHE MELTED GORTEX IMPLANT PREVIOUSLY INSTALLED AT LIP LINE AND GAVE RPTR SECOND AND THIRD DEGREE BURNS OVER FACE AND EYES. HAD DEBRIDING TREATMENTS FOR A MONTH AND HOSPITALIZATION. RPTR STILL HAS EYE AND NERVE DAMAGE, STILL UNABLE TO BE FITTED FOR GLASSES ALMOST 2 YEARS LATER. SURGERY DONE AT LASER CTR.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td>OUTPATIENT TREATMENT FAC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>INVALID DATA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Last Updated:</td>
<td>11/2/2010 9:17 AM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recd: 978</td>
<td>Page: 1,969</td>
<td>Date Last Updated: 11/2/2010 9:17 AM</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** UNK
- **Device Type:** LASER FOR SKIN RESURFACING
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

REPORter INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** OTHER

Date Last Updated: 11/2/2010 9:17 AM

Recd: 978

Page: 1,970

Date Last Updated: 11/2/2010 9:17 AM
<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1023262</th>
<th>Mfr Name:</th>
<th>VISX, INCORPORATED</th>
<th>Date Received</th>
<th>01-Nov-2001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Feb-1999</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): 305 - PATIENT</td>
<td></td>
<td>Event Location (F12):</td>
<td>UNKNOWN</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 07-NOV-2001: RPTR HAD LASIK PERFORMED ON BOTH EYES. SINCE THIS EVENT RPTR HAS DEVELOPED FLOATER IN FIELD OF VISION. THESE ARE VERY ANNOYING. RPTR WORKS ON A COMPUTER UNDER FLOURESCENT LIGHT ALL DAY. THE FLOATERS ARE WORSE DURING THIS TIME.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNKNOWN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 07-NOV-2001:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VISX
- **Device Type:** LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1023957</th>
<th>Mfr Name:</th>
<th>SPECTRANETICS CORP.</th>
<th>Date Received</th>
<th>01-Feb-2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>22-Jan-2002</td>
<td>Event Report Type:</td>
<td>DEATH</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>31-Jan-2002</td>
<td>Event Outcome (B2):</td>
<td>DEATH</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Volun 04-FEB-2002: PT UNDERGOING REMOVAL OF PACEMAKER LEADS. SPECTRANETICS LASER WITH SPECTRANETICS SHEATH USED TO REMOVE CALCIFIED LEAD. MULTIPLE BURNS ALONG THE INNER WALL OF THE SUPERIOR VENA CAVA. PT TAKEN TO THE OR FOR EMERGENT REPAIR. PERMANENT NEUROLOGIC DAMAGE AND DEATH DUE TO CLAMP TIME FOR EXTENSIVE INJURY REPAIR. AUTOPSY DECLINED. LACERATION WERE FOUND DURING SUERGERY OF THE INNOMINATE VEIN AND SUPERIOR. VENA CAVA LEADS WERE EPICARDIAL LEAD AND INTERNAL CARDIOVERSION DEFIBRILLATOR.

Concomitant Medical Products:
SPECTRANETICS SHEATH.

Mfr Name: SPECTRANETICS CO.
Address: 96 TALAMINE COURT
COLORADO SPRINGS, CO 80907
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
04-FEB-2002:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand**: SPECTRANETICS CO LASER
- **Device Type**: LASER, CVX 300
- **Catalog**: 0
- **Serial**: (“confidential”)
- **Lot**: 0
- **Other ID**: 0000140350 TDI

**Reprocessed & Reused**: N/A

REPORTER INFORMATION:
- **Name**: [redacted]
- **Address**: [redacted]
- **Email**: [redacted]
- **Phone**: [redacted]
- **International**: [redacted]
- **Fax**: [redacted]
- **Health Professional**: Yes
- **Occupation**: 500 - RISK MANAGER

Date Last Updated: 11/2/2010 9:17 AM

Recd: 980  Page: 1,974  Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1023977
Mfr Name: E S C SHARPLAN

**Event Date (B3):** 01-Jan-2000
**Report Date (B4):** 04-Feb-2002
**Report Date (F8):**
**Date Mfr Rec’d (G4):**
**Event Report Type:** MALFUNCTION
**Event Outcome (B2):**
**Reporter Occupation (E3):** 001 - PHYSICIAN
**Device Operator:** HEALTH PROFESSIONAL
**Adverse Event (B1):** Problem (B1): Y
**Event Location (F12):** OTHER
**Report Source (G3):**

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Age (F9):**
**Expiration Date:**
**Device Usage (H8):**
**Manufacture Date (H4):**

**Event Description (B5):**
Volun 05-FEB-2002: IN 1999, MFR ADVERTISED AND MARKETED THIS LASER MACHINE FOR HAIR REMOVAL, TATTOO REMOVAL AND THE TREATMENT OF LEG VEINS. THE MACHINE DOES NOT WORK IN ANY OF THESE AREAS. RPTR HAD ONE PT THEY TREATED FOR 1 1/2 YRS FOR HAIR REMOVAL. THE TREATMENTS DID NOT WORK. RPTR CONTACTED THE MFR WHICH TOLD RPTR THAT THE MACHINE WOULD NOT WORK ON THE THREE AREAS WITHOUT A 60,000 DOLLAR UPGRADE. THE MACHINE ALREADY COST RPTR ALMOST 140,000 DOLLARS. THE MACHINE WAS APPROVED BY FDA. ACCORDING TO RPTR, THE APPROVAL WAS BASED ON ITS SIMILARITY TO A PREVIOUS MODEL. THE APPROVAL WENT THROUGH IN 3 MOS HOWEVER IT TAKES A YEAR TO SEE THAT THE MACHINE WORKS OR NOT. THE COUNTRY IN WHICH RPTR LIVES APPRAISED THE MACHINE FOR 14,000 DOLLARS FOR TAX PURPOSES. RPTR DOES NOT UNDERSTAND HOW IT COULD DEPRECIATE THAT MUCH IN JUST 2 YEARS. RPTR NO LONGER USES THE MACHINE.

**Concomitant Medical Products:**

**Mfr Name:** ESC SHARPLAN
**Address:** 100 MORSE ST
NORWOOD, MA 02062
UNITED STATES

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**
05-FEB-2002:
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** MULTI LIGHT SYSTEM/PHOTODERM
- **Device Type:** LASER HAIR REMOVAL
- **Device Type:** SA2301001
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** MFG DATE 11/98

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 001 - PHYSICIAN
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1024294</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
<th>Date Received</th>
<th>08-Mar-2002</th>
</tr>
</thead>
</table>

**Event Date (B3):** 01-Mar-2001  
**Report Date (B4):** 08-Mar-2002  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** LAY USER/PATIENT  
**Event Location (F12):** UNKNOWN  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Reporter Occupation (E3):** OTHER  
**Report Source (G3):** LAY USER/PATIENT  
**Device Age (F9):**  
**Manufacture Date (H4):**  
**Expiration Date:**  
**Device Usage (H8):**  
**Event Description (B5):**  
Volun 14-MAR-2002: RPTR STATED THEY WENT TO PRIVATE MD'S OFFICE FOR LASER HAIR REMOVAL AND RPTR WAS BURNED ON THE NECK, THE UPPER LIP AND THE CHIN. RPTR STATED THEY USED HOME CARE PRODUCTS ON THE BURNS IN ADDITION TO A SAMPLE LOTION FROM THE PHYSICIAN'S OFFICE. IN ADDITION, RPTR SAW A DERMATOLOGIST WHO GAVE THEM PRESCRIPTION CREAMS TO USE ON THE BURNS. RPTR STATED THAT THE PRESCRIPTION CREAMS WORK VERY SLOW AND THEY HAVE BEEN LEFT WITH SCARS. RPTR STATED THAT THEIR PRIVATE MD'S OFFICE INFORMED THEM THAT THE DEVICE WAS MALFUNCTIONING PRIOR TO THIS EVENT BUT THEY STILL CONTINUED TO USE IT.  
**Concomitant Medical Products:**  
NA  
**Mfr Name:** COHERENT  
**Address:** *PLEASANTON, CA *UNITED STATES  
**Device Available for Evaluation:** *  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
14-MAR-2002:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** LIGHT SHEAR ET LASER SUSYTEM DIODE
- **Device Type:** LASER HAIR REMOVAL DEVICE
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N/A

### REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Health Professional:** No
- **Occupation:** OTHER
**MAUDE EVENT REPORT (FOI)**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No: MW1025413</th>
<th>Mfr Name: UNKNOWN</th>
<th>Date Received: 24-Jun-2002</th>
</tr>
</thead>
</table>

**Event Date (B3):** 28-May-2002  
**Report Date (B4):** 24-Jun-2002  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Reporter Occupation (E3):** 305 - PATIENT  
**Device Operator:** LAY USER/PATIENT  

**Product Code:** (SU)-EPILATOR, HIGH FREQUENCY, NEEDLE-TYPE (KCW)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):**  

**Event Description (B5):**  
*Vol 01-JUL-2002: IMMEDIATELY AFTER RECEIVING LASER HAIR REMOVAL TREATMENT OF THEIR EYEBROW, THE RPTR'S LEFT EYE WAS EXTREMELY IRRITATED AND SENSITIVE TO LIGHT. A SEGMENTAL PARALYSIS OF LEFT PUPIL WAS NOTICEABLE. RPTR WAS SEEN WITHIN HRS OF THE LASER TREATMENT BY AN OPHTHALMOLOGIST. INFLAMMATION AND DISCOMFORT OF EYE OCCURRED. WITHIN 24-72 HRS AFTER PREDNISONE EYE DROPS THE SHAPE OF PUPIL CHANGED FROM OBLONG SHAPE TO A MORE ROUNDED SHAPE BUT IRRITATION, DISCOMFORT, SPASMS AND LIGHT SENSITIVITY REMAINED. THE LEFT PUPIL APPEARS TO BE STUCK IN ONE POSITION AND IS VERY SLUGGISH IN ITS REACTION TO LIGHT. BLURRED VISION HAS DEVELOPED IN THEIR LEFT EYE AND THE RPTR EXPERIENCES AND CONTINUES TO EXPERIENCE INCREASED IRRITATION AND EVEN PAIN IN THE LEFT EYE WITH READING AND WITH A CHANGE IN LIGHTING.*

**Concomitant Medical Products:**  

<table>
<thead>
<tr>
<th>Mfr Name: *</th>
<th>Address: *</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>*UNKNOWN</td>
<td></td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
01-JUL-2002:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: LIGHT SHEER LASER DIODE
- Device Type: LASER USED FOR PERMANENT HAIR REMOVAL
- Reprocessed & Reused: N/A

- Device Type: *
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1026695
Mfr Name: LASER PERIPHERALS, LLC.

Event Date (B3): 31-Oct-2002
Report Date (B4): 07-Nov-2002
Report Date (F8):

Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 100 - OTHER HEALTH CARE PROFESSIONAL
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): HOSPITAL
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 14-NOV-2002: DURING NASAL LASER SURGICAL PROCEDURE A SMALL FIRE OCCURRED ON THE SURGICAL FIELD BURNING A 1 INCH HOLE THROUGH THE DRAPE AND BATH BLANKET. IT WAS DETERMINED THAT THE LASER FIBER WAS ACCIDENTALLY CLAMPED RESULTING IN A CRACK IN THE FIBER WHICH CAUSED THE LIGHT ENERGY TO ESCAPE OUT THIS SITE. NO INJURY TO THE PT.

Concomitant Medical Products:

Mfr Name: LASER PERIPHERALS
Address: 1000 BOONE AVE NORTH STE 300
GOLDEN VALLEY, MN 55427
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 14-NOV-2002:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th><strong>Brand:</strong></th>
<th>BARE LASER FIBER</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Type:</strong></td>
<td>LASER FIBER</td>
</tr>
<tr>
<td><strong>Device Type:</strong></td>
<td>DBLF-60-1</td>
</tr>
<tr>
<td><strong>Catalog:</strong></td>
<td>*</td>
</tr>
<tr>
<td><strong>Serial:</strong></td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td><strong>Lot:</strong></td>
<td>LP-271</td>
</tr>
<tr>
<td><strong>Other ID:</strong></td>
<td>*</td>
</tr>
</tbody>
</table>

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th><strong>Name:</strong></th>
<th>(b) (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Address:</strong></td>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Health Professional:</strong></th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EMAIL:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(b) (b)</td>
</tr>
<tr>
<td><strong>International:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Fax:</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Occupation:** 100 - OTHER HEALTH CARE PROFESSIONAL
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1026853</th>
<th>Mfr Name:</th>
<th>NIDEK, INC.</th>
</tr>
</thead>
</table>

| Event Date (B3):       | 11-Dec-2001 |
| Report Date (B4):      | 25-Nov-2002 |
| Event Date (F8):       |             |
| Date Mfr Rec'd (G4):   |             |

| Event Report Type:     | INJURY      |
| Event Outcome (B2):    | REQUIRED INTERVENTION |
| Reporter Occupation (E3): | 305 - PATIENT |
| Device Operator:       | HEALTH PROFESSIONAL |

| Product Code:          | (OP)-EXCIMER LASER SYSTEM (LZS) |
| Device Age (F9):       |                                     |
| Expiration Date:       |                                     |

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vol 03-DEC-2002: MULTIPLE COMPLICATIONS AFTER LASIK SURGERY PERFORMED BY DR. AT MEDICAL CENTER COMPLICATIONS INCLUDE PERMANENT LOSS OF VISION IN BOTH EYES.</td>
</tr>
</tbody>
</table>

| Concomitant Medical Products: | |

| Mfr Name: | UNK |
| Address:  | UNK |
|           | UNK, |
|           | UNKNOWN |

| Device Available for Evaluation: | * |
| Device Evaluated by Manufacturer (H3): | No Answer |

| Remedial Action (H7): | |
| Correction/Removal No (H9): | |
| Additional Mfr Narrative (H10 & H11): | 03-DEC-2002: |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** NIDEK EC 5000
- **Device Type:** LASER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [b] (b)
- **Address:** [b] (b)
- **Health Professional:** No
- **EMAIL:** [b] (b)
- **Phone:** [b] (b)
- **International:**
- **Fax:**
- **Occupation:** 305 - PATIENT
MAUDE EVENT REPORT (FOI)

**SORTED BY**

Date Received

<table>
<thead>
<tr>
<th>Report No: MW1027193</th>
<th>Mfr Name: UNKNOWN</th>
</tr>
</thead>
</table>

**Event Date (B3):** 16-Apr-2002
**Report Date (B4):** 06-Jan-2003
**Report Date (F8):**
**Date Mfr Rec'd (G4):**

**Event Description (B5):**
Volun 13-JAN-2003: IN 2001, PT HAD SUCCESSFUL ELECTIVE SURGERY TO REPLACE THE LENS IN EACH EYE TO CORRECT SEVERE FARSIGHTEDNESS AND ASTIGMATISM. A YEAR LATER A CLOUDINESS DEVELOPED IN LEFT EYE, WHICH DR DESCRIBED AS A SECONDARY MEMBRANE AND SAID IT WAS VERY COMMON. A PROCEDURE USING THE YAG LASER WAS PERFORMED AND PT HAD A FOLLOW-UP VISIT ON 5/17/2002. WHILE ON VACATION IN LATE 7/2002, PT NOTICED A DISCOLORATION ON THE OUTER RIM OF LEFT EYE. DR DIAGNOSED THIS AS PTERYGium. WHEN PT ASKED IF THIS WAS CAUSED BY THE YAG LASER, HE ASSURED PT THAT IT WAS DUE TO SUN EXPOSURE. PT DOESN'T PLAY GOLF OR TENNIS, AND DOESN'T SUN BATHE OR WORK OUTDOORS, SO PT'S NOT EXPOSED TO THE SUN ENOUGH TO CAUSE THIS KIND OF DAMAGE. PT ALSO WEARS SUNGLASSES WHEN THEY ARE IN THE SUN. PT WOULD LIKE TO KNOW IF THERE ARE REPORTS OR RESEARCH ABOUT THE YAG LASER CAUSING A PTERYGium-LIKE GROWTH.

**Concomitant Medical Products:**

| Mfr Name: * |
| Address: * |
| UNKNOWN |

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
13-JAN-2003:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: YAG LASER
- Device Type: LASER FOR TREATMENT OF SECONDARY MEMBRANE FOLLOWING CATARACT
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- EMAIL: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]
- Health Professional: No
- Occupation: 305 - PATIENT

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1027265  Mfr Name: BOSTON SCIENTIFIC CORP.

Event Date (B3): 10-Jan-2002  Event Report Type: INJURY  Adverse Event (B1): Problem (B1): Y
Report Date (B4): 14-Jan-2003  Event Outcome (B2): REQUIRED INTERVENTION  Event Location (F12): HOSPITAL
Report Date (F8):  
Date Mfr Rec'd (G4):  
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  Report Source (G3):
Device Operator: HEALTH PROFESSIONAL

Device Age (F9):  
Expiration Date:  
Device Usage (H8):  

Event Description (B5):
Volun 22-JAN-2003: LASER BEAM FIBER SNAPPED AND BURNED MD'S FIRST FINGER ON R HAND.

Concomitant Medical Products:

Mfr Name: *
Address: *

Device Available for Evaluation: N

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):  
Additional Mfr Narrative (H10 & H11): 22-JAN-2003:

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** BOSTON SCIENTIFIC LUMENIS FIBER DEVICE
- **Device Type:** LASER FIBER
- **Device Type:** SLIM LINE 365
- **Catalog:** 840-842
- **Serial:** (*confidential*)
- **Lot:** 020602
- **Other ID:** *

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- **Name:** *
- **Address:** [b] (6) [b] (6) [b] (6) [b] (6)
- **Health Professional:** Yes

**EMAIL:**
- **Phone:** [b] (6) [b] (6) [b] (6) [b] (6)
- **International:**
- **Fax:**

**Occupation:** 500 - RISK MANAGER
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Date Received</th>
<th>02-Nov-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary Report No:</td>
<td>MW1028222</td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>CONVERGENT LASER TECHNOLOGIES</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>04-Apr-2003</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Date (B3):</td>
<td>04-Apr-2003</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>14-Apr-2003</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>14-Apr-2003</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 28-APR-2003: LASER FIBER PIECE BROKE OFF IN LEG AND KIDNEY PELVIS - REMOVED BY M.D - SURGEON.</td>
</tr>
</tbody>
</table>

#### Concomitant Medical Products:

- NA

#### Mfr Name: CONVERGENT LASER TECHNOLOGIES

#### Address:

- 900 ALICE STREET
- OAKLAND, CA 94607
- UNITED STATES

#### Device Available for Evaluation: Y

#### Device Evaluated by Manufacturer (H3): No Answer

#### Remedial Action (H7):

#### Correction/Removal No (H9):

#### Additional Mfr Narrative (H10 & H11):

- 28-APR-2003:

---
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASER FIBER
- **Device Type:** LASER FIBER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 20212304-01
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** *(b)(6)*
- **Address:** *(b)(6)*
- **Health Professional:** Yes
- **EMAIL:** *(b)(6)*
- **Phone:** *(b)(6)*
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1029227
Mfr Name: LUMENIS, INC.

Event Date (B3): 03-Dec-2002
Report Date (B4): 24-Jul-2003
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Occupation (E3): 305 - PATIENT
Device Operator: OTHER

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): PUBLIC VENUE
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:

Device Operator: Date Mfr Rec'd (G4):

Device Evaluated by Manufacturer (H3):
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-AUG-2003:

Event Description (B5):
Volun 13-AUG-2003: TREATMENT WITH LIGHT SHEER DIODE WAS ON FACE AND NECK. RIGHT AFTER TREATMENT FULL WAS BRIGHT RED, SKIN WAS WAVY AS IF INJURED FROM BELOW EPIDERMIS. AS TIME PASSED 2-4 MONTHS, WATCHED AS FACIAL SKIN COLLAPSED AND THINNED. APPEARS AS IF LASER OVER HEATED COLLAGEN WHICH COLLAPSED. PT'S FACE WAS ROUND AND PT HAD EXCELLENT THICK, STRONG SKIN. PT'S CHECKS ONCE SO FAT PEOPLE WOULD SQUEEZE THEM ARE NOW SO TIGHT AND THIN THAT PT IS UNABLE TO PINCH ANY SKIN UP. TEMPLES NOW INDENT-CHECK FAT GONE- JAW AND CHIN MISSHAPED. FACE IS SORE ALL THE TIME - FEELS VERY TIGHT.

Concomitant Medical Products:

Mfr Name: LUMENIS
Address: 1249 QUARRY LANE
SUITE 100
PLEASTON, CA 94566
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3):
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
13-AUG-2003:

Date Last Updated: 11/2/2010  9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer, or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LIGHT SHEER DIODE
- **Device Type:** LASER HAIR REMOVAL
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**

**Occupation:** 305 - PATIENT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1029810
Mfr Name: ETHICON ENDO-SURGERY, INC.

Event Date (B3): 07-Oct-2002
Report Date (B4): 26-Sep-2003
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: INJURY
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE

Mfr Name: ETHICON ENDO-SURGERY, INC.
Address:

Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): Y

Event Location (F12): UNKNOWN
Report Source (G3):

Device Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4): Expiration Date:

Device Usage (H8):

Event Description (B5):
Volun 30-OCT-2003: PT WAS TREATED FOR BENIGN PROSTATE HYPERPLASIA USING LASER ABLATION. PT WAS CONCERNED ABOUT ERECTILE DYSFUNCTION AS A SIDE EFFECT OF THE PROCEDURE BUT WAS ASSURED BY THE SURGEON THAT LASER ABLATION WOULD NOT DAMAGE THE NERVES OR BLOOD VESSELS THAT AFFECTED THEIR ERECTILE FUNCTION. UNFORTUNATELY, PT DID SUFFER ERECTILE DYSFUNCTION AND CAN NOW ONLY SUSTAIN A PARTIAL ERECTION THAT IS INSUFFICIENT FOR SEXUAL INTERCOURSE. PT WAS SUBSEQUENTLY INFORMED BY DR. THAT THIS HAD NEVER BEFORE HAPPENED WITH AN OF HIS PREVIOUS PTS. THE OTHER UROLOGIST WHO TREATED PT HOWEVER, DID INFORM PT THAT THEY HAD APPARENTLY SUFFERED NERVE DAMAGE AS A RESULT OF THE PROCEDURE.

Concomitant Medical Products:

Mfr Name: ETHICON ENDO-SURGERY, INC., A DIVISION OF JOHNSON & JOHNSON
Address: *

*, UNKNOWN

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
30-OCT-2003:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand:</th>
<th>INDIGO LASER SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type:</td>
<td>LASER ABLATION</td>
</tr>
<tr>
<td>Device Type:</td>
<td>NA</td>
</tr>
<tr>
<td>Catalog:</td>
<td>NA</td>
</tr>
<tr>
<td>Serial:</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot:</td>
<td>NA</td>
</tr>
<tr>
<td>Other ID:</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N/A

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>(b) (b)</td>
</tr>
</tbody>
</table>

Health Professional: No

<table>
<thead>
<tr>
<th>EMAIL:</th>
<th>(b) (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>(b) (6)</td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

Occupation: 305 - PATIENT
**MAUDE EVENT REPORT (FOI)**

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1030639</th>
<th>Mfr Name:</th>
<th>SHARPLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received:</td>
<td>16-Dec-2003</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 16-Dec-2003</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 500 - RISK MANAGER</td>
<td>Event Location (F12): HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 09-JAN-2004: CO2 LASER WAS TESTED WITH NO PROBLEMS. LASER WAS TURNED OFF. WHEN TURNED BACK ON TO BEGIN PROCEDURE THERE WAS A MESSAGE DISPLAYED "DEFICIENT PRESSURE--CALL SERVICE." THE LASER WAS TURNED OFF AND ON AGAIN WITH THE SAME MESSAGE DISPLAYED. REP NOTIFIED.

**Concomitant Medical Products:**

**Mfr Name:** SHARPLAN

**Address:** *

*, UNKNOW

**Device Available for Evaluation:** *

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

09-JAN-2004:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: SHARPLAN LASER
Device Type: LASER
Device Type: 1075
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: MARIE NASSEFF
Address: 1690 UNIV AVE #480
ST. PAUL, MN 55104

Health Professional: Yes

EMAIL: 
Phone: (651) 232-5113
International: 
Fax: 

Occupation: 500 - RISK MANAGER
## MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### Event Details

<table>
<thead>
<tr>
<th><strong>Voluntary Report No:</strong></th>
<th>MW1030899</th>
<th><strong>Mfr Name:</strong></th>
<th>RADIANCY (ISRAEL) LTD.</th>
<th><strong>Date Received:</strong></th>
<th>22-Jan-2004</th>
</tr>
</thead>
</table>

**Event Date (B3):** 16-Dec-2003  
**Report Date (B4):** 22-Jan-2004  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)  
**Adverse Event (B1):** Problem (B1): Y  
**Event Location (F12):** UNKNOWN  
**Report Source (G3):** OTHER

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** OTHER  
**Reporter Occupation (E3):** 305 - PATIENT  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:**  
**Device Usage (H8):**

### Event Description (B5):

Volun 02-FEB-2004: REPORTER WAS BURNED BY A LASER REP. DURING A TRAINING PROCEDURE. THEY WERE TREATING SUN SPOTS. REPORTER RECEIVED 1ST AND 2ND DEGREE BURNS AS A RESULT OF THIS PROCEDURE. THE REP AND RADIANCY HAVE DECIDED AFTER THE FACT THAT THE LASER WAS SET AT A SETTING THAT WAS TOO HIGH FOR REPORTER'S SKIN TYPE. THE LASER REP, WAS FOLLOWING A CHART THAT WAS SET BY RADIANCY DURING THE PROCEDURE.

### Concomitant Medical Products:

- **Mfr Name:** RADIANCY  
- **Address:** *  
  *  
  *, ISRAEL

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**  
02-FEB-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>RADIANCY SKINSTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>*</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1032436</th>
<th>Mfr Name:</th>
<th>VISX, INCORPORATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>31-Mar-2004</td>
<td>Event Report Type:</td>
<td>*</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Jun-2004</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>INVALID DATA</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 26-AUG-2004: PT HAD LASIX SURGERY 3 MOS AGO AND HAS HAD VERY SLOW RECOVERY PERIOD. WAS BLINDED FOR DAYS AND STILL HAS DRY EYE, GLARE, HALOS, SHADOWING, GHOSTING. WAS NOT INFORMED THE THE CORNEAL NERVE WAS CUT DURING SURGERY AND THAT THERE WAS RISK OF NO NERVE REGENERATION. PT FEELS FDA SHOULD DO MORE TO INFORM PUBLIC OF RISKS. THE SURGEON HAS NOW REFUSED TO SEE PT ANY MORE.

**Concomitant Medical Products:**

- **Mfr Name:** VISX
- **Address:** *
- **Device Available for Evaluation:** *
- **Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

26-AUG-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** VISX STAR IV
- **Device Type:** LASER MACHINE
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1032760</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>02-Jul-2004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>18-Jul-2004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 15-OCT-2004: THIS DOES NOT WORK JUST BOGUS LIGHTS AND TAKING USER'S MONEY.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>IMAGES OF FORT WORTH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UNKNOWN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>15-OCT-2004:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASER TEK 5000
- **Device Type:** LASER HAIR THERAPY
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1032803</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
<th>Date Received</th>
<th>22-Jul-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>23-Jun-2004</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>Omitted</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Problem (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>OTHER</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Device Operator:</td>
<td>OTHER</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Volun 20-OCT-2004: HOMIUM LASER FIBER (200) - NOTED SMOKE COMING OUT OF FIBER UP BY MACHINE WHILE PROCEDURE GOING ON. PROCEDURE STOPPED. FIBER REMOVED. NO APPARENT INJURY TO PT.

Concomitant Medical Products:

Mfr Name: LUMINIS LASER
Address: *
*,
*,
UNKNOWN

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): |
Additional Mfr Narrative (H10 & H11): |
20-OCT-2004:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** HOMIUM
- **Device Type:** LASER FIBER (200)
- **Device Type:** 804-850
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes

**Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1034405

Mfr Name: UNKNOWN

Event Date (B3): 01-Jan-2005
Report Date (B4): 25-Jan-2005
Report Date (F8): 
Date Mfr Rec'd (G4): 

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 305 - PATIENT
Device Operator: INVALID DATA

Adverse Event (B1): Y
Problem (B1): N
Event Location (F12): UNKNOWN
Report Source (G3): INVALID DATA

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): 
Expiration Date: 
Device Usage (H8): 

Event Description (B5):
Volun 28-JAN-2005: BURNING BY LASER CAUSING SKIN BRUISING AND RASHES.

Concomitant Medical Products:

Mfr Name: *
Address: *
*, UNKNOWN

Device Available for Evaluation: *

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
28-JAN-2005:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: *
Device Type: LASER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: (b) (6)
Address: (b) (6)

Email: (b) (6)
Phone: (b) (6)
International: 
Fax: 

Health Professional: No

Occupation: 305 - PATIENT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1034504</th>
<th>Mfr Name: UNKNOWN</th>
</tr>
</thead>
</table>

**Event Date (B3):** 15-May-2003  
**Report Date (B4):** 28-Jan-2005  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  

**Event Report Type:** INJURY  
**Event Outcome (B2):** DISABILITY OR PERMANENT DAMAGE  
**Reporter Occupation (E3):** 305 - PATIENT  
**Device Operator:** HEALTH PROFESSIONAL  
**Adverse Event (B1):** Y  
**Problem (B1):** N  
**Event Location (F12):** UNKNOWN  
**Report Source (G3):**  

**Product Code:** (OP)-EXCIMER LASER SYSTEM (LZS)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Usage (H8):**  

**Event Description (B5):**  
Volun 08-FEB-2005: SEVERE AND DEBILIATING NIGHT VISION COMPLICATIONS FROM LASIK SURGERY, DAYTIME CONTRAST COMPLICATIONS AS WELL.  

**Concomitant Medical Products:**  
- **Mfr Name:** *  
- **Address:** *  
- **UNKNOWN**  

**Device Available for Evaluation:** *  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 08-FEB-2005:  

Recd: 997  
Page: 2,007  
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### DEVICE INFORMATION:

- **Brand:** LASIK
- **Device Type:** LASER VISION CORRECTION
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

### Reprocessed & Reused: N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name</th>
<th>[b] (b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Health Professional</td>
<td>No</td>
</tr>
<tr>
<td>Occupation</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>EMAIL:</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>Phone:</td>
<td>[b] (b)</td>
</tr>
<tr>
<td>International</td>
<td></td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
</tbody>
</table>

Date Last Updated: 11/2/2010 9:17 AM
### Event Description (B5):

Volun 11-FEB-2005: PT RECEIVED A LASER TREATMENT FOR HAIR REMOVAL FROM UPPER LIP AREA WHICH HAD ONLY FINE HAIRS- AND CHIN. IN THE ENSUING 4 MONTHS, IN THE UPPER LIP AREA, PT HAS HYPOPIGMENTATION AND MANY, MANY "WRINKLES" WHICH BEGAN APPEARING 3 WEEKS AFTER THE TREATMENT AND HAS CONTINUED UNTIL NOW. THEY WERE NOT THERE PRIOR TO THE PROCEDURE. THIS IS VERIFIED BY CLOSE FRIENDS AND SPOUSE. PT HAD NO WRINKLES ON THEIR FACE AT ALL LAST FALL. PT ALSO HAS A SLIGHTLY DIFFERENT SENSATION IN THAT AREA. MORE LINES ARE APPEARING EACH DAY. THE CENTER REFUSES TO TAKE ANY RESPONSIBILITY OR GIVE ANY ANSWERS TO WHAT IS HAPPENING. THE PROCEDURE WAS EXPLAINED TO PT BUT NONE OF THESE SIDE EFFECTS WERE INCLUDED AND PT SIGNED A CONSENT FORM THAT THEY LATER READ IN FULL AND HYPOPIGMENTATION AND SKIN TEXTURE CHANGES ARE INCLUDED BUT NOT ELABORATED ON IN THE CONSENT FORM OR BY THE TECHNICIAN. PT SPOKE TO DR, WHO HAS A CHAIN OF THESE LASER CENTERS, BUT HE REFUSES ANY RESPONSIBILITY AND ONLY OWNED UP TO THE HYPOPIGMENTATION BECAUSE IT WAS SO OBVIOUS. HE SAYS THE WRINKLES WERE NOT CAUSED BY HE LASER. PT BELIEVES THIS LASER TREATMENT FOR HAIR REMOVAL IS DANGEROUS. PT IS AFRAID OF WHAT ELSE MAY HAPPEN TO UPPER LIP AREA NOW. PT ASKS IF CANCER IS A POSSIBILITY.

### Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNK</td>
<td>UNK, UNK, UNKNOWN</td>
</tr>
</tbody>
</table>

### Device Available for Evaluation: *

### Device Evaluated by Manufacturer (H3): No Answer

### Remedial Action (H7):

### Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
11-FEB-2005:

DEVICE INFORMATION:

- **Brand:** UNK
- **Device Type:** LASER-GENTLELASE/COOLGLIDE/GENTLE YAG
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]

- **Health Professional:** No
- **Occupation:** 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1034826</th>
<th>Mfr Name:</th>
<th>BOSTON SCIENTIFIC CORP.</th>
<th>Report Date (B4):</th>
<th>04-Mar-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>04-Mar-2005</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>04-Mar-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td>Single Use (H5):</td>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Volun 11-MAR-2005: DURING A CYSTO LASER VAPORIZATION OF A BLADDER STONE THE LASER FIBER FRACTURED AT THE POINT OF ATTACHMENT TO THE HOLMIUM LASER UNIT. THE FIBER WAS BEING ACTIVATED BY THE UROLOGIST AND THE FIBER FRACTURED CAUSING THE FIBER TO BREAK OFF AND CAUSE A BURN MARK ON THE LASER, RN'S WARMUP JACKET AND SCRUP TOP. THERE WAS NO INJURY TO THE PT, OTHER STAFF OR EQUIPMENT.

Concomitant Medical Products:

- Mfr Name: BOSTON SCIENTIFIC
- Address: *
  NATICK, MA 01760
  UNITED STATES
- Device Available for Evaluation: *
- Device Evaluated by Manufacturer (H3): No Answer
- Remedial Action (H7): 
- Correction/Removal No (H9): 
- Additional Mfr Narrative (H10 & H11): 11-MAR-2005:
CDRH
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** SLIM LINE 1000
- **Device Type:** LASER HOLMIUM FIBER
- **Catalog:** SLIM LINE 1000
- **Serial:** (*confidential*)
- **Lot:** 112002
- **Other ID:** UNK

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)

Health Professional: No Information

EMAIL: (b) (6)

Phone: (b) (6)

International: Fax:

Occupation: 002 - NURSE

Date Last Updated: 11/2/2010 9:17 AM
Page: 2,012
### MAUDE EVENT REPORT (FOI)

#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1035546</th>
<th>Mfr Name:</th>
<th>UNKNOWN</th>
</tr>
</thead>
</table>

**Date Received**

**Event Date (B3):** 08-Apr-2005

**Report Date (B4):** 23-May-2005

**Report Date (F8):**

**Date Mfr Rec'd (G4):**

**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

**Device Operator:**

**Event Report Type:** OTHER

**Event Outcome (B2):** OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

**Report Location (F12):**

**Reporter Occupation (E3):**

**Device Usage (H8):**

**Event Description (B5):**

Volun 02-AUG-2006: A LIGHTSHEER DIODE LASER WAS USED ON MY UPPER LIP AREA FOR HAIR REMOVAL. IT CAUSED SKIN DISCOLORATION - LIGHTENING IN SOME AREAS.

**Concomitant Medical Products:**

**Mfr Name:** LASER SPA

**Address:**

STATEN ISLAND, NY *

UNITED STATES

**Device Available for Evaluation:**

Y

**Device Evaluated by Manufacturer (H3):**

No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

02-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** DIODE
- **Device Type:** LASER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *
- **Reprocessed & Reused:** Y

**REPORTER INFORMATION:**

- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** (*)
- **International:**
- **Fax:**
- **Health Professional:** No
- **Occupation:** 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1035557</th>
<th>Mfr Name:</th>
<th>LUMENIS, INC.</th>
<th>Date Received</th>
<th>26-May-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>20-May-2005</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Volun 23-AUG-2006: DURING URETEROSCOPY, PIECE OF LASER FIBER TIP BROKE OFF DURING USE IN RENAL PELVIS, UNABLE TO BE RETRIEVED. DR NOTIFIED THE PATIENT, WILL MEDICATE WITH LASIX AND HAVE PATIENT STRAIN URINE. MAY REQUIRE ADDITIONAL SURGICAL INTERVENTION IF PATIENT DOES NOT PASS SPONTANEOUSLY.

**Concomitant Medical Products:**

- **Mfr Name:** LUMENIS
- **Address:**
  - *
  - *
  - UNKNOWN

**Device Available for Evaluation:** Y
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
23-AUG-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: LUMINIS
Device Type: LASER PROBE
Device Type: 200
Catalog: *
Serial: (*confidential*)
Lot: 26671104
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

EMAIL:  
Phone: (*)
International:  
Fax:  

Occupation: 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1036114
Mfr Name: LASERSCOPE

Event Date (B3): 22-Jul-2005
Report Date (B4): 22-Jul-2005
Date Mfr Rec'd (G4):

Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)

Adverse Event (B1): Problem (B1): Y

Report Date (B4): 22-Jul-2005

Event Location (F12): HOSPITAL

Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 01-May-2007
Single Use (H5):
Device Usage (H8):

Event Description (B5):
Volun 16-AUG-2006: DURING CYSTOSCOPIC PHOTOSELECTIVE VAPORIZATION OF PROSTATE PROCEDURE, LASER FIBER DEVELOPED CRACK APPROXIMATELY 12MM FROM LASER TIP DURING OPERATIVE PROCEDURE. FIBER REMOVED AND REPLACED WITH NEW FIBER. BECAUSE OF SIMILAR PROBLEMS WITH LASER FIBERS -7/2005 - FIBER FLASHED OFF WITH RESULT OF TIP APPROXIAMTELY 11MM DISCHARGED FROM FIBER WITH RESULTANT NEED TO RETRIEVE FIBER TIP FROM BLADDER-. SEVERAL FIBERS HAVE BEEN RETURNED TO COMPANY FOR TIP DISLODGMENT OF LASER FIBER.

Concomitant Medical Products:

Mfr Name: LASERSCOPE
Address: 3070 ORCHARD DRIVE
SAN JOSE, CA 95134
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: GREENLIGHT OV ADDSTAT
- **Device Type**: LASER FIBER
- **Device Type**: 0010-2080
- **Catalog**: *
- **Serial**: (*confidential*)
- **Lot**: 10-2080-518A-1093
- **Other ID**: *

**Reprocessed & Reused**: N
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1036407</th>
<th>Mfr Name:</th>
<th>ACMI CORPORATION</th>
<th>Date Received: 25-Aug-2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>12-Aug-2005</td>
<td>Event Report Type:</td>
<td>OTHER</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>24-Aug-2005</td>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 21-AUG-2006: DURING PROCEDURE USING HOLMIUM LASER, THE LASER FIBER BROKE INSIDE THE SCOPE. BROKEN PIECE RETRIEVED WITHOUT ISSUE.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>ACMI (DORNIER MED TECH)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>SOUTHBOROUGH, MA 01772 UNITED STATES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>21-AUG-2006:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** DORNIER
- **Device Type:** LASER FIBER (REUSABLE)
- **Device Type:** HF0600RSSM-5
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** *

**Reprocessed & Reused:** N

REPORTER INFORMATION:

**Name:** [redacted]

**Address:** [redacted]

**Health Professional:** Yes

**EMAIL:** [redacted]

**Phone:** [redacted]

**International:** [redacted]

**Fax:**

**Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1036569  Mfr Name: CANDELA LASER CORP.

Event Date (B3): 31-Aug-2005
Report Date (B4): 07-Sep-2005
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: OTHER
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): UNKNOWN
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 18-AUG-2006: CANDELA LASER FAULTED WITH BEAM SHUTTER MALFUNCTION. THE LASER "TEST FIRE" WAS OPERATIONAL. THE BEAM SHUTTER MALFUNCTION OCCURRED @ START OF PROCEDURE.

Concomitant Medical Products:

Mfr Name: CANDELA LASER CORP.
Address: 530 BOSTON POST RD.
         WAYLAND, MA 01778
         UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: CANDELA PULSE DYE
- Device Type: LASER
- Device Type: SCLERO PLUS
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [Redacted]
- Address: [Redacted]
- Health Professional: Yes
- EMAIL: [Redacted]
- Phone: [Redacted]
- International: [Redacted]
- Fax: [Redacted]
- Occupation: 002 - NURSE
Event Description (B5):
Volun 16-AUG-2006: THE PATIENT WAS UNDERGOING A LASER ABLATION OF THE PROSTATE. THE SURGEON WAS USING THE HOLMIUM LASER UNIT WHEN HE FELT A SHARP PAIN IN HIS RIGHT HAND. WHEN HE REMOVED HIS GLOVE HE NOTICED TWO SMALL BURNS, ONE ON HIS MIDDLE FINGER AND ONE ON HIS INDEX FINGER. THE DISPOSABLE LASER FIBER HAD BECOME STRIPPED AND BROKEN OFF AT THE SITE WHERE IT EXITS THE CONNECTOR. THE FIBER IS CONNECTED TO THE UNIT VIA AN OBLONG SHAPED RUBBER CONNECTOR. THE SURGEON WAS HOLDING THE CONNECTOR IN HIS RIGHT HAND (AS HE HAS ALWAYS DONE) TO DIRECT THE LASER BEAM. HE WAS TREATED IN EMERGENCY DEPARTMENT. THE BURNS WERE SMALL AND NOT FELT TO BE SERIOUS. TO DATE NO SERIOUS SEQUELAE HAVE DEVELOPED THAT REPORTER IS AWARE OF. THE PATIENT WAS NOT HARMED IN ANY WAY. IT IS FELT THAT THE RISK OF SERIOUS INJURY EXISTS IF THIS MALFUNCTION WAS TO RECUR. THE LASER UNIT IS A RENTAL UNIT. THEY ALSO SUPPLY THE DISPOSABLE LASER FIBER. THE LASER FIBER IS DISTRIBUTED TO FORTEC MEDICAL INC. VIA BOSTON SCIENTIFIC ADDRESSES UNKNOWN. THE FIBER IS MANUFACTURED BY LUMENIS IN ISRAEL. NO ADDRESS IS AVAILABLE TO REPORT.

Concomitant Medical Products:

Mfr Name: LUMENIS DISTRIBUTED VIA FORTEC MEDICAL INC.
Address: 101 WILLMAN RD.
STRESTBORO, OH 44241
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

16-AUG-2006:

DEVICE INFORMATION:

- **Brand:** DUO TONE SITE LITE
- **Device Type:** LASER FIBER
- **Device Type:** M006840840F
- **Catalog:** 840-846
- **Serial:** (*confidential*)
- **Lot:** 32490805
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** MGR.
- **Address:**
- **Health Professional:** Yes

EMAIL: [Redacted]
Phone: [Redacted]
International: [Redacted]
Fax: [Redacted]

Occupation: 500 - RISK MANAGER
## MAUDE EVENT REPORT (FOI)

### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1037099</th>
<th>Mfr Name:</th>
<th>SYNECTICS MEDICAL, INC.</th>
<th>Date Received:</th>
<th>04-Nov-2005</th>
</tr>
</thead>
</table>

**Event Date (B3):** 09-Feb-2005  
**Report Date (B4):** 03-Nov-2005  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:**  
**Device Operator:** OTHER  

**Event Description (B5):**  
Volun 15-AUG-2006: NURSE SEVERLY BURNED LOWER PART OF MY FACE CAUSING SCARS AND NERVE DAMAGE. TOLD IT WAS SAFE FOR AFRO AMERICANS.

**Concomitant Medical Products:**

- **Mfr Name:** SYNERON MEDICAL LTD.  
- **Address:** *

- **Device Available for Evaluation:** *  
- **Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 15-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** AORORA
- **Device Type:** LASER HAIR REMOVAL
- **Device Type:** DS/HR
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MW1037100</td>
<td>SYNECTICS MEDICAL, INC.</td>
<td>10-Jul-2004</td>
<td>03-Nov-2005</td>
<td>INJURY</td>
<td>REQUIRED INTERVENTION</td>
<td>Y</td>
<td>Y</td>
<td>UNKNOWN</td>
<td>OTHER</td>
</tr>
</tbody>
</table>

Report Date (F8):

Date Mfr Rec'd (G4):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Operator:

Other

Event Description (B5):

Volun 15-AUG-2006: NURSE SEVERELY BURNED MAJORITY OF MY FACE WITH AURORA LASER MACHINE CAUSING PERMANENT SCARS TOLD LASER SAFE FOR AFRO AMERICANS.

Concomitant Medical Products:

Mfr Name: SYNERON MEDICAL LTD.

Address: *

*, DE *

UNITED STATES

Device Available for Evaluation:

*

Device Evaluated by Manufacturer (H3):

No Answer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

15-AUG-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** AURORA
- **Device Type:** LASER HAIR REMOVAL
- **Device Type:** DS/HR
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: **N**
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1037101 Mfr Name: SYNECTICS MEDICAL, INC.

Event Date (B3): 07-Feb-2005 Event Report Type: INJURY Adverse Event (B1): Y Problem (B1): Y

Event Date (B4): 03-Nov-2005 Event Outcome (B2): REQUIRED INTERVENTION

Report Date (F8): Event Location (F12): UNKNOWN

Date Mfr Rec'd (G4): Reporter Occupation (E3): 600 - ATTORNEY Report Source (G3):

Device Operator: OTHER

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Age (F9): Manufacture Date (H4):

Expiration Date: Single Use (H5):

Device Usage (H8):

Event Description (B5):
Volun 15-AUG-2006: NURSE SEVERELY BURNED LOWER FACE WITH LASER MACHINE CAUSING SCARS TOLD LASER WAS SAFE FOR AFRO AMERICANS.

Concomitant Medical Products:

Mfr Name: SYNERON MEDICAL LTD.
Address: *
*, DE *
UNITED STATES

Device Available for Evaluation: *

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
15-AUG-2006:

Date Last Updated: 11/2/2010 9:17 AM

Recd: 1,008 Page: 2,029
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** AURORA
- **Device Type:** LASER HAIR REMOVAL
- **Device Type:** DS/HR
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N
Voluntary Report No: MW1037851  Mfr Name: VISX, INCORPORATED

Event Date (B3): 23-Jun-2004  Event Report Type: INJURY
Report Date (B4): 26-Jan-2006  Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8):  
Date Mfr Rec’d (G4):  
Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Volun 09-FEB-2006: PT HAD LASIK SURGERY TO BOTH EYES TO CORRECT TO 20/20. THE FOLLOWING MORNING AT POST OP RIGHT EYE CORRECTED TO 20/20-3 BUT PT COULD NOT SEE OUT OF LEFT EYE. THEY GAVE PT A PINHOLE AND THEY COULD SEE 20/40-2. HOWEVER, PT WAS SHOCKED BECAUSE PT COULD NOT SEE HANDS, FINGERNAILS, THE TECHNICIAN'S FACE AND LEFT EYE HAD GHOSTING, GLARE AND STAR BURSTING EVEN THOUGH PT COULD SEE THRU THE PINHOLE. PT TOLD THE DR THAT THEY COULD NOT MAKE OUT HANDS, THEY WERE FUZZY, AND HOW COULD THEY HAVE LOST SO MUCH CLOSE UP VISION. PT CAN UNDERSTAND NEEDING READING GLASSES, BUT WHEN YOU CANNOT SEE WHERE YOUR FINGERNAILS START OR STOP OR SEE THE LINES ON YOUR HANDS, IT WAS AS IF PT'S CLOSE UP VISION HAD BEEN BLINDED. THE DR SAID IT WOULD TAKE SOME TIME TO STABILIZE AND THAT PT WOULD PROBABLY NEED AN ENHANCEMENT IN A FEW MONTHS AND TO GIVE IT TIME. THE DR ALSO MUMBLED SOMETHING ABOUT WEAK EYE MUSCLES. EVEN THOUGH PT TOLD BOTH THE TECHNICIAN AND DR ABOUT PROBLEMS WITH LEFT EYE, NOTHING WAS WRITTEN IN CHART ABOUT THESE PROBLEMS, AND PT DID NOT KNOW UNTIL THEY REQUESTED COPIES OF MEDICAL RECORDS. THREE DAYS LATER VISION STARTED FLUCTUATING AND HAS BEEN FLUCTUATING FOR OVER 1 YEAR AND ABOUT 2 MONTHS LATER EXTREME EYE DRYNESS AND BURNING STARTED AND PT HAS BEEN IN PAIN SINCE THEN. PT BELIEVES PRODUCT USE ERROR TO BE THAT THEY WERE NOT A GOOD CANDIDATE FOR LASIK AND THE DR DID NOT TELL THEM. PT NO LONGER DRIVES, HAD TO QUIT JOB AND UNABLE TO DO HOUSEWORK DUE TO CONSTANT PAIN AND BURING IN EYES AND HAVE HAD LOSS OF VISION.

Concomitant Medical Products:

Mfr Name: VISX, INC
Address: *  
SANTA CLARA, CA *
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Date Last Updated: 11/2/2010  9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
09-FEB-2006:

DEVICE INFORMATION:

- **Brand:** STAR S4 ACTIVE TRAK ECIMER LASER SYSTEM AND WAVESCAN
- **Device Type:** LASER SYSTEM
- **Device Type:** NOT KNOWN
- **Catalog:** NOT KNOWN
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

#### SORTED BY

Date Received: 02-Nov-2010

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name:</th>
<th>TRIMEDYNE, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW1038377</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>12-Dec-2005</th>
<th>Event Report Type:</th>
<th>MALFUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>23-Mar-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>INVALID DATA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>01-Aug-2009</td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 12-APR-2006: 1230 LASER PROBE BROKE OUTSIDE OF PT WHILE TIP WAS INSERTED IN PT. TIP WAS REMOVED, SAFELY CLEAN BREAK MATERIAL. PT ASLEEP BY ANESTHESIA.

**Concomitant Medical Products:**

NA

**Mfr Name:** FLEX MAX  
**Address:** 15091 BAKE PARKWAY  
IRVINE, CA 92618  
UNITED STATES

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 12-APR-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

<table>
<thead>
<tr>
<th>Brand</th>
<th>TRIMEDYNE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER PROBE</td>
</tr>
<tr>
<td>Device Type</td>
<td>REF B365</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>50527</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1038608  Mfr Name: LASERSCOPE

Event Date (B3): 30-Dec-2005  Report Date (B4): 12-Apr-2006
Report Date (F8):  
Date Mfr Rec’d (G4):  

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Event Description (B5):
Volun 28-APR-2006: I HAD LASER HAIR REMOVAL DONE ONCE FOR MY UNIBROW BY MD. I USED THE TOPICAL ANESTHETIC NUMBING CREAM AND SHAVED THE AREA TO BE LASERED. AFTER THE PROCEDURE I GOT REALLY SWOLLEN AND THE SKIN GOT HARDENED AND I GOT BLISTED REALLY BAD. DR GAVE ME "FOUGERA BETAMETHASONE VALERATE CREAM" TO APPLY THERE AND SAID WHEN I GET HOME TO PUT ICE ON IT. WHEN I GOT HOME I NOTICED A LOT OF FLUIDS COMING FROM THE AREA. THIS WAS DONE ON A SATURDAY AND DR WOULDN'T BE BACK IN UNTIL THE MONDAY COMING UP, AS HE SAID TO CALL HIM IF I HAVE ANY PROBLEMS SO HE COULD GIVE ME SOMETHING. I THEN CALLED DR TO PRESCRIBE ME SOMETHING BUT WOULDN'T UNLESS I CAME IN BUT AT THIS POINT I WAS REALLY LOOKING BAD AND COULDN'T LEAVE MY HOME. I HAD MAJOR SWELLING FOR MORE THAN A WEEK. DR SAID HE WOULD HAVE GIVEN ME ANTIBIOTICS FOR INFECTION BUT THE DAMAGE WAS ALREADY DONE AND I SCABBED AND GOT SCARRING. I HAD A FOLLOW UP TO SEE DR FOR HELP AND HE SAID THAT HE WOULDN'T PAY FOR ME SEEKING HELP TO HELP FIGURE AND FIX THE PROBLEM ASIDE FROM DOING LASER WITH THE "AREA" TO GET RID OF THE COLOR OF THE SCAR BUT AT THIS POINT I DIDN'T WANT ANYMORE LASER DONE BY HIM. I FEEL I GOT BURNED BY THE LASER OR DR PERFORMED THE PROCEDURE WRONG. HE USED THE LYRA LASERSCOPE I BELIEVE. I HAVE COSMETIC DAMAGE ON MY FACE AND I AM REALLY UNHAPPY AND HURT. KEEP IN MIND THAT I ONLY HAD THE LASER HAIR REMOVAL DONE ONCE.

Concomitant Medical Products:
NA

Mfr Name: LYRA
Address: *
*,
UNKNOWN

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
28-APR-2006:

DEVICE INFORMATION:

- **Brand:** LASERSCOPE
- **Device Type:** LASER
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: **N**

REPORTER INFORMATION:

- **Health Professional:** No
- **Occupation:** 305 - PATIENT

DATE LAST UPDATED: 11/2/2010 9:17 AM

Recd: 1,011  Page: 2,036  Date Last Updated: 11/2/2010 9:17 AM
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personal, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1038624</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>IRIDEX CORPORATION</td>
</tr>
</tbody>
</table>

| Event Date (B3):      | 06-Mar-2006 |
| Report Date (B4):     | 07-Apr-2006 |
| Report Date (F8):     |             |
| Date Mfr Rec'd (G4):  |             |

| Event Report Type:    | MALFUNCTION |
| Event Outcome (B2):   | OTHER SERIOUS (IMPORTANT MEDICAL EVENTS) |
| Reporter Occupation (E3): | 002 - NURSE |
| Device Operator:      | HEALTH PROFESSIONAL |

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volon 04-MAY-2006: LASER HEADPIECE WOULD NOT WORK DURING SURGICAL CASE. IT WOULD NOT FIRE AT ALL. DELAY IN SURGERY TO GET ANOTHER HEADPIECE.</td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**

**Mfr Name:** IRIDEX

**Address:**

* MOUNTAIN VIEW, CA 94043
* UNITED STATES

**Device Available for Evaluation:** R

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

04-MAY-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HEADPIECE LASER
- **Device Type:** LASER HEADPIECE USED IN RETINAL SURGERY
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Voluntary Report No:** MW1038731  |  **Mfr Name:** LASERSCOPE

**Event Date (B3):** 10-Apr-2006  |  **Event Report Type:** MALFUNCTION
**Report Date (B4):** 10-Apr-2006  |  **Adverse Event (B1):** Problem (B1): Y
**Report Date (F8):**  |  **Event Outcome (B2):**
**Date Mfr Rec’d (G4):**  |  **Reporter Occupation (E3):** 500 - RISK MANAGER
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
**Device Operator:** HEALTH PROFESSIONAL
**Device Age (F9):** Manufacture Date (H4):
**Expiration Date:** 01-May-2006  |  **Device Evaluated by Manufacturer (H3):** No Answer
**Device Usage (H8):**

**Event Description (B5):**
Volun 08-MAY-2006: LASERSCOPE PVP PASER FIBERS X3, TIP FELL OFF OF 3 FIBERS. ALL PIECES REMOVED FROM BLADDER PER PHYSICIAN. EVACUATOR USED TO EVACUATE BLADDER.

**Concomitant Medical Products:**

**Mfr Name:** FORTEC MEDICAL
**Address:** *
  *
  *
  UNKNOWN

**Device Available for Evaluation:** N

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):**
08-MAY-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** LASERSCOPE, PVP LASER, FIBERS X3
- **Device Type:** LASERSCOPE GREEN LIGHT PV-ADDSTAT FIBERS
- **Serial:** (*confidential*)
- **Lot:** 10-2080-520A-2
- **Other ID:** REF: 0010-2080

**Reprocessed & Reused:** N

**REPORter INFORMATION:**

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER

**EMAIL:** [redacted]
**Phone:** [redacted]
**International:** [redacted]
**Fax:** [redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1038771</th>
<th>Mfr Name:</th>
<th>BOSTON SCIENTIFIC CORP.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 27-Mar-2006  
**Event Report Type:** MALFUNCTION  
**Event Outcome (B2):**  
**Report Date (F8):** 27-Mar-2006  
**Report Location (F12):** HOSPITAL  
**Date Mfr Rec'd (G4):**  
**Product Code:** (GU)-DISLODGER, STONE, BASKET, URETERAL, METAL (FFL)  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:** 01-Jul-2009  
**Single Use (H5):**  
**Device Usage (H8):**  

**Event Description (B5):**
Volun 11-MAY-2006: MD REQUESTED SPECIFIC BASKET FOR STONE EXTRACTION. UPON USING "SEGURA BASKET," WIRES OF BASKET BROKEN. ANOTHER TYPE OF BASKET WAS USED.

**Concomitant Medical Products:**

**Mfr Name:** BOSTON SCIENTIFIC CORP  
**Address:** ONE BOSTON SCIENTIFIC PLACE  
NATICK, MA 01760  
UNITED STATES

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**
**Correction/Removal No (H9):**
**Additional Mfr Narrative (H10 & H11):** 11-MAY-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** SECURA DRETLER BASKET
- **Device Type:** LASER BASKET, 4 WIRE
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** 7845178
- **Other ID:** REF#320-104
- **Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** *
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No: MW1038936</th>
<th>Mfr Name: UNKNOWN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 15-Mar-2006</td>
<td>Event Report Type: INJURY</td>
</tr>
<tr>
<td>Report Date (B4): 29-Apr-2006</td>
<td>Event Outcome (B2): REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 19-MAY-2006: PT REC'D LASER HAIR REMOVAL TREATMENT OF FACE -UPPER LIP, CHIN, SIDEURNS- FOR A TOTAL OF 4 SESSIONS THROUGH 2005. IN 03/05, PT SAW HYPERTRICHOSIS OF FACIAL HAIR -THROAT CLOSE OF CHIN, SIDEURNS, AND JAW LINE- CLOSE TO WHERE LASER HAD BEEN ADMINISTERED.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: *</td>
<td>Address: *</td>
</tr>
<tr>
<td></td>
<td>*</td>
</tr>
<tr>
<td>Device Available for Evaluation: N</td>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td>Correction/Removal No (H9):</td>
</tr>
</tbody>
</table>
| Additional Mfr Narrative (H10 & H11): | 19-MAY-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand**: ALEXANDRITE
- **Device Type**: LASER
- **Device Type**: *
- **Catalog**: *
- **Serial**: (*confidential*)
- **Lot**: *
- **Other ID**: *

**Reprocessed & Reused**: N
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1039403
Mfr Name: DORNIER MEDTECH AMERICA, INC.

Event Date (B3): 16-May-2006
Report Date (B4): 30-May-2006
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: MALFUNCTION
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (B4): 30-May-2006
Event Location (F12): HOSPITAL

Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): Manufacture Date (H4):
Expiration Date: 01-Mar-2009
Device Usage (H8):

Event Description (B5):
Volun 16-JUN-2006: PT ADMITTED DUE TO LEFT RENAL CALCULI SCHEDULED TO HAVE LEFT RETROGRADE PYELOGRAM LEFT FLEXIBLE URETEROSCOPY LASER LITHOTRISPY. PLACEMENT OF LEFT URETERAL STENT. DURING CASE A LOUD POP WAS HEARD, FIBER OFF STERILE FIELD AND LASER WAS INACTIVATED AND FIBER REMOVED. FIBER HAD BROKEN.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC
Address: ROBERTS BLVD
KENNEDAW, GA 30144
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-JUN-2006:
Device Information:

Brand: DORNIER MEDTECH LASER GMBIT
Device Type: LASER FIBER WIRES

Catalog: CE0123
Serial: (*confidential*)
Lot: B1106-035
Other ID: REF#HF0400RGSM

Reprocessed & Reused: N

Reporter Information:

Name: (b) (6)
Address: (b) (b)

Health Professional: Yes

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1039430  Mfr Name: DORNIER MEDTECH AMERICA, INC.

Date Received: 01-Jun-2006  Event Date (B3): 17-May-2006  Event Report Type: MALFUNCTION
Report Date (B4): 01-Jun-2006  Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Report Date (F8):  Report Date (F4): 01-Jun-2006  Event Location (F12): HOSPITAL
Date Mfr Rec'd (G4):  Adverse Event (B1): Problem (B1): Y
Voluntary Report No:  Report Source (G3): HEALTH PROFESSIONAL
MW1039430  Reporter Occupation (E3): 500 - RISK MANAGER
Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Age (F9): Manufacture Date (H4): Expiration Date: 31-Oct-2008
Single Use (H5):
Device Usage (H8):

Event Description (B5):
Volun 16-JUN-2006: PT ADMITTED FOR LEFT URETERAL STONE-PROCEDURE CYSTOSCOPY URETEROSCOPY - AND ATTEMPTED LASER LITHOTRIPSY OF KIDNEY STONE. DURING PROCEDURE THE LASER BECAME INEFFECTIVE AND IT WAS NOTED LASER FIBERS NOT WORKING. FIBERS REMOVED AND FOUND TO BE BROKEN. BROKEN FIBERS FOUND AND REMOVED. PROCEDURE ATTEMPTED X2 AFTER THAT WITH SAME RESULTS-FIBER BROKE. SOME DISCUSSION AS TO FIBERS BEING REFURBISHED. ONLY 20% OF STONE WAS FRAGMENTED USING LASER.

Concomitant Medical Products:

Mfr Name: DORNIER MEDTECH AMERICA, INC.
Address: 1155 ROBERTS BOULEVARD
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
16-JUN-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** DORNIER MEDTECH LASER, GMBIT
- **Device Type:** LASER FIBER WIRES
- **Catalog:** (*)confidential*)
- **Serial:** E4205-039
- **Lot:** E4205-039
- **Other ID:** REF. HF0200DSSM
- **Reprocessed & Reused:** N

REPORTER INFORMATION:
- **Name:** [Redacted]
- **Address:** [Redacted]
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1039989</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
<th>Date Received</th>
<th>09-Aug-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>27-Jun-2006</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>28-Jul-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
<td>Event Location (F12):</td>
<td>HOSPITAL</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 24-AUG-2006: PT GIVEN SPINAL ANESTHESIA AND POSITIONED ON TABLE. SCOPE INSERTED WHEN GREENLIGHT LASER MACHINE TURNED ON, PROBLEM 46 APPEARED ON SCREEN INDICATING INTERNAL POWER PROBLEM. PROCEDURE ABORTED. LASER SENT BACK TO MANUFACTURE FOR REPAIR. NO PT HARM.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>3070 ORCHARD DR</td>
</tr>
<tr>
<td></td>
<td>SANJOSE, CA 95134</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 24-AUG-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

<table>
<thead>
<tr>
<th>Brand</th>
<th>GREEN LIGHT LASER MACHINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>LASER</td>
</tr>
<tr>
<td>Device Type</td>
<td>0010-9230</td>
</tr>
<tr>
<td>Catalog</td>
<td>*</td>
</tr>
<tr>
<td>Serial</td>
<td>(<em>confidential</em>)</td>
</tr>
<tr>
<td>Lot</td>
<td>*</td>
</tr>
<tr>
<td>Other ID</td>
<td>*</td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

REPORTER INFORMATION:

| Name:          | [b] (6)                  |
| Address:       | [b] (6)                  |
| Health Professional: | Yes                  |
| EMAIL:         |                          |
| Phone:         | [b] (6)                  |
| International: |                          |
| Fax:           |                          |
| Occupation:    | 500 - RISK MANAGER       |

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1040285</th>
<th>Mfr Name:</th>
<th>LASERSCOPE</th>
</tr>
</thead>
</table>

**Event Date (B3):** 24-Jun-2006  
**Report Date (B4):** 28-Aug-2006  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Age (F9):**  
**Expiration Date:** 01-Apr-2007  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Report Date (B4):** 28-Aug-2006  
**Event Location (F12):** HOSPITAL  
**Event Description (B5):** Volun 11-SEP-2006: DURING USE OF THE LASERSCOPE GREENLIGHT PV FIBER, THE TIPS DETACHED ON 3 DIFFERENT FIBERS. LOT 10-2080-617N X 2; LOT 10-2070-626W X 1. THE TIPS WERE RETRIEVED FROM THE SURGICAL FIELD. THE PROCEDURE WAS COMPLETED WITH USE OF THE 4TH FIBER. THERE WAS NO INJURY TO THE PATIENT.  
**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Concomitant Medical Products:**  

**Mfr Name:** LASERSCOPE  
**Address:** SAN JOSE, CA  
**UNITED STATES**  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 11-SEP-2006:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

    Brand: GREENLIGHT PV  
    Device Type: LASER FIBER  
    Device Type: 0010-2880  
    Catalog: *  
    Serial: (*confidential*)  
    Lot: 10-2080-617N  
    Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

    Name: [redacted]  
    Address: [redacted]  
    Health Professional: Yes  
    EMAIL: [redacted]  
    Phone: [redacted]  
    International: [redacted]  
    Fax: [redacted]

    Occupation: 500 - RISK MANAGER

Date Last Updated: 11/2/2010 9:17 AM

MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Event Date (B3): 08-Sep-2006
Report Date (B4): 12-Sep-2006
Event Report Type: INJURY
Adverse Event (B1): Y
Problem (B1): Y
Event Date (B3): 08-Sep-2006
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Event Location (F12): HOSPITAL
Reporter Occupation (E3): 500 - RISK MANAGER
Event Report Type: INJURY
Device Operator: HEALTH PROFESSIONAL
Report Date (F8): 12-Sep-2006
Event Location (F12): HOSPITAL
Report Source (G3):

Event Description (B5):

Concomitant Medical Products:

Mfr Name: COHERENT MEDICAL GROUP
Address: *
* *
* UNKNOWN
Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
03-OCT-2006:

DEVICE INFORMATION:

Brand: LUMENIS
Device Type: LASER, OPHTHALMIC, DIODE
Device Type: NOVUS VERDI 18-217
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [D] [B] [6]
Address: [D] [B] [6]

Health Professional: Yes

EMAIL: [D] [B] [6]
Phone: [D] [B] [6]
International: Fax:

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

### MAUDE EVENT REPORT (FOI)

**SORTED BY**

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW1040616</th>
<th>Mfr Name:</th>
<th>CHIRON TECHNOLAS GMBH</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>31-May-2004</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>05-Oct-2006</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>600 - ATTORNEY</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>INVALID DATA</td>
</tr>
</tbody>
</table>

| Product Code: | (OP)-EXCIMER LASER SYSTEM (LZS) |
| Device Age (F9): |                         |
| Expiration Date: |                                |
| Device Usage (H8): |                               |

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volun 11-OCT-2006: WE ARE TRYING TO UNDERSTAND WHAT WENT WRONG WITH EYE SURGERY OF 14 PATIENTS. THESE SURGERIES WHERE DONE IN 2004. PATIENTS BEFORE THAT REVEAL NO PROBLEMS AND BECAME OK WITH TREATMENT AS EXPECTED. PATIENTS OF BECAME WORSE THAN WERE APPARENTLY BECAUSE THE HEAD OF THE LASER WAS NOT PROPERLY FUNCTIONING AND HAD SOME DISTURBS ON SURGERY. WE WOULD LIKE TO KNOW IF THERE ARE ANY SECURITY RULES FOR THIS PRODUCT AND ANY DEMANDS ON MAINTENANCE FOR IT THAT SHOULD HAVE BEEN OBSERVED.</td>
</tr>
</tbody>
</table>

| Concomitant Medical Products: |

| Mfr Name: | CHIRON TECHNOLAS |
| Address: | * |
|          | *, UNKNOWN |

| Device Available for Evaluation: | Y |
| Device Evaluated by Manufacturer (H3): | No Answer |

| Remedial Action (H7): |

| Correction/Removal No (H9): |

<table>
<thead>
<tr>
<th>Additional Mfr Narrative (H10 &amp; H11):</th>
</tr>
</thead>
<tbody>
<tr>
<td>11-OCT-2006:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** KERACOR 116
- **Device Type:** LASER EXCIM
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** No
- **Email:** (b) (6)
- **Phone:** (*)
- **International:**
- **Fax:**
- **Occupation:** 600 - ATTORNEY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>28-Sep-2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4): 12-Oct-2006</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Volun 17-OCT-2006: A MALE WITH METASTATIC COLON CANCER TO THE LUNG WAS ADMITTED WITH A BRONCHIAL LESION. DURING A BRONCHOSCOPY WITH YAG LASER PROCEDURE TO STOP WITH BLEEDING, THE SURGEON IMMEDIATELY NOTED THAT THE YAG LASER BEAM HAD CAUSED A BURN TO THE TUMOR AND SURROUNDING TISSUE. THE LASER FIBER TIP APPEARED DAMAGED UPON INSPECTION AFTER THE EVENT.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>2006/01/01 OLYMPUS BF TYPE 1T180 BRONCHOCOVIDESCOPE</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LASERSCOPE</td>
<td></td>
</tr>
<tr>
<td>Address: * SAN JOSE, CA 95134 UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: Y</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
</tr>
<tr>
<td>17-OCT-2006:</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ENDOSTAT
- **Device Type:** LASER FIBER FOR LASERSCOPE KTP/YAG LASER
- **Device Type:** *
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: Y
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1041216
Mfr Name: BIOLITEC, INC.

Event Date (B3): 17-Nov-2006
Report Date (B4): 29-Nov-2006
Report Date (F8):
Date Mfr Rec'd (G4):

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 002 - NURSE
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Problem (B1): Y
Event Location (F12): HOSPITAL
Report Source (G3):

Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):

Concomitant Medical Products:
NA

Mfr Name: BIOLITEC
Address: 515 SHAKER RD
          EAST LONG MEADOWS, MA 01028
          UNITED STATES

Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
04-DEC-2006:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: BIOLITEC SIDEFIBER ASSEMBLY 980MM DCDD
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: A06-0174-A
Other ID: REF# SE-980-DL

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Occupation: 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No</th>
<th>Mfr Name: LUMENIS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Nov-2006</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>27-Nov-2006</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 08-DEC-2006: DURING HOLMIUM LASER ABLATION OF PROSTATE, THE TIPS OF LASER FIBER 'EXPLODED' SEPARATING THE METAL TIP. TIP RETRIEVED. SECOND LASER FIBER USED AND IT 'SHORTED OUT' AS SOON AS ENERGY WAS APPLIED. &quot;IT SMOKED AND DEPOSITED DEBRIS INSIDE THE PROSTATIC URETHRA&quot;. PHYSICIAN STOPPED USING LASER AND COMPLETED OPERATION WITH RESECTOSCOPE. (HOLMIUM LASER WAS TESTED AND WAS DEEMED TO BE IN PROPER WORKING ORDER.)</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: LUMENIS</td>
<td></td>
</tr>
<tr>
<td>Address: 2400 CONDENSA ST.</td>
<td></td>
</tr>
<tr>
<td>SANTA CLARA, CA 95051</td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: R</td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3): No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 08-DEC-2006</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: DUOTOME SIDELITE 550
Device Type: LASER FIBER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: 45500906
Other ID: *

Reported & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: Yes

EMAIL: [b] (6)
Phone: [b] (6)
International:
Fax:

Occupation: 500 - RISK MANAGER
Event Date (B3): 30-Mar-2007
Report Date (B4): 02-Apr-2007
Event Date (B3): 30-Mar-2007
Report Date (B4): 02-Apr-2007
Event Report Type: INJURY
Date Mfr Rec'd (G4):
Device Operator: HEALTH PROFESSIONAL
Voluntary Report No: MW1042452
Mfr Name: BOSTON SCIENTIFIC CORP.
Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)
Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer
Concomitant Medical Products:
Event Location (F12): HOSPITAL
Report Source (G3):
Adverse Event (B1): Y
Problem (B1): Y
Event Outcome (B2):
Reporter Occupation (E3): 002 - NURSE
Event Description (B5):
Volun 10-APR-2007: SURGERY PATIENT SCHEDULED FOR HOLIMUM LASER VAPORIZATION OF PROSTATE. REPRESENTATIVES PRESENT FROM LUMENIS - LASER COMPANY- AND BOSTON SCIENTIFIC - FIBER COMPANY - TO ASSIST FACILITY WITH PERFORMANCE ISSUES. SIDE FIRING FIBER OPENED AT BEGINNING OF CASE. SURGEON BEGAN PROSTATE RESECTION. SUBSEQUENTLY TIP OF FIBER BROKE OFF DURING RESECTION, AND DISLODGED IN PROSTATE TISSUE. SURGEON REMOVED TISSUE FROM PT, AND FELT THE TIP WAS ALSO REMOVED. PROCEEDED TO OPEN AN ADDITIONAL FIBER TO COMPLETE CASE. WHILE SURGEON WAS USING THE FIBER, SHE RECEIVED A JOLT OF ENERGY IN HER HAND, AND RECEIVED A BURN THROUGH HER GLOVE ONTO HER FINGER. CASE WAS SUBSEQUENTLY ABORTED AT THAT TIME. USED FOR 60 MINUTES.
Concomitant Medical Products:
Mfr Name: BOSTON SCIENTIFIC
Address:  
MARLBOROUGH, MA 
UNITED STATES
Device Available for Evaluation: R
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 10-APR-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** DUOTOME SIDE LITE 550
- **Device Type:** LASER FIBER FOR PROSTATE RESECTION
- **Device Type:** DUOTOME SIDE LITE
- **Catalog:** 840-841
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (b)
- **Health Professional:** Yes
- **EMAIL:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**
- **Occupation:** 002 - NURSE
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW1042640

Mfr Name: APPLIED MEDICAL RESOURCES CORP.

Date: 20-Apr-2007

Event Date (B3): 11-Apr-2007

Report Date (B4): 20-Apr-2007

Event Report Type: MALFUNCTION

Event Outcome (B2): 500 - RISK MANAGER

Adverse Event (B1): Problem (B1): Y

Event Location (F12): HOSPITAL

Report Source (G3): HEALTH PROFESSIONAL

Voluntary Report No:

Device Operator: HEALTH PROFESSIONAL

Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)

Device Age (F9):

Expiration Date:

Device Usage (H8):

Event Description (B5):


Concomitant Medical Products:

Mfr Name: APPLIED MEDICAL

Address:

RANCHO SANTA MARGARITA, CA *
UNITED STATES

Device Available for Evaluation: Y

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

01-MAY-2007:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: *
- Device Type: LASER LITHOTRIPSER
- Device Type: UNK
- Catalog: *
- Serial: (*confidential*)
- Lot: *
- Other ID: *

Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [b] (b)
- Address: [b] (b)
- Health Professional: Yes

EMAIL: [b] (b)
Phone: [b] (b)
International:
Fax:

Occupation: 500 - RISK MANAGER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW4002195</th>
<th>Mfr Name:</th>
<th>MEHL/BIOPHILE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>17-Nov-1997</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>06-Apr-1998</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>LAY USER/PATIENT</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Adverse Event (B1): | Y | Problem (B1): | N |
| Event Location (F12): | OTHER |
| Report Source (G3): | |

Event Description (B5):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Volun 22-APR-1998: RPTR'S CLIENT HAD BEEN A FREQUENT CLIENT OF A SPA & OWNERS SUGGESTED TO THEM THAT AS AN ALTERNATIVE TO ELECTROLYSIS HAIR REMOVAL PROCEDURE, SHE SHOULD TRY A NEW PROCESS USING LIGHT ENERGY FROM A RUBY LASER, CALLED CHROMOS 694 DEPILATION LASER, TO REMOVE HAIR ON HER LEGS & UNDERARMS. ON NOVEMBER 17,1997, CLIENT PAID $1,500.00 FOR A SERIES OF LASER HAIR REMOVAL SESSIONS ON HER LEGS. NEITHER OF SPA OWNERS ARE MEDICAL DOCTORS OR REGISTERED NURSES. FIRST TREATMENT WAS ON NOVEMBER 17,1997, & THEY PERFORMED LASER PROCEDURE ON CLIENT. PROCEDURE ON NOVEMBER 17, 1997 WAS VERY PAINFUL, & CLIENT EXPRESSED HER CONCERN TO SPA OWNERS ABOUT BURNING & DISCOLORATION OF HER LEGS DURING PROCEDURE. OPERATORS CONTINUED PROCEDURE EXPLAINING THAT PAIN WAS A COMMON SIDE EFFECT FROM PROCEDURE, & SHE PLACED ICE ON MOST PAINFUL AREAS & CONTINUED LASER HAIR REMOVAL. TWO OWNERS OF SPA SAID THAT BURNING & DISCOLORATION OF HER LEGS WAS A COMMON TEMPORARY SIDE EFFECT OF LASER HAIR REMOVAL SYSTEM. CLIENTS EXPERIENCED GREAT PAIN AS A RESULT OF BURNS ON HER UPPER & LOWER LEGS, & WENT TO DOCTOR ON NOVEMBER 19,1997. DOCTOR DIAGNOSED HER WITH FIRST & SECOND DEGREE BURNS ON HER UPPER & LOWER LEGS. THESE BURNS PROMPTLY TURNED TO LONG BLISTERS IN A PATTERN CONSISTENT WITH LASER HAIR REMOVAL ON HER LEGS. RPTR ENCLOSED COPIES OF PHOTOS TAKEN TWO DAYS AFTER LASER TREATMENT. AS A RESULT OF HER INJURIES, CLIENT HAS SUFFERED SEVERE PAIN & SUFFERING, SKIN DISCOLORATION, PIGMENT DISCOLORATION, & SCARRING ON HER UPPER & LOWER LEGS. AS OF MARCH 16, 1998, CLIENT IS STILL EXPERIENCING DISCOLORATION & PIGMENTATION DIFFERENCE ON HER UPPER & LOWER LEGS WHERE SHE WAS TREATED WITH LASER HAIR REMOVAL SYSTEM. OWNERS OF SPA HAD REPRESENTED TO CLIENT THAT LASER HAIR REMOVAL SYSTEM WOULD BE VIRTUALLY "PAINLESS," "CONVENIENT," & A SAFE ALTERNATIVE TO ELECTROLYSIS." OWNERS OF SPA NEGLIGENCELY USED CHROMOS 694 LASER HAIR REMOVAL SYSTEM ON CLIENT & DID NOT INFORM HER THAT THIS PROCEDURE WOULD CAUSE FIRST & SECOND DEGREE BURNS, & LEAVE HER WITH PERMANENT SKIN PIGMENTATION & SCARRING. AS A RESULT OF NEGLIGENCE OF SPA OWNERS & MFG DEFECT IN LASER, CLIENT HAS SUFFERED GREAT PHYSICAL, EMOTION, & PSYCHOLOGICAL DAMAGE. CLIENT IS CURRENTLY EMPLOYED AS A FLIGHT ATTENDANT, & LEADS A VERY ACTIVE LIFESTYLE, INCLUDING A WARDROBE WHICH REVEALS HER LEGS NINETY PERCENT (90%) OF THE TIME. AS A RESULT OF HER INJURIES, HAS NOT BEEN ABLE TO WEAR HER NORMAL CLOTHES. BROCHURE THAT WAS GIVEN TO CLIENT PROMISES " CHROMOS 694 DEPILATION LASER IS FDA CLEARED FOR HAIR REMOVAL, & HAS BEEN USED SUCCESSFULLY FOR THOUSANDS OF TREATMENTS WORLDWIDE. THERE HAS BEEN NO SCARRING OR LONG TERM SIDE EFFECTS ASSOCIATED WITH TREATMENT." UPON A SUPERFICIAL INVESTIGATION INQUIRY TO FDA, FDA HAS NOT CONFIRMED WITH ATTORNEY THAT THIS PROCESS HAS BEEN CLEARED THROUGH THEM FOR USE IN THE PUBLIC SALON INDUSTRY. ASIDE FROM THIS, THERE ALSO REMAINS QUESTION OF WHETHER SALON WAS PROPERLY LICENSED TO PERFORM THIS LASER HAIR REMOVAL PROCESS ON ITS CLIENTS.

Concomitant Medical Products:

NA

Mfr Name: MEHL/BIOPHILE
Address: 100 ALEXANDRIA BLVD STE 6
OVIEDO, FL 32765
UNITED STATES

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):

DEVICE INFORMATION:

Brand:  CHROMOS DEPILATION LASER
Device Type:  LASER
Device Type:  CHROMOS 694
Catalog:  NA
Serial:  (*confidential*)
Lot:  NA
Other ID:  NA

Reprocessed & Reused:  N/A
Concomitant Medical Products:

NI

Mfr Name: THERMOLASE CORP.
Address: 2055D LUNA RD.
CARROLLTON, TX 75006
UNITED STATES

Device Available for Evaluation: *
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
20-AUG-1998:
DEVICE INFORMATION:

- **Brand:** LITE TOUCH LT 100A
- **Device Type:** LASER INSTRUMENT
- **Device Type:** NI
- **Catalog:** NI
- **Serial:** (*confidential*)
- **Lot:** NI
- **Other ID:** NI

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW4002874</th>
<th>Mfr Name: SUNRISE TECHNOLOGIES, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Jan-2000</td>
<td>Event Report Type: MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>11-Sep-2000</td>
<td>Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3): OTHER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
</tr>
<tr>
<td>Device Code:</td>
<td></td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 29-SEP-2000: IT HAS COME TO RPTR'S ATTENTION THAT MISLEADING CLAIMS REGARDING SUNRISE TECHNOLOGIES' HYPERION LTK LASER ARE BEING PROMULGATED BY THE CO AND NORDEN LASER VISION ASSOCIATES. IN NORDEN'S 9/6/00 NEWS RELEASE - WHICH HAS BEEN DISSEMINATED BY SUNRISE TECHNOLOGIES - DIR PRAISES THE PROCEDURE AS &quot;SO SAFE AND VIRTUALLY PAIN FREE&quot;: THE NEWS RELEASE ALSO ERRONEOUSLY DESCRIBES TREATMENT WITH THE HYPERION LTK AS A &quot;THREE-SECOND 'NO TOUCH' PROCEDURE.&quot; YET, THE NEWS RELEASE NEGLECTS TO MENTION THAT SUNRISE TECHNOLOGIES' LASER IS FDA-APPROVED ONLY FOR THE TEMPORARY REDUCTION OF HYPEROPIA, AS THE TREATMENT'S CORRECTIVE EFFECT HAS A TENDENCY TO DIMINISH SIGNIFICANTLY OVER TIME. FURTHERMORE, DURING AN 8/22/00 INTERVIEW, SUNRISE TECHNOLOGIES' PRESIDENT AND CEO RESPONDED TO CNNFN REPORTER'S QUESTION OF WHETHER THE HYPERION LTK HAS ANY SIDE EFFECTS BY STATING, &quot;WHAT OUR CLINICAL TRIALS SHOWED WAS THAT IN TERMS OF LASER RELATED AdVERSE EVENTS, WE HAVE ZERO, SO IT REALLY HAS A FANTASTIC SAFETY PROFILE.&quot; THEN EXPLAINS THAT WHAT PTS USUALLY EXPERIENCE WITH THE TREATMENT IS &quot;AN IMMEDIATE ABILITY TO SEE NEAR AND THEN USUALLY THEIR DISTANCE VISION IS IMPROVED BUT THEN IMPROVES EVEN MORE AS TIME GOES.&quot; RPTR BELIEVES THAT THESE STATEMENTS, ISSUED WITHOUT ANY WARNING ABOUT - AND IN DIRECT CONTRADICTION TO - THE TREATMENT'S HIGH REGRESSION RATE, ARE PURPOSELY MISLEADING.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: SUNRISE TECHNOLOGIES INTL, INC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address: 3400 WARREN AVE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FREMONT, CA 94538</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNITED STATES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
</tr>
</tbody>
</table>

Recd: 1,029  Page: 2,072  Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
29-SEP-2000:

DEVICE INFORMATION:

Brand: HYPERION LTK
Device Type: LASER
Device Type: NI
Catalog: NI
Serial: (*confidential*)
Lot: NI
Other ID: NI

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5002548</th>
<th>Mfr Name: ALCON REFRACTIVE HORIZONS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>14-Mar-2000</td>
<td></td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>05-Jun-2007</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>306 - PATIENT FAMILY MEMBER OR FRIEND</td>
<td></td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
<td>Problem (B1): Y</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 15-JUN-2007: MY SPOUSE UNDERWENT LASIK SURGERY TO CORRECT HIS VISION. I RECENTLY RECEIVED A NOTICE OF RECALL FOR A SYSTEM. THAT NOTICE CONTAINED A DESCRIPTION OF THE SYMPTOMS OF THE FAILURE OF THE PROCEDURE: &quot;THE PRODUCT WAS RECALLED BECAUSE USE OF THE ALCON REFRACTIVE HORIZONS CUSTOMCORNEA ALGORITHM FOR MYOPIA WITH AND WITHOUT ASTIGMATISM WITH THE LADAR6000 EXCIMER LASER CAUSED CORNEAL ABNORMALITIES -&quot;CENTRAL ISLANDS&quot;- AND DECREASED VISUAL SHARPNESS -VISUALACUITY- IN PATIENTS WITH MYOPIA WITH AND WITHOUT ASTIGMATISM. THESE &quot;CENTRAL ISLANDS&quot; MAY NOT BE CORRECTABLE WITH LASERS AND THE DECREASE IN VISUAL ACUITY MAY NOT BE CORRECTABLE WITH GLASSES OR CONTACT LENSES. MY SPOUSE HAS HAD THESE SYMPTOMS DATING FROM THE TIME OF THE SURGICAL PROCEDURE. ALTHOUGH THE DATA IN THE NOTICE INDICATES THAT THE RECALL IS IN SPECIFIC TO THE PRODUCT LISTED, WHETHER THIS PRODUCT WAS USED OR NOT--THOSE ARE SYMPTOMS WHICH HE HAS BEEN UNABLE TO CORRECT.</td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td>SYSTEM CLASS I</td>
<td></td>
</tr>
<tr>
<td>Mfr Name: ALCON REFRACTIVE HORIZONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>15-JUN-2007:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)
SORTED BY
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
Brand: ALCON REFRACTIVE HORIZONS LADAR6000 EXCIMER LASER
Device Type: LASER SURGICAL EQUIPMENT

Reprocessed & Reused: N

REPORTER INFORMATION:
Name: [b] (6)
Address: [b] (6)

EMAIL: [b] (6)
Phone: [b] (6)
International: 
Fax: 

Health Professional: No

Occupation: 306 - PATIENT FAMILY MEMBER OR FRIEND
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5002846  Mfr Name: GREENWALD SURGICAL CO., INC.  Date Received: 26-Jun-2007

Event Date (B3): 29-Apr-2007  Event Report Type: INJURY  Adverse Event (B1): Problem (B1): Y
Date Mfr Rec'd (G4): 26-Jun-2007  Report Date (F8): 002 - NURSE  Report Source (G3): HEALTH PROFESSIONAL

Event Description (B5): Volun 06-JUL-2007: PT ADMITTED FOR LEFT URETEROCELE REPAIR. THIS WAS COMPLETED WITH THE BUGBEE ELECTRODE (THROUGH THE PED. CYSTOSCOPE), PT DISCHARGED AND RETURNED 240 LATER WITH PAIN AND UP WBC, RETAINED URINE, SIGNS OF PERITONITIS. PT TRANSFERRED TO HOSP IN 2002. THERE THEY DETERMINED THAT THE TIP OF THE BUGBEE HAD BROKEN OFF AND WAS IMBEDDED IN THE BLADDER WALL. PT REQUIRED OPEN SURGERY TO RETRIEVE THE TIP. PT THEN HAD UNEVENTFUL RECOVERY.

Concomitant Medical Products:

Mfr Name: GREENWALD SURGICAL CO.  Address: ,
Device Available for Evaluation: N  Device Evaluated by Manufacturer (H3): No Answer
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):  Correction/Removal No (H9):  Additional Mfr Narrative (H10 & H11): 06-JUL-2007:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**
- **Brand:** BUGBEE
- **Device Type:** LASER TIP
- **Device Type:** EET107B
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:** RED 4 FR
- **Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**
- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Occupation:** 002 - NURSE
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:**
- **Fax:** [redacted]
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5003999</th>
<th>Mfr Name:</th>
<th>NONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>20-Apr-2004</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Report Date (F8): 06-Oct-2007
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 305 - PATIENT
Device Operator:
Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Age (F9): Manufacture Date (H4): |
Expiration Date: Single Use (H5):
Device Usage (H8): |
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Volun 18- OCT- 2007: OVER 3 AND HALF YEARS AGO, LASER EYE SURGERY ROBBED A BOY OF HIS INNOCENCE. IN 2004 WAS, BY FAR, THE MOST LIFE ALTERING EXPERIENCE I HAVE EVER HAD. THIS SURGERY RUIN ED OVER 20 YEARS OF HARD WORK AND DEDICATION. THE SAME YEAR, YOU PERFORMED WAVEFRONT GUIDED LASER EYE SURGERY ON MY VIRGIN CORNEAS. AT THE TIME, MY SCOP TIC PUPILS WERE MEASURED AT WELL OVER 8MM. THE OPTICAL ZONE IMPOSED ON MY CORNEAS FOR SURGERY WAS 6MM. THEREFORE, YOU OPERATED ON MY EYES, KNOWING THAT ANYTIME MY PUPILS DILATED OVER 6MM, MY EYESIGHT WOULD BE WORTHLESS. SINCE NO ABERROMETER AT THE TIME OF MY SURGERY WAS ABLE TO EVALUATE CORNEAS OVER 6 TO 6.5MM, ANY "BLEND ZONE" GIVEN ON MY EYES WAS WORTHLESS. ONLY 6 OF 8.25MMS OF MY EYES REC'D THE FULL TREATMENT FROM THE SURGERY. IT IS MY ESTIMATE THAT I SPEND OVER 75% OF THE DAY WITH MY PUPILS LARGER THAN THE GIVEN OPTICAL ZONE, THUS RENDERING MY VISION ABSOLUTELY WORTHLESS THE MAJORITY OF THE DAY. FOR THE REST OF MY LIFE, I WILL SUFFER FROM PURE VISUAL HELL. I HAVE SEVERE GLARE, STAR BURSTING, DOUBLE VISION, SEVERELY DRY EYES, TRACE CATARACTS, SEVERE LIGHT SENSITIVITY, SEVERE FLOATERS -A RESULT FROM THE COMBINATION OF PILOCARPINE AND THE MICROKERATOME USED FOR THE MUTILATION OF MY CORNEA FLAP-, AND A DECENTERED ABLATION. IN ADDITION, WITHIN MY OPTICAL ZONE, THERE WAS AN INCREASE IN HIGH ORDER ABERRATIONS -HOA-, INCLUDING COMA. ON TOP OF ALL THIS, I NOW HAVE IRREGULAR ASTIGMATISM AS WELL. ALL THIS IS A DIRECT RESULT FROM THE SURGERY. ONE CAN ONLY IMAGINE THE PSYCHOLOGICAL SIDE EFFECTS THIS HAS CAUSED FOR ME. I HAVE SINCE BEEN COMPLETELY UNEMPLOYED, AS OF SEVERAL MONTHS AFTER THE SURGERY. I LEFT TO STUDY ABROAD BECAUSE I BELIEVED YOU, AND EVEN TRUSTED YOU AFTER MY SURGERY. YOU TOLD ME THAT ANOTHER SURGERY COULD HELP. SO I WAITED TO BE SURE, I WAITED FOR SURGERY METHODS TO IMPROVE. INSTEAD OF WORKING, I WENT BACK TO SCHOOL, AND TRIED TO READ AND STUDY AS BEST I COULD CONSIDERING THE CIRCUMSTANCES. I USED THE MOTIVATION OF "FIXING" MY EYES TO FUEL ME THROUGH GRADUATE SCHOOL. I LOOKED FORWARD EVERY DAY TO BE "HEALED." HOWEVER, AFTER MY ARRIVAL BACK IN THE U.S., AFTER BEING OUT OF THE COUNTRY FOR ONE YR, I WENT DIRECTLY TO YOUR OFFICE TO HEAR IF YOU COULD HELP ME. YOU SAID THAT ANOTHER SURGERY COULD POSSIBLY HELP. YOU WANTED TO DESTROY MORE OF MY CORNEAL TISSUE AND PERFORM A SURGERY TO FIX WHAT YOU HAVE CAUSED. YOUR INTENTION WAS NEVER TO INCREASE MY OPTICAL ZONE, WHICH I NOW KNOW IS THE REAL PROBLEM WHICH YOU NEVER ADMITTED TO AND REPEATEDLY LIED ABOUT. YOU SAID, THE TYPICAL RESPONSE THAT I AM "ONE OF THE 1 OR 2% OF POST REFRACTIVE SURGERY PATIENTS WITH UNSUCCESSFUL RESULTS BUT KEEP WAITING, YOUR EYES NEED TO HEAL OVER TIME." REAL TEXTBOOK WORDING ON HOW TO AVOID A LAWSUIT AND ALLOW MY STATUTE OF LIMITATIONS TO PASS BY. ANY FINANCIAL SETTLEMENT BROUGHT ABOUT FROM A LITIGATION CASE AGAINST YOU WOULD HAVE BEEN FAIR AND JUST. IT WOULD HAVE HELPED RESTORE SOME STABILITY IN MY LIFE AND ALLOW ME TO PUT MYSELF BACK ON MY FEET. BUT YOUR CUNNING TACTICS TO LET THE STATUTE OF LIMITATIONS PASS ME BY WAS REMARKABLE. THROUGH YOUR LIES ABOUT HEALING TIME, TO YOUR LIES ABOUT NOT KNOWING THE CAUSE OF MY PROBLEMS, YOU COVERED YOURSELF WELL. BUT AS A RESULT, YOU RUINED MY LIFE AND MY FAMILY'S LIVES AS WELL. I HAVE CUT OFF ALL CONTACT WITH MY FAMILY, SINCE THE ONLY EMOTION I HARBOUR NOW IS DEPRESSION. I WRITE THIS LETTER TO YOU WITH THAT SAME EMOTION. WE BOTH KNOW THAT THERE WILL NEVER BE A SOLUTION TO MY PROBLEMS. WITH THE OVERWHELMING RISK OF ECTASIA ON MY ALREADY THINNED AND WEAKENED CORNEAS, COMBINED WITH MY LARGE PUPIL SIZE, I WILL NEVER BE A CANDIDATE FOR FURTHER SURGERY. I AM FOREVER A PRISONER WITHIN MY BODY. I HAVE NO EMPLOYMENT, NOR CAN I MAINTAIN EMPLOYMENT. I RARELY DRIVE, READ, WRITE, OR DO ANY OF THE OTHER THINGS I ONCE LOVED. HAVING LASIK SURGERY HAS BEEN THE WORSE MISTAKE OF MY LIFE. IT HAS LITERALLY COST ME MY LIFE. I HAVE CRIED EVERY DAY FOR OVER THE PAST 36 MONTHS. I HAVE TRIED SEVERAL ANTI DEPRESSANTS WITHOUT ANY SUCCES

Concomitant Medical Products:

PILOCARPINE, 1%

Mfr Name:
Address: ,

Recd: 1,032 Page: 2,079 Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
18-OCT-2007:

DEVICE INFORMATION:

Brand: *
Device Type: LASER

Device Type:
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N
Event Description (B5):
Volun 17-OCT-2007: IN 2007, I HAD LASIK SURGERY AT THE EYE CENTER PERFORMED BY A DR. HE USED THE VISX STAR S4 EXCIMER LASER. MY VISION AFTER THE PROCEDURE WAS 20/50 FOR DISTANCE AND UNABLE TO VISUALIZE ANY DETAIL ON ANYTHING WITHIN ARM'S REACH. HIS EXPLANATION IS THAT THE LASER OVERCORRECTED MY VISION BECAUSE MY "CORNEAL TISSUES WERE TOO RECEPTIVE TO THE LASER." I NOW AM UNABLE TO DRIVE AT NIGHT, MY DEPTH PERCEPTION IS SO FAULTY THAT I OFTEN STUMBLE. MY GLASSES ARE SO THICK, I APPEAR CROSS-EYED. I GOT CAUGHT OUT AFTER DARK THE OTHER NIGHT AND HAD THE CHOICE OF SITTING ALONE IN A DARK CAR FOR 30 MINUTES WAITING FOR GLAUCOMA DROPS TO HELP OR DRIVING DOWN DARK ROADS TO AVOID LIGHTS, CARS, AND PEDESTRIANS. I SEE DOUBLE VISION STARBURSTS AT TRAFFIC LIGHTS, SO I'M UNABLE TO DETERMINE WHICH WAY OR WHEN TO GO. I CAN NOT LONGER TELL TIME BY MY WATCH, CHECK MY CALLER ID, OR TAKE MY MEDICATIONS WITHOUT MY GLASSES OR A MAGNIFYING GLASS. I COULD DO THESE THINGS BEFORE LASIK! I CAN NO LONGER DRIVE TO THE STORE AT NIGHT FOR A CARTON OF MILK OR GO TO THE MOVIES. I COULD DO THESE THINGS BEFORE LASIK! . DIAGNOSIS OR REASON FOR USE: LASER VISION CORRECTION.

Concomitant Medical Products:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Additional Mfr Narrative (H10 & H11):**
17-OCT-2007:

**DEVICE INFORMATION:**

- **Brand:** VISX STAR S4 EXCIMER LASER
- **Device Type:** LASER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

- **Name:** [blurred]
- **Address:** [blurred]
- **Health Professional:** Yes
- **Occupation:** 305 - PATIENT

**EMAIL:** [blurred]
**Phone:** [blurred]
**International:**
**Fax:**
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>30-Nov-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>DISABILITY OR PERMANENT DAMAGE</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>DURING CYSTOSCOPY AND LEFT URETERORENOSCOPY USING ROLMIUM LASER LITHOTRIPSY, THE TIP OF THE LASER FIBER WIRE SHEARED OFF. THIS WAS RETRIEVED BY PHYSICIAN WITH SIGNIFICANT DIFFICULTY. THE LASER FIBER WAS A REUSEABLE PRODUCT. THE SLT HFE FIBERS ARE PROVIDED STERILE WHEN NEW AND ARE REUSEABLE.</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>N</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

**Concomitant Medical Products:**

- **Mfr Name:** SLT
- **Address:** MONTGOMERYVILLE, PA UNITED STATES

**Device Available for Evaluation:** N

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

14-JAN-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: SLT
- Device Type: LASER FIBERT
- Device Type: HFE272-SMA
- Catalog: (*confidential*)
- Serial: (*confidential*)
- Lot: 624306-084
- Other ID:

- Reprocessed & Reused: N

REPORTER INFORMATION:

- Name: [redacted]
- Address: [redacted]
- Email: [redacted]
- Phone: [redacted]
- International: [redacted]
- Fax: [redacted]

- Health Professional: Yes
- Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>10-Feb-2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4)</td>
<td>24-Feb-2008</td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Report Source (G3):</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 05-MAY-2008: DURING THE EARLY 2007, I UNDERWENT LASIK SURGERY. I WASN'T AS COMFORTABLE AS I EXPECTED AFTER THE FIRST COUPLE OF DAYS, BUT I EXPECTED THINGS TO PICK UP. I THOUGHT MY FEELINGS WERE USUAL FEELINGS AFTER HAVING SURGERY. BY THE BEGINNING OF THE 2ND WEEK I WOKE UP AND PANICKED, BECAUSE I WAS EXPERIENCING EXTREME PAIN IN MY EYES AND ANY LIGHT INTENSIFIED THE PAIN. I CONTACTED THE FACILITY WHERE THE SURGERY TOOK PLACE AND THEY ASKED ME TO COME IN. MY HUSBAND HAD TO DRIVE ME WHILE I WORE DARK PATCHES PURCHASED AT THE PHARMACY, DARK SUNGLASSES AND COVERED IN THE CORNER OF THE CAR, BECAUSE OF THE INTENSE PAIN CAUSED BY ANY LIGHT GETTING THROUGH. I HAD TO BE EVALUATED IN A DARK ROOM, BECAUSE I WAS UNABLE TO OPEN MY EYES IF THE LIGHT WAS ON. I WAS DIAGNOSED WITH IRITIS BY THE SURGEON AND PLACED BACK ON STEROID DROPS. THE PROBLEM SEEMED TO GET BETTER FOR ANOTHER WEEK OR SO AND THEN RETURNED REPEATEDLY. AFTER MANY TRIPS BACK TO THE FACILITY, THE SURGEON EXPRESSED THAT, I HAD TO HAVE HAD SOME UNDERLYING MEDICAL CONDITION PRIOR TO THE SURGERY THAT I WAS NOT AWARE OF. ONE NIGHT MY HUSBAND HAD TO TAKE ME TO EYE EMERGENCY ROOM BECAUSE MY EYES WERE SO BAD. EYE EMERGENCY ROOM WHO RESPECTED AND APPARENTLY HAD RECEIVED TRAINING FROM MY SURGEON AGREED WITH HIS DIAGNOSIS, AND AGAIN PUT ME BACK ON THE STEROID DROPS. THE SURGEON EXPLAINED THAT THEY COULD NOT DO ANYTHING MORE FOR ME AND REFERRED ME TO MY OPHTHALMOLOGIST FOR BLOOD WORK AND A CHEST X-RAY WHICH ALL CAME BACK FINE. NOW A LITTLE OVER YEAR LATER, MY VISION HAS STARTED TO REVERT BACK TO ITS ORIGINAL STATE, I EXPERIENCE DAILY BOUTS OF PAIN SHOOTING BEHIND MY EYES, OCCASIONAL BLURRED VISION - I HAVE TO LOOK AWAY AND REFOCUS - AND NO ONE SEEMS TO BE ABLE TO TELL ME WHY.</td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
05-MAY-2008:

DEVICE INFORMATION:

Brand:
Device Type: LASER
Device Type:
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax:

Health Professional: No

Occupation: 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5006431
Mfr Name: NONE

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>02-Feb-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (B4):</td>
<td>25-Apr-2008</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
</tr>
<tr>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
</tr>
<tr>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Volun 02-MAY-2008: HAD LASIK EYE SURGERY IN 2008, DEVELOPED A SEVERE EYE INFECTION IN THE LEFT EYE BY SIX DAYS LATER. I WAS TOLD BY DR THAT THERE WAS A FOREIGN OBJECT. HE DESCRIBED THE OBJECT AS A PIECE OF WOOD OR SOMETHING. THE ONLY PROBLEM WAS THAT I DID NOT GO OUT OF THE HOUSE THE ENTIRE WEEKEND. I DID NOT SEE WHAT WAS TAKEN OUT, I FELT THAT IF IT WAS SOMETHING THAT IT WOULD HAVE BEEN SENT WITH ME FOR AN ACTUAL SAMPLE TO PRESENT TO THE HOSPITAL FOR CULTURE SAMPLES. LASIK WITH NO FOLLOWUP APPOINT TO CHECK THE EYES, TWO DAYS AFTER THE ORIGINAL DATE, NOTIFIED DR AT 8:00 THAT MORNING, AND BY 11:00 I HAD TO GO HOME. MY LEFT EYE WAS HURTING AND WATERING EXCESSIVELY. HE SAID THAT HE WOULD COME IN AND LOOK AT THE EYE THAT DAY. I TOLD HIM THAT I WOULD MEET HIM AT HIS OFFICE THE NEXT DAY AT 9:30, TREATED BY LASIK SURGEON - LASER CENTER, WITH STRONGEST ANTIBIOTICS TO TREAT INFECTION. ON THREE DAYS LATER, RETURNED TO DR SELKIN FOR ADDITIONAL TREATMENT. I WAS ADVISED TO GO TO A FACILITY TO HAVE TISSUE SAMPLES TO IDENTIFY THE CAUSE OF THE INFECTION. LOSS OF VISION DUE TO INFECTION FOR SEVERAL WEEKS. ONLY ABLE TO SEE SHADOW IMAGES. EXTREME PAIN DUE TO INFECTION. BOTH EYES WERE CORRECTED WITH LASIK, THE RIGHT EYE FOR CLOSE VISION, THE LEFT FOR DISTANCE. I HAVE NO DEPTH PERCEPTION OR FOCUS ON OBJECTS 2FT AWAY WITHOUT THE USE OF GLASSES IN THE RIGHT EYE. THE GLASSES I HAVE TO WEAR ARE SO THAT I DON'T HAVE THE DOUBLE VISION IN THE RIGHT EYE. I AM UNABLE TO DRIVE AT NIGHT, THE STARBURST EFFECT IS TOO INTENSE TO FOCUS IN THE LEFT EYE. I HAVE TO CLOSE THE EYE TO SEE. WITHOUT THE GLASSES WHICH IS ONLY FOR THE RIGHT, THE LEFT LENS IS CLEAR WITH NO CORRECTIVE MAGNIFICATION I EXPERIENCE A CIRCLE AROUND AN ILLUMINATED SURFACE LIGHT, ETC. BECAUSE OF THE INFECTION MY IRIS IS FIXED AND WILL NOT DILATE. WHICH INCREASES THE LIGHT IN MY LEFT EYE AND CAUSES PAINFUL EYE AND HEADACHES IN THE LEFT EYE.

Concomitant Medical Products:
Mfr Name: ,
Address: ,

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
02-MAY-2008:

DEVICE INFORMATION:
Brand:
Device Type: LASER
Device Type:
Catalog:
Serial: (*confidential*)
Lot:
Other ID:
Reprocessed & Reused: N/A

REPORTER INFORMATION:
Name:
Address:
EMAIL:
Phone:
International:
Fax:
Health Professional: No
Occupation: 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5006448</th>
<th>Mfr Name:</th>
<th>NONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Aug-2006</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>26-Apr-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec’d (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**


**Concomitant Medical Products:**

UNK. I WAS THE PT, NOT THE DR.

**Mfr Name:** UNK
**Address:** UNK
**UNKNOWN**

**Device Available for Evaluation:** N
**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

05-MAY-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** VISX
- **Device Type:** LASER
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

Reprocessed & Reused: N
Event Description (B5):
Volun 12-MAY-2008: IT IS STILL TOO EARLY FOR ME TO DEFINITIVELY EVALUATE MY "ADVANCED" -MAYBE IT'S CALLED WAVEFRONT?- LASIK, SINCE THE EYE DOCTOR TELLS ME THAT IT TAKES SEVERAL MONTHS TO STABILIZE. I'M TRYING TO BE PATIENT, BUT I'M STILL WAITING. I HAVE SEVERE MYOPIA, AND THE SURGERY DID SEEM TO IMPROVE MY VISION GREATLY IN THAT REGARD. I CAN READ ROAD SIGNS, IF THE PRINT IS LARGE ENOUGH, WITHOUT GLASSES NOW, WHEREAS BEFORE I WOULD NOT BE ABLE TO RECOGNIZE A PERSON'S FEATURES IF THEIR FACE WAS 3 FEET AWAY. HOWEVER, MY VISION IS BLURRY, AND I SUSPECT THAT IS A BIT OF ASTIGMATISM THAT HOPEFULLY CAN STILL BE CORRECTED IF I AM ALLOWED TO GO IN FOR A FOLLOW UP PROCEDURE. THE HALOS AROUND LIGHTS AT NIGHT HAVE SUBSIDED BUT ARE NOT TOTALLY GONE. I AM UNABLE TO FOCUS A CAMERA PERFECTLY THROUGH THE VIEWFINDER. I HOPE THAT I CAN HAVE A CORRECTION MADE, BUT IF NOT I AM GOING TO HAVE TO ASK TO GET GLASSES AND HOPE THAT MY VISION WILL BE CLEARER. I DID NOT GO INTO THIS PROCEDURE WITH UNREALISTIC EXPECTATIONS. AT BEST, I WAS HOPING THAT I WOULD HAVE INCREDIBLY CLEAR VISION, LIKE A CELEBRITY IN THE PROMOTIONAL POSTERS MUST HAVE, BECAUSE I KNOW HE WOULD NOT SETTLE FOR "CLOSE ENOUGH." AT WORST, I WAS HOPING THAT AT LEAST I COULD FUNCTION IF I LOST MY GLASSES, AND THIS IS THE CASE. HOWEVER, I DO FEEL THAT PEOPLE SHOULD BE VERY CAREFUL ABOUT WHAT THEY THINK WILL HAPPEN AFTER LASIK. SO FAR I HAVE NOT HAD ANY COMPLICATIONS OTHER THAN DRY EYES, BUT IT IS STILL TOO EARLY TO TELL ABOUT THAT EITHER. NOW THAT I TALK TO MY FRIENDS WHO RAVED ABOUT THE SURGERY THAT THEY HAD DONE YEARS AGO, I FIND OUT THAT THEIR VISION IS NOT PERFECT EITHER, BUT THEY DON'T SEEM TOO CONCERNED ABOUT THAT. PEOPLE NEED TO KNOW THAT IT IS A COMPLEX SURGERY AND TO GET THINGS PERFECT IS NOT GUARANTEED. THEY EITHER NEED TO READ THE FINE PRINT, WITH THEIR GLASSES, OR THE DOCTORS NEED TO BE MORE HONEST AND SPEND MORE TIME WITH THE PT TO MAKE SURE THEY UNDERSTAND ALL OF THE DETAILS. I AM IN THE MIDST OF SEVERAL FOLLOW UP EXAMS AT MY OPTOMETRIST. HE HAS PRONOUNCED MY VISION TO BE 20/20, ALTHOUGH I AM TELLING HIM THAT MY VISION IS STILL BLURRY. HE TELLS ME THAT THE EYES ARE STILL HEALING ON THE CELLULAR LEVEL, AND THAT THEY ARE DRY. I AM WAITING BEFORE I CAN FULLY EVALUATE THE EFFECTIVENESS OF THE PROCEDURE, BUT IT HAS BEEN SEVERAL MONTHS AND I STILL DO NOT HAVE PERFECT VISION. I DO NEED READING GLASSES, BUT AT THE AGE OF 50 I WAS EXPECTING THIS. IT IS MY FAR DISTANCE VISION THAT I AM CONCERNED ABOUT. TLC LASER EYE CENTER, LANSING, MI. DATES OF USE: OUTPATIENT SURGERY. DIAGNOSIS OR REASON FOR USE: SEVERE MYOPIA WITH ASTIGMATISM.

Concomitant Medical Products:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Mfr Name: 
Address: ,

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-MAY-2008:

DEVICE INFORMATION:

Brand: CUSTOM LASIK
Device Type: LASER SURGERY
Device Type:
Catalog: 
  Serial: (*confidential*)
  Lot:
Other ID:

Reprocessed & Reused: N/A
### MAUDE EVENT REPORT (FOI)

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5006547</th>
<th>Mfr Name:</th>
<th>NONE</th>
<th>Date Received</th>
<th>01-May-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event Date (B3):</strong></td>
<td>08-Mar-2007</td>
<td><strong>Event Report Type:</strong></td>
<td>INJURY</td>
<td><strong>Adverse Event (B1):</strong></td>
<td>Y</td>
</tr>
<tr>
<td><strong>Report Date (B4):</strong></td>
<td>01-May-2008</td>
<td><strong>Event Outcome (B2):</strong></td>
<td>REQUIRED INTERVENTION</td>
<td><strong>Problem (B1):</strong></td>
<td>N</td>
</tr>
<tr>
<td><strong>Report Date (F8):</strong></td>
<td></td>
<td><strong>Reporter Occupation (E3):</strong></td>
<td>305 - PATIENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Date Mfr Rec’d (G4):</strong></td>
<td></td>
<td><strong>Device Operator:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product Code:</strong></td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td><strong>Manufacture Date (H4):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Device Age (F9):</strong></td>
<td></td>
<td><strong>Single Use (H5):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Expiration Date:</strong></td>
<td></td>
<td><strong>Device Usage (H8):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Event Description (B5):</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Concomitant Medical Products:

Mfr Name: 
Address: 

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-MAY-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- Brand: *
- Device Type: LASER
- Catalog:
- Serial: (*confidential*)
- Lot:
- Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

- Name: [REDACTED]
- Address: [REDACTED]
- EMAIL: [REDACTED]
- Phone: [REDACTED]
- International: [REDACTED]
- Fax: [REDACTED]
- Health Professional: Yes
- Occupation: 305 - PATIENT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5006548
Mfr Name: NONE

Event Date (B3): 01-Apr-2000
Report Date (B4): 01-May-2008
Report Date (F8):
Date Mfr Rec’d (G4):

Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 305 - PATIENT
Device Operator:

Adverse Event (B1): Y
Problem (B1): N

Report Date (B4): 01-May-2008

Event Location (F12): Reporter Occupation (E3):
Report Source (G3):

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 12-MAY-2008: IN 2000, I WAS DIAGNOSED AS HAVING A NARROWING OF A CANAL - I THINK IT WAS CALLED - IN MY EYES THAT MIGHT CAUSE GLAUCOMA IN THE EVENT OF SEVERE CHANGE IN BLOOD PRESSURE. LASER SURGERY TO CORRECT THE DEFECT WAS RECOMMENDED. UNFORTUNATELY, I WAS UNABLE TO KEEP THE FOLLOW-UP MONITORING APPOINTMENT WITH THE LASER SURGEON. SINCE THEN, AND MOST NOTICEABLY, WHEN I BECAME PERI-MENOPAUSAL, I HAVE BEGUN TO EXPERIENCE BLURRING/DUPLICATE VISION, AND HALOS. IT IS MORE SEVERE WHEN MY EYES ARE STRAINED, ESPECIALLY, AFTER USING THE COMPUTER FOR A LONG PERIOD. I HAD ATTRIBUTED THE SYMPTOMS TO DETERIORATION DUE TO AGE, BUT TODAY I HEARD A PROGRAM ON NATIONAL PUBLIC RADIO WHICH DESCRIBED EXACTLY THE SAME SYMPTOMS FROM LASIK SURGERY IN A SMALL PERCENTAGE OF PT'S. I DO NOT HAVE MY RECORDS AVAILABLE, BUT COULD RETRIEVE MORE ACCURATE INFO IF IT WOULD BE HELPFUL. PLEASE LET ME KNOW.

Concomitant Medical Products:

Mfr Name:  
Address: 

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
12-MAY-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand:
Device Type: LASER

Device Type:
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)
EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax:

Health Professional: No
Occupation: 305 - PATIENT
CDRH

MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5006555
Mfr Name: BAUSCH & LOMB, INC.

Event Date (B3): 18-Sep-2007
Report Date (B4): 01-May-2008
Report Date (F8): 01-May-2008
Date Mfr Rec’d (G4): Report Date (F4): 01-May-2008
Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Adverse Event (B1): Y
Problem (B1): N
Reporter Occupation (E3): Device Operator:
305 - PATIENT

Event Description (B5):
Volun 08-MAY-2008: I HAD TO HAVE PRK DONE AGAIN AFTER MY FIRST PROCEDURE IN 2006. FOR SOME UNKNOWN REASON I HAD BECOME FARSIGHTED AND MY NEAR VISION WAS VERY POOR; I REALLY COULD NOT SEE WELL AT ALL. AFTER THE SECOND PROCEDURE I WAS IN A GREAT DEAL OF PAIN. I DEVELOPED DRY EYE FOR A TIME. I HAD PAIN RADIATING DOWN MY FACE AND ACROSS MY FACE TO MY EAR. THE DOCTORS INSISTED THAT THE PAIN HAD NOTHING TO DO WITH THE PRK. I WAS TOLD THAT THE PROCEDURE COULD BE DONE AGAIN TO IMPROVE THE VISION IN MY RIGHT EYE; WHICH I DECLINED. PRESENTLY I AM ON MEDICATION FOR TRIGEMINAL NEURALGIA. THE VISION IN MY LEFT EYE IS QUITE GOOD, BUT MY RIGHT EYE IS WEAKER THAN THE LEFT. OF COURSE I NEED READING GLASSES. I WILL NEED GLASSES FOR DRIVING IN THE FUTURE. I WENT TO A VERY REPUTABLE DOCTOR, BUT I AM VERY DISAPPOINTED WITH THE RESULTS OF MY 2 PRKS. I WANTED TO MENTION THAT I ALSO SEE HALOS AT NIGHT WHEN I DRIVE.

Concomitant Medical Products:
Mfr Name: ZYOPTIC LASER BAUSCH&LOMB
Address: , UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
08-MAY-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** ZYOPTIC
- **Device Type:** LASER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5006591</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mfr Name:</td>
<td>NONE</td>
</tr>
</tbody>
</table>

| Event Date (B3):     | 27-May-2005 |
| Report Date (B4):    | 01-May-2008 |
| Event Report Type:   | INJURY      |
| Adverse Event (B1):  | Y           |
| Problem (B1):        | N           |
| Event Date (F3):     | 27-May-2005 |
| Event Outcome (B2):  |             |
| Reporter Occupation (E3): | 305 - PATIENT |
| Device Operator:     |             |
| Event Location (F12):|             |
| Report Source (G3):  |             |

| Product Code:        | (OP)-EXCIMER LASER SYSTEM (LZS) |
| Device Age (F9):     | Manufacture Date (H4):           |
| Expiration Date:     | Single Use (H5):                 |
| Device Usage (H8):   |                                 |

| Event Description (B5): | Volun 09-MAY-2008: CATARACT SURGERY WITH LASIK TOUCHUP RESULTED IN VERY POOR NIGHT VISION AND SUBSTANTIAL INCREASE IN FLOATERS. |

Concommitant Medical Products:

| Mfr Name: | , |
| Address: | |

| Device Available for Evaluation: | N |
| Device Evaluated by Manufacturer (H3): | No Answer |

Remedial Action (H7): 
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 
09-MAY-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:**
- **Device Type:** LASER
- **Device Type:**
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:** [REDACTED]
- **Address:** [REDACTED]
- **Email:** [REDACTED]
- **Phone:** [REDACTED]
- **International:** [REDACTED]
- **Fax:** [REDACTED]
- **Occupation:** 305 - PATIENT

Health Professional: No
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5006604</th>
<th>Mfr Name:</th>
<th>NONE</th>
</tr>
</thead>
</table>

**Event Date (B3):** 01-Oct-2000  
**Report Date (B4):** 01-May-2008  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Reporter Occupation (E3):** 305 - PATIENT  
**Device Operator:** HEALTH PROFESSIONAL  
**Adverse Event (B1):** Y  
**Problem (B1):** N  
**Report Date (F8):**  
**Event Location (F12):**  
**Report Source (G3):**  
**Product Code:** (OP)-EXCIMER LASER SYSTEM (LZS)  
**Device Age (F9):** Manufacture Date (H4):  
**Expiration Date:** Single Use (H5):  
**Device Usage (H8):**  

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>MODEL XXXX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>AUSTIN, TX</td>
</tr>
<tr>
<td></td>
<td>UNITED STATES</td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):**  
12-MAY-2008:

**Event Description (B5):**
Volun 12-MAY-2008: AFTER LASIK SURGERY, I NOW HAVE VERY POOR NIGHT VISION AND WILL MOST LIKELY HAVE TO STOP DRIVING AT NIGHT WITHIN THE NEXT FEW YEARS. I SEE HALOS AND STAR BURSTS. IT APPEARS AFTER SOME DIGGING AND RESEARCH ON MY OWN, I HAVE UNUSUALLY LARGE PUPIL SUCH THAT THE LASIK CUT/TREATMENT AREA WAS SMALLER THAN THE PUPIL. SO DURING THE DAY AND BRIGHT LIGHT THE PUPIL CONTRACTS TO A SMALLER SIZE, AND IS WITHIN THE TREATED AREA AND MY VISION IS O.K. IT'S NOT 20/20, BUT CLOSER TO 20/30 OR 20/35. HOWEVER AS IT GETS DARKER OR CLOUDY, MY PUPIL EXPANDS AND THE OUTER PART OF THE PUPIL GOES OUTSIDE OF THE TREATED AREA AND MY VISION GETS WORSE. THEN IN TOTAL DARKNESS AT NIGHT A LARGER PORTION OF MY PUPIL IS OUTSIDE OF THE TREATED AREA, CAUSING THE HALOS AND STAR BURSTS. SOMETIMES IT'S SO BAD THAT I HAVE TO TURN ON THE INSIDE CAR LIGHT TO HELP SHRINK MY PUPIL AND TO SHRINK THE STAR BURSTS. KNOWING WHAT I KNOW NOW, MY DOCTOR SHOULD HAVE TOLD ME THAT THIS WOULD BE A SIDE EFFECT OF HAVING A LARGE PUPIL. THERE IS A GOOD CHANCE THAT KNOWING THIS AND THE SEVERE OUTCOME, I MIGHT NOT HAVE HAD THE PROCEDURE.
CDRH
MAUDE EVENT REPORT (FOI)
SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: 
Device Type: LASER
Device Type: 
Catalog: 
Serial: (*confidential*)
Lot: 
Other ID: 

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

Health Professional: No

EMAIL: [b] (6)
Phone: 
International: 
Fax: 

Occupation: 305 - PATIENT
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name:</th>
<th>Event Date (B3): 13-Apr-2004</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW5006671</td>
<td>NONE</td>
<td>Date Received</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>04-May-2008</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Report Type:</td>
<td>INJURY</td>
<td></td>
</tr>
<tr>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
</tr>
<tr>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volun 09-MAY-2008: LASER VISION CORRECTION SURGERY. AN INEXPERIENCED SURGEON OR DEFECTIVE MACHINE CUT FLAP TOO DEEP LEAVING A BULGE ON MY EYE. SECOND SURGERY IN 2005 -BY THE SAME SURGEON- TO REMOVE BULGE, DAMAGES THE CORNEA AND LEAVES ME WITH THE UNCURABLE EYE DISEASE PINGUECULA. THE SURGEON CONTENDS I HAVE DRY EYE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation: N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11): 09-MAY-2008:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:**
- **Device Type:** LASER VISION CORRECTION SURGERY MACHINE
- **Device Type:**
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:**
  - **Other ID:**
- **Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Email:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT

Date Last Updated: 11/2/2010 9:17 AM

Recd: 1,044

Page: 2,105
Event Description (B5):
Volun 09-MAY-2008: LASIK SURGERY - BOTH EYES HAVE THE OPTICAL ZONE DECENTERED, ONE SO SEVERELY THAT MY VISION IS EXTREMELY BLURRY OUT OF THAT EYE AND THE OTHER IS ONLY MILDLY BLURRY, BUT THE BLURRINESS OF THE BAD EYE INTERFERES WITH THE VISION IN THE GOOD EYE. SEVERE DRY EYES. HALOS AND STARBURSTING, ESPECIALLY AT NIGHT. VISION FLUCTUATES THROUGHOUT THE DAY. I WAS GIVEN "MONOVISION" WITHOUT TESTING WITH A CONTACT LENS STIMULATION FIRST TO SEE IF I COULD ADJUST TO MONOVISION. I WAS NOT INFORMED VERY WELL OF ALL THE POTENTIAL DANGERS AND NOT INFORMED AT ALL OF THE LOSS OF CONTRAST I WOULD EXPERIENCE WITH MONOVISION. I WAS NOT INFORMED THAT THERE WOULD BE A STRONG POSSIBILITY FOR A LOSS OF VISUAL ACUITY AND WHAT THAT WOULD MEAN TO ME IN FUNCTIONAL TERMS. I NEVER WOULD HAVE SACRIFICED THE SHARPNESS OF VISION I USED TO HAVE JUST TO GO WITHOUT GLASSES. A CONSUMER IS NOT PROTECTED FROM SOMEONE TAKING THEIR MONEY AND PERFORMING THE OPERATION - EVEN IF THEY ARE A POOR CANDIDATE FOR LASIK, BECAUSE OF TORT REFORM. THE CONSUMER HAS NO PROTECTION.

Concomitant Medical Products:

Mfr Name:
Address:

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
09-MAY-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:**
- **Device Type:** LASER KERATOME
- **Device Type:**
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-Dec-2007</td>
<td>INJURY</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Outcome (B2):</th>
<th>Reporter Occupation (E3):</th>
<th>Event Location (F12):</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>305 - PATIENT</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Mfr Rec'd (G4):</th>
<th>Product Code:</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-May-2008</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td>Device Operator:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Description (B5):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volun 15-MAY-2008: I RECEIVED LASER EYE SURGERY IN LATE 2007. WITHIN 3 MONTHS, IT WAS CLEAR THAT I NEED TO HAVE MY RIGHT EYE TREATED AGAIN.</td>
</tr>
</tbody>
</table>

Concomitant Medical Products:

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Device Available for Evaluation:</th>
<th>Device Evaluated by Manufacturer (H3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>No Answer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Remedial Action (H7):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction/Removal No (H9):</td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
</tr>
<tr>
<td>15-MAY-2008:</td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>DEVICE INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand:</strong> LASIK</td>
</tr>
<tr>
<td><strong>Device Type:</strong> LASER EYE SURGERY</td>
</tr>
</tbody>
</table>

| **Catalog:** |
| **Serial:** (*confidential*) |
| **Lot:** |
| **Other ID:** |

| Reprocessed & Reused: | N/A |

<table>
<thead>
<tr>
<th>REPORTER INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong> [REDACTED]</td>
</tr>
<tr>
<td><strong>Address:</strong> [REDACTED]</td>
</tr>
<tr>
<td><strong>Health Professional:</strong> No</td>
</tr>
</tbody>
</table>

| **Email:** [REDACTED] |
| **Phone:** [REDACTED] |
| **International:** |
| **Fax:** |

| **Occupation:** 305 - PATIENT |

Date Last Updated: 11/2/2010  9:17 AM
Recd: 1,046  Page: 2,109
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5007039</th>
<th>Mfr Name:</th>
<th>VISIX INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>20-Aug-2001</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>25-May-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>401 - BIOMEDICAL ENGINEER</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Volun 30-MAY-2008: IN 2001, I HAD LASIK, FIRST ON ONE EYE AND THEN ON THE OTHER EYE ONE WEEK LATER, AT A CLINIC. I HAVE STRUGGLED WITH DRY EYE EVER SINCE, RANGING FROM MILDLY TO SEVERELY ANNOYING. DESPITE HAVING TRIED PUNCTAL PLUGS, DAILY HOT COMPRESSIONS, AND DOXYCYCLINE THERAPY, MY MEIBOMIAN GLANDS HAVE NEVER RETURNED TO NORMAL FUNCTION. OF COURSE, I HAVE SINCE LEARNED THIS IS CONSIDERED A 'MINOR' LASIK 'SIDE EFFECT', MOST LIKELY DUE TO THE PERMANENT NERVE DAMAGE WROUGHT BY THE MICROKERATOME - HANSATEME- AND EXCIMER LASER -VISX- DEVICES YOUR AGENCY HAS APPROVED FOR MEDICALLY UNNECESSARY PURPOSES. I OBSERVED MY FIRST FLOATERS--SIGNS OF A POSTERIOR VITREOUS DETACHMENT--WITHIN WEEKS OF THE LASIK SURGERY - REPORTED SEPTEMBER 2001. THIS I HAVE LEARNED IS DUE TO THE HIGH PRESSURE CAUSED BY THE SUCTION RING USED WITH THE MICROKERATOME, WHICH YOUR AGENCY HAS APPROVED FOR MEDICALLY UNNECESSARY PURPOSES. I NOTICED DOUBLE VISION SYMPTOMS, ESPECIALLY AT NIGHT, SOON AFTER THE SURGERY. I WAS RELIEVED IN 2002 THAT I WAS ABLE TO GET A PRESCRIPTION THAT SEEMED TO RELIEVE THESE SYMPTOMS. HOWEVER, OVER THE NEXT SEVERAL YEARS, I WENT IN FOR SEVERAL MORE PRESCRIPTIONS, EACH PROVING A BIT LESS SATISFACTORY THAN THE LAST. FINALLY, IN 2007, I WAS DIAGNOSED WITH POST-LASIK ECTASIA, AS MY CORNEAL TOPOGRAPHIES SHOWED THE TRADEMARK SIGN OF INFERIOR STEEPENING, WHICH ACCOUNTED FOR MY INCREASING CYLINDER AND INCREASING SYMPTOMS OF DOUBLE/MULTIPLE VISION. I HAVE THICK CORNEAS, HAD STABLE REFRACTION FOR 2 YEARS, AND MEASUREMENTS OF FLAP THICKNESS WITH AN ARTEMIS DEVICE SHOWED NO SIGNS OF A TOO-DEEP FLAP THICKNESS. IN OTHER WORDS, I WAS A 'PERFECT' CANDIDATE, WHOSE PREOPERATIVE TOPOGRAPHY -WHICH SHOWED ~0.5 D OF INFERIOR STEEPENING- WOULD PROBABLY NOT BE TURNED AWAY TODAY DESPITE THE NEW 'STRICTER' GUIDELINES BEING SUGGESTED. THE REALITY OF COURSE, IS THAT NOBODY IS A GOOD CANDIDATE TO HAVE THEIR CORNEAL STRENGTH WEAKENED BY A THIRD BY A MICROKERATOME, FOR NO MEDICALLY INDICATED PURPOSE. HOWEVER, THIS BUTCHERY REMAINS APPROVED BY YOUR AGENCY. THE REALITY IS THAT KERATOCONUS REMAINS POORLY UNDERSTOOD. AT THIS POINT, I'M STILL -BARELY- CORRECTABLE TO 20/20, SO BY SOME ACCOUNTS I'M 'NORMAL', DESPITE THE FACT THAT ONE CAN SEE 20/20 -OR 20/16- WITH SIGNIFICANT IRREGULAR ASTIGMATISM THAT IS ANYTHING BUT 'NORMAL'. THIS HAS BEEN KNOWN IN THE KERATOCONUS LITERATURE FOR YEARS. YET YOUR AGENCY CONTINUES TO EMPLOY OUTDATED VISUAL ACUITY MEASUREMENTS AS THE 'CLINICAL OUTCOME' MEASUREMENT FOR APPROVING DEVICES. THIS IS CONVENIENT FOR THE DOCTORS, ESPECIALLY SO BECAUSE '20/20' HAS BEEN POPULARLY MISUNDERSTOOD AS 'PERFECT' VISION, WHEN IT IS ANYTHING BUT. IN THE LAST SEVERAL YEARS, I HAVE READ WITH INTEREST ABOUT 'WAVEFRONT-GUIDED' TREATMENTS, WITH AN INTEREST IN REDUCING MY IRREGULAR ASTIGMATISM. I HAVE BEEN SHOCKED AND APPALLED TO SEE THAT DEVICES MARKETED AS BEING EFFECTIVE IN REDUCING HIGHER-ORDER ABERRATIONS HAVE ACTUALLY SHOWN NO DATA TO THIS EFFECT, WHATSOEVER. IN FACT, THEY MERELY REDUCE THE AMOUNT OF INDUCED HIGHER-ORDER ABERRATIONS. THEY HAVE REDUCED HOAS IN PATIENTS WITH INITIALLY HIGH LEVELS, BUT THE REDUCTIONS HAVE BEEN SMALL. IT'S SHOCKING THAT DEVICES KNOWN TO INCREASE HIGHER-ORDER ABERRATIONS -ON AVERAGE/ ARE APPROVED FOR GENERAL USE. SHOULD NOT PEOPLE BE WARNED THAT THEIR HOAS--THEIR QUALITY OF VISION--/ WILL/ BE REDUCED? -THOUGH MAYBE NOT ENOUGH THAT THEY'LL NOTICE OR CARE. NOW I AM CONSIDERING A TOPOGRAPHY-GUIDED ABLATION, AS THIS IS THE ONLY APPROACH THAT HAS SOME TRACK RECORD OF CONSISTENTLY REDUCING IRREGULAR ASTIGMATISM AND HOAS BY SIGNIFICANT AMOUNTS. INDEED, SEVERAL DOCTORS IN ANOTHER COUNTRY HAVE NOW SEVERAL CASES OF IMPROVING FORME FRUSTE KERATOCONUS PATIENTS' BEST-CORRECTED VISION. HOWEVER, YOUR AGENCY HAS NOT SEEN FIT TO AT LEAST GIVE HUMANITARIAN APPROVAL TO THE LASER REFRACTIVE SURGERY DEVICES THAT /DO/ HAVE A RECORD IN REDUCING IRREGULAR ASTIGMATISM -E.G. THE SUITE FROM IVIS TECHNOLOGIES AND/OR THE TOPOGRAPHY-GUIDED OPTIONS FROM WAVELIGHT-, WHICH IS A LEGITIMATE
Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
30-MAY-2008:

DEVICE INFORMATION:
  Brand: STAR LASER
  Device Type: LASER
  Device Type:
    Catalog:
    Serial: (*confidential*)
    Lot:
    Other ID:

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received: 02-Jun-2008
Event Date (B3): 31-May-2008
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Adverse Event (B1): Y
Problem (B1): Y
Report Date (B4): 02-Jun-2008
Event Location (F12): Reporter Occupation (E3): 305 - PATIENT
Event Report Type: OTHER
Report Date (F8): 02-Jun-2008
Event Outcome (B2): REQUIRED INTERVENTION
Adverse Event (B1): Y
Problem (B1): Y
Date Mfr Rec'd (G4): Voluntary Report No: MW5007108
Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Operator: Voluntary Report No: MW5007108
Device Age (F9): Manufacture Date (H4): Expiration Date: Single Use (H5): Device Usage (H8):
Event Description (B5):
Volun 09-JUN-2008: HAD LASER TEETH WHITENING TREATMENT. A GEL LIKE SOLUTION WAS APPLIED TO A MOUTH PIECE, PLACED INTO MY MOUTH, THEN A LASER-LIGHT- WAS PLACED TOUCHING MY LIPS. TREATMENT LASTED APPROX. 30 MIN. THERE WAS A TINGLING FEELING IN MY LIPS. TECH SAID IT WAS NORMAL, IT WOULD GO AWAY. WELL, IT GOT WORST WITH TIME, MY LIPS STARTED SWELLING TO TRIPLE THERE SIZE, THIS IS 48 HOURS LATER AND CONTINUE SWOLLEN AND BURNED DRY AND WHITE SPOTS. I AM CONCERNED ABOUT THIS REACTION. SHOULD I SEEK THE ADVICE OF A DERMATOLOGIST OR APPLY SOMETHING TO MY LIPS? IT IS DIFFICULT TO EAT COLD OR HOT FOOD. I AM ALLERGIC TO IODINE AND SEAFOOD. THE MOUTH PIECE HAD A BAD CHEMICAL TASTE "UNK". I JUST WANT TO KNOW WHAT TO DO! ASAP. CALLED THE COMPANY AND THEY WERE NOT VERY HELPFUL. I UNDERSTAND THAT THE PRODUCT IS SAFE, BUT I HAD A BAD REACTION THAT NEEDS TO BE ADDRESSED. DATES OF USE: 2008, 30-35 MINUTES. DIAGNOSIS OR REASON FOR USE: TEETH WHITENING.

Concomitant Medical Products:

Mfr Name: UNKNOWN
Address:

Device Available for Evaluation:

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11): 09-JUN-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:**
- **Device Type:** LASER
- **Device Type:** UNK
- **Catalog:** UNK
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:**

**Reprocessed & Reused:** N/A
Voluntary Report No: MW5007223
Mfr Name: VISX INCORPORATED, A SUBSIDIARY OF AMO INC.

Event Date (B3): 22-Aug-2000
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Adverse Event (B1): Y
Problem (B1): Y
Event Location (F12):
Report Source (G3):
Device Operator: HEALTH PROFESSIONAL

Report Date (B4): 05-Jun-2008
Event Description (B5):
Volun 11-JUN-2008: I WAS DAMAGED BY LASIK IN MY LEFT EYE IN 2000. HE FINALLY ADMITTED THAT I HAD A DECENTRATION AND WRINKLES IN MY FLAP, BUT THAT HE DIDN'T HAVE THE LASER TO FIX THE PROBLEM. I HAD TO GO TO A SPECIALIST IN ANOTHER COUNTRY, TO TRY TO GET MY EYE FIXED BUT IT WAS DAMAGED TOO BAD AND I HAD TO RECEIVE A CORNEAL TRANSPLANT. DR TOLD ME HE WOULD FOOT THE BILL OR REIMBURSE ME FOR THE SURGERIES THAT IT WOULD TAKE TO FIX MY EYE, I BELIEVED HIM AND NEVER WENT TO A LAWYER. ONCE IT CAME TIME TO BE REIMBURSED, HE SAID HE DIDN'T REMEMBER SAYING THAT HE WOULD REIMBURSE ME, AND MY STATUTE OF LIMITATIONS RAN OUT. I NEVER REC'D A DIME FROM HIM. I HAD TO FOOT THE BILL ON THIS BY MYSELF. I LOST MY HOUSE FROM THESE HIGH SURGERY BILLS AND NOW HAVE TO LIVE WITH A CORNEAL TRANSPLANT BECAUSE OF THIS DR. NOT ONE TIME OVER THE YEARS HAS HE EVER DROPPED A CALL OR A LETTER TO SEE HOW MY EYE WAS DOING. THIS GUY SHOULDN'T EVEN BE A DR IN MY OPINION. HE NOW HAS A CLINIC IN ANOTHER COUNTRY, AND I WONDER HOW MANY OTHER PEOPLE HE HAS DAMAGED SINCE ME.

Concomitant Medical Products:

Mfr Name: VISX INCORPORATED, A SUBSIDIARY OF AMO INC.
Address: 
Device Available for Evaluation: No Answer
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11):
11-JUN-2008:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VISIX LASER
Device Type: LASER
Catalog: 
Serial: (*confidential*)
Lot: 
Other ID: 

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]
EMAIL: [redacted]
Phone: [redacted]
Health Professional: No
International: 
Fax: 
Occupation: OTHER

Date Last Updated: 11/2/2010 9:17 AM
Page: 2,116
Recd: 1,049
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5007344</th>
<th>Mfr Name:</th>
<th>BAUSCH &amp; LOMB, INC.</th>
<th>Date Received</th>
<th>13-Jun-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Nov-2003</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (B4)</td>
<td>13-Jun-2008</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
<td>Problem (B1):</td>
<td>N</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):

Volun 20-JUN-2008: IN 2003, I UNDERWENT A BILATERAL LASIK PROCEDURE ON MY EYES AT LASIK PLUS. A DR PERFORMED THE PROCEDURE. IN THE MOS AND YRS THAT FOLLOWED I DEVELOPED WORSENING VISION, STARBURSTSS AND HALOS, UNTIL THE POINT THAT IMAGES BEGAN TO DOUBLE AND MULTIPLY. I DID NOT KNOW IT AT THE TIME BUT HAVE SINCE BEEN EVALUATED BY OTHER DRS AND TOLD THAT I NOW HAVE A CONDITION CALLED ECTASIA AND IT IS DIRECTLY DUE TO HAVING UNDERWENT LASIK. IN 2005, MY LEFT EYE HAD GOTTEN SO BAD THAT I HAD TO HAVE A CORNEA TRANSPLANT. MY RIGHT EYE ALSO HAS ECTASIA AND WILL REQUIRE A TRANSPLANT AS WELL. FOR ME THE "PROBLEM" AND "USER ERROR" IS THE FACT THAT I FEEL LASIK PLUS DOES NOT ALLOW FOR ADEQUATE SCREENING, LASIK PLUS ADVERTISES AS THOUGH EVERYONE IS A PERFECT CANDIDATE FOR THE PROCEDURE. THERE HAS BEEN NO LASTING LAW TO PREVENT THEM FROM CONTINUING EXPLICITLY ADVERTISE AS AN EQUALLY SAFE CHOICE AS WEARING GLASSES. WHILE IT MIGHT BE SAFE FOR SOME, IT IS NOT SAFE FOR EVERYONE! YET THE ADVERTISING TOUTS THE SAFETY AND HYPE. ONE BIG OPERATIONAL HAZARD THAT ALLOWED THE MISTAKE ON MY EYES TO HAPPEN WAS THE LACK OF ATTN TO DETAIL. MY CHART WAS NOT GIVEN ADEQUATE TIME FOR SCRUTINY OR DISCUSSION. I WAS NOT ALERTED TO THE FACT THAT MY CORNEAS WERE THIN, OR THAT THIS WAS AN IMPORTANT VARIABLE FOR A SAFE PROCEDURE. AT THE TIME OF MY PROCEDURE, I WAS CRAMMED INTO A ROOM WITH 6 OTHER PTS AND NOT GIVEN ANY PERSONAL TIME WITH THE DR TO ASK QUESTIONS. MEDICAL HISTORY IS A SENSITIVE TOPIC, AND ONE THAT SHOULD NOT HAVE BEEN DISCUSSED HASTEFULLY IN FRONT OF SEVERAL OTHER PTS. I WISH I HAD KNOWN THAT MY CORNEAS WERE THINNER THAN NORMAL, I MYSELF WOULD HAVE OBJECTED TO THE OPERATION. I HAVE A SEPARATE COMPLAINT AGAINST THE LASIK PLUS DR.

Concomitant Medical Products:

Mfr Name: *
Address: *
*,
UNKNOWN
Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
20-JUN-2008:

DEVICE INFORMATION:

Brand: BAUSCH AND LOMB
Device Type: LASER
Device Type: *
Catalog: *
Serial: (*confidential*)
Lot: *
Other ID: *

Reprocessed & Reused: N
Voluntary Report No: MW5007367  Date Received: 10-Jun-2008

Event Date (B3): 01-Jan-1999  Event Report Type: INJURY  Adverse Event (B1): Y
Report Date (B4): 10-Jun-2008  Event Outcome (B2):
Report Date (F8):
Date Mfr Rec'd (G4):

Event Location (F12): Reporter Occupation (E3): OTHER
Report Source (G3): Device Operator:

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9): Manufacture Date (H4):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 25-JUN-2008: I TREATED WITH DR. CT FOR LASER TATTOO REMOVAL FOR A TATTOO ON MY LEFT SHIN. MY FIRST TREATMENT WAS IN 1999 ... TO DATE, I STILL HAVE A HALF-REMOVED, TATTOO. THE REASON BEING, IS THAT MY LAST LASER TREATMENT CREATED AN AWFUL REACTION. MY SKIN BECAME INFLAMED, DEEPLY REDDENED/SCARRED, AND SEVERELY ITCHY AND KEOLOIDED. ONE MIGHT ARGUE THAT THIS IS THE NORMAL REACTION, HOWEVER, I HAVE NOT GONE BACK FOR A TREATMENT SINCE 2000, AND STILL AM HAVING CONSTANT INFLAMMATIONS, BLEEDING, DARKER SCARRING, TO THIS DAY. MY SKIN APPEARS TO HAVE BEEN HALF BURNED OFF. IT IS ATROCIOUS. I GET A "FLARE-UP" AT LEAST EVERY OTHER MONTH, OF WHICH I CANNOT HEAL. IT NEVER STOPS. THESCRATCHING MAKES RAISED BUMPS IN THE EXACT SHAPE OF MY TATTOO. IT HAS SCARED ME FROM RETURNING TO FINISH THE REMOVAL PROCESS. YET, I HAVE SUFFERED THROUGH COUNTLESS SUMMERS OF NO SHORTS, OR DRESSES. THIS HALF REMOVED BUMPY DISASTER IS RUINING MY LIFE! I AM MORE SELF CONSCIOUS OF THE RESULTS OF THE HALF REMOVAL, THAN OF THE INITIAL TATTOO. I REALLY FELT IT FAIR TO MENTION, THAT I AM NOT SOLD ON TATTOO LASER SURGERY. I MAY BE AN EXCEPTION OF SOME SORT, BUT I SUFFER DAILY. THOUGH THE BEST MESSAGE WOULD PROBABLY BE DON'T GET ONE IN A VISIBLE PLACE, IF AT ALL, REMOVAL IS NOT ALWAYS AN EASY OPTION.

Concomitant Medical Products:

Mfr Name:
Address:

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
25-JUN-2008:

DEVICE INFORMATION:

Brand:
Device Type: LASER TATTOO REMOVAL
Device Type:
Catalog:
  Serial: (*confidential*)
  Lot:
Other ID:

Reprocessed & Reused: N/A
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5007778</th>
<th>Mfr Name:</th>
<th>BIOLITEC, INC.</th>
</tr>
</thead>
</table>

**Event Date (B3):** 23-Jul-2008  
**Event Report Type:** MALFUNCTION  
**Adverse Event (B1):** Problem (B1): Y

**Report Date (B4):** 23-Jul-2008  
**Event Outcome (B2):**

**Report Date (F8):**

**Date Mfr Rec’d (G4):**

**Product Code:** (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)

**Device Operator:** HEALTH PROFESSIONAL

**Device Usage (H8):**

**Event Description (B5):**

**Concomitant Medical Products:**

**Mfr Name:** BIOLITEC  
**Address:** 515 SHAKER ROAD  
EAST LONGMEADOW, MA  
UNITED STATES

**Device Available for Evaluation:** Y

**Device Evaluated by Manufacturer (H3):** No Answer

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):** 30-JUL-2008:
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** BIOLITIC SIDEFIBER ASSEMBLY, 980NM DIODE
- **Device Type:** LASER FIBER
- **Device Type:** SF-980-DL
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** E08-0287-B
- **Other ID:** CRM083006

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5008014</th>
<th>Mfr Name:</th>
<th>VISX INCORPORATED, A SUBSIDIARY OF AMO INC.</th>
<th>Date Received</th>
<th>15-Aug-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>30-May-2004</td>
<td>Event Report Type:</td>
<td>INJURY</td>
<td>Adverse Event (B1):</td>
<td>Y</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>600 - ATTORNEY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>21-AUG-2008</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5): Volun 21-AUG-2008: LASIK EYE SURGERY RESULTING IN PARTIAL BLINDNESS IN RIGHT EYE.

Concomitant Medical Products: SURGEONS.

Mfr Name: 
Address: 

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
21-AUG-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: VISIX - LASER
Device Type: LASER
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N
### MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

#### Voluntary Report No: MW5008735

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>07-Oct-2008</td>
<td>13-Oct-2008</td>
<td>INJURY</td>
<td>OTHER SERIOUS</td>
<td>Y</td>
<td>Y</td>
<td>OTHER</td>
<td>OTHER</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Event Description (B5):

Volun 29-OCT-2008: LASER FIBER TIP BROKE OFF IN PT'S BLADDER.

#### Concomitant Medical Products:

NA

#### Device Available for Evaluation:

No Answer

#### Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):

29-OCT-2008:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: FIBER TECH GMBH
Device Type: LASER FIBER
Device Type: BARE FIBER FT IR365/400ST/3SM-F
Catalog: (*confidential*)
Serial: Lot: 0807044
Lot: Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: Address:
(b) (6) (b) (b)

EMAIL:
Phone: (b) (6)
International:
Fax:

Health Professional: Yes

Occupation: OTHER
**MAUDE EVENT REPORT (FOI)**

**SORTED BY**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**Date Received**

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5008873</th>
<th>Mfr Name:</th>
<th>FIBERTECH USA, INC.</th>
<th>Date Received</th>
<th>04-Nov-2008</th>
</tr>
</thead>
</table>

**Event Date (B3):** 07-Oct-2008  
**Report Date (B4):** 13-Oct-2008  
**Report Date (F8):**  
**Date Mfr Rec'd (G4):**  
**Product Code:** (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)  
**Device Operator:** HEALTH PROFESSIONAL  
**Event Description (B5):** Volun 10-NOV-2008: LASER FIBER TIP BROKE OFF IN PT'S BLADDER.  
**Device Available for Evaluation:** N  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 10-NOV-2008:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** FIBER TECH GMBH
- **Device Type:** LASER FIBER
- **Device Type:** BARE FIBER FT IR365/4005T/35M-F
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:** 0807044
- **Other ID:**

**Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Email:**
- **Phone:**
  - **International:**
- **Fax:**

**Health Professional:** Yes

**Occupation:** 002 - NURSE
### MAUDE EVENT REPORT (FOI)

**Sorted By**

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5009628</th>
<th>Mfr Name: RELIANT TECHNOLOGIES, INC.</th>
<th>Date Received: 14-Jan-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>01-Mar-2007</td>
<td>Event Report Type: INJURY</td>
<td>Adverse Event (B1): Y</td>
</tr>
<tr>
<td>Report Date (B4)</td>
<td>14-Jan-2009</td>
<td>Event Outcome (B2):</td>
<td>Problem (B1): N</td>
</tr>
<tr>
<td>Report Date (F8)</td>
<td></td>
<td>Reporter Occupation (E3): 305 - PATIENT</td>
<td>Event Location (F12):</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator: HEALTH PROFESSION</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 27-JAN-2009: HYPERPIGMENTATION CAUSED BY FRAXEL LASER SKIN RESURFACING: I WENT TO A DERMATOLOGIST FOR SKIN LIGHTENING TREATMENT, SPECIFICALLY TO ELIMINATE A FEW DARK SPOTS ON MY FACE CAUSED BY CYSTIC ACNE. MY DOCTOR HIGHLY RECOMMENDED FRAXEL AND WAS ADVISED THAT I WOULD NEED SEVERAL TREATMENTS TO ACHIEVE BEST RESULTS. I WENT IN FOR MY FIRST -AND ONLY- TREATMENT IN 2007. WE STARTED BY TAKING "BEFORE" PHOTOS, SO WE COULD MONITOR MY PROGRESS OVER THE COURSE OF THE TREATMENTS. THE PROCEDURE WENT EXACTLY AS I HAD BEEN TOLD. SOME MILD PAIN, SOME REDNESS AND SWELLING ON DAY TWO AND THREE, FOLLOWED BY SOME PEELING FOR ABOUT A WEEK. I DID EVERYTHING THE DOCTOR TOLD ME TO -- USED 50+ SUNSCREEN. USED MILD CLEANSERS DURING THE HEALING PHASE, DIDN'T SCRUB MY FACE. INITIALLY I NOTICED SOME IMPROVEMENT IN MY SKIN'S TEXTURE BUT ALSO NOTICED DARKNESS ACROSS MY CHEEKS WHERE PREVIOUSLY THERE HAD BEEN NONE. I'M SO GLAD THAT WE HAD THOSE "BEFORE" PHOTOS AS A REFERENCE BECAUSE WHEN I WENT IN IN MAY FOR MY FOLLOW-UP VISIT, THE "AFTER" PHOTOS CONFIRMED NEW HYPERPIGMENTATION, WHICH MY DOCTOR DETERMINED WAS DUE TO THE FRAXEL. BECAUSE OF MY SKIN'S REACTION TO THE FIRST TREATMENT, I DECIDED NOT TO SCHEDULE SUBSEQUENT TREATMENTS. MY DOCTOR THEN PRESCRIBED A HYDROQUINONE CREAM, WHICH ELIMINATED MY DARK ACNE SPOTS WITHIN SIX WEEKS. I'VE CONTINUED TO USE IT OFF AND ON FOR OVER A YEAR ON THE HYPERPIGMENTATION CAUSED BY THE FRAXEL LASER BUT IT HASN'T COMPLETELY ELIMINATED THE HYPERPIGMENTATION. DATE OF USE: 2007. DIAGNOSIS OR REASON FOR USE: DARK ACNE SPOTS. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED? NO.

**Concomitant Medical Products:**

- **Mfr Name:** RELIANT TECHNOLOGIES
- **Address:** MOUNTAIN VIEW, CA UNITED STATES
- **Device Available for Evaluation:** N
- **Device Evaluated by Manufacturer (H3):** No Answer
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
27-JAN-2009:

DEVICE INFORMATION:

Brand: FRAXEL
Device Type: LASER SKIN RESURFACER

Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5009887  Mfr Name: NIDEK, INC.

Event Date (B3): 10-Feb-2006  Event Report Type: OTHER  Adverse Event (B1): N
Report Date (B4): 09-Feb-2008  Event Outcome (B2):
Report Date (F8): 11-Feb-2009  Reporter Occupation (E3): OTHER  Event Location (F12):
Date Mfr Rec'd (G4): 09-Feb-2009  Device Operator: LAY USER/PATIENT  Report Source (G3):

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):
Volun 11-FEB-2009: PE STATES AFTER A SECOND LASER SURGERY, SHE EXPERIENCED FLOATERS IN BOTH EYES. PE STATES THAT THE DOCTOR TOLD HER THAT THE SURGERY DID NOT CAUSE THE FLOATERS. REPORTS THAT SHE WENT TO HER EYE CARE DOCTOR AND WAS TOLD THAT SHE HAD SEVERE DRY EYES, EPITHELIAL INGROWTH, IN HER RIGHT EYE AND SAHARA SANDS IN HER LEFT EYE. STATES THAT THE DOCTOR WHO DID THE LASER SURGERY DID NOT FIND THESE PROBLEMS AND WILL NOT RETURN HER PHONE CALLS.

Concomitant Medical Products:

Mfr Name:
Address: 47651 WESTINGTON HOUSE DR
FREMOUNT, CA 94539
UNITED STATES

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
11-FEB-2009:

Report Date (F8): 09-Feb-2008  Event Outcome (B2):
Report Date (F8): 11-Feb-2009  Reporter Occupation (E3):
Date Mfr Rec'd (G4): 09-Feb-2009  Device Operator: LAY USER/PATIENT  Report Source (G3):

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Age (F9): Manufacture Date (H4):
Expiration Date: Single Use (H5):
Device Usage (H8):

Event Description (B5):
Volun 11-FEB-2009: PE STATES AFTER A SECOND LASER SURGERY, SHE EXPERIENCED FLOATERS IN BOTH EYES. PE STATES THAT THE DOCTOR TOLD HER THAT THE SURGERY DID NOT CAUSE THE FLOATERS. REPORTS THAT SHE WENT TO HER EYE CARE DOCTOR AND WAS TOLD THAT SHE HAD SEVERE DRY EYES, EPITHELIAL INGROWTH, IN HER RIGHT EYE AND SAHARA SANDS IN HER LEFT EYE. STATES THAT THE DOCTOR WHO DID THE LASER SURGERY DID NOT FIND THESE PROBLEMS AND WILL NOT RETURN HER PHONE CALLS.

Concomitant Medical Products:

Mfr Name:
Address: 47651 WESTINGTON HOUSE DR
FREMOUNT, CA 94539
UNITED STATES

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
11-FEB-2009:
MAUDE EVENT REPORT (FOI)

DEVICE INFORMATION:

Brand: NIDEK QUEST
Device Type: LASER SYSTEM

Reprocessed & Reused: N/A
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MW5011210</td>
<td>NONE</td>
<td>15-Feb-2008</td>
<td>INJURY</td>
<td>Y</td>
<td>REQUIRED INTERVENTION</td>
<td>305 - PATIENT</td>
<td></td>
<td>02-Nov-2010</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>21-May-2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volun 28-MAY-2009:</td>
<td>I HAD LASIK PERFORMED IN 2008. THE PROCEDURE CAUSED ME TO WIND UP WITH DRY EYE SYNDROME. I WAS TOLD TO USE RESTASIS, TAKE BIOTEAR GEL CAPS AND EAT A LOT OF OMEGA 3 FOODS. I HAVE TO PUT DROPS/GEL IN MY EYES ON AN HOURLY BASIS DUE TO THE PAIN. I CAN'T USE THE AIR CONDITIONING OR BE OUTSIDE BECAUSE OF THE WIND/HEAT/SUN -I LIVE IN DRY.- I HAVE TROUBLE CONCENTRATING AT WORK DUE TO PAIN. I WORK ON A COMPUTER ALL DAY AND I HAVE AN AC RETURN DIRECTLY ABOVE ME. I WAS TOLD MY LIFE WOULD CHANGE -I THOUGHT THEY MEANT FOR THE BETTER, NOT WORSE-. I SPEND MORE MONEY NOW THAN I DID BEFORE I HAD THE SURGERY. I STILL WEAR GLASSES, THE ONLY DIFFERENCE IS I AM IN CONTINUAL PAIN AND HAVE LIMITATIONS IN MY DAILY ROUTINES. IF I HAD BEEN PROPERLY INFORMED, I WOULD HAVE SAID, NO, THANK YOU. THE PAIN IS NOT WORTH BEING ABLE TO SEE BETTER -AND I STILL DON'T HAVE 20/20-. I HAD ALMOST A MINUS NINE --9- DIOPTER IN BOTH EYES. BELIEVE ME IN THE SEVEREST OF PAIN, THERE ARE TIMES WHEN THOUGHTS COME TO YOU LIKE I DON'T WANT TO LIVE LIKE THIS. I CAN'T DO THIS ANY MORE. THE ONLY THING THAT KEEPS ME GOING IS THAT I KNOW IN MY HEART THAT GOD IS GOOD AND HE IS GOING TO HELP ME OVERCOME THIS. IT'S EMOTIONALLY FRUSTRATING BECAUSE THERE ISN'T ANYTHING ANYONE CAN REALLY DO.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>28-MAY-2009:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

    Brand: NONE
    Device Type: LASER USED FOR LASIK
    Catalog:
    Serial: (*confidential*)
    Lot:
    Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

    Name: [b] (6)
    Address: [b] (6)
    EMAIL: [b] (6)
    Phone: [b] (6)
    International:
    Fax:

    Health Professional: No
    Occupation: 305 - PATIENT

Recd: 1,058
Page: 2,134

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5011601
Mfr Name: BAUSCH & LOMB, INC.

Event Date (B3): 27-Dec-2004
Report Date (B4): 17-Jun-2009
Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Report Date (F8): 305 - PATIENT
Event Location (F12):
Report Date (B4): 17-Jun-2009

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Operator: HEALTH PROFESSIONAL

Event Description (B5):
Volun 23-JUN-2009: I WENT TO A LASIK CTR ADVERTIZING 'THROW AWAY YOUR GLASSES FOREVER.' I WAS TOLD THAT NOBODY GETS COMPLICATIONS AND DON'T WORRY, YOU'RE GOING TO LOVE IT. I ORIGINALLY HAD MONOVISION WHICH MADE ME VERY DISORIENTED, AND EVENTUALLY I HAD ACUTE VERTIGO. I HAD THE MONOVISION REVERSED HOPING THIS WOULD HELP. WITHIN TWO DAYS, I WAS HOSPITALIZED WITH INTENSE VERTIGO THAT WAS EVEN WORSE. I WAS NEARSIGHTED IN ONE EYE AND FARSIGHTED IN THE OTHER WITH INDUCED ASTIGMATISM. MY VERTIGO NEVER STOPPED AND I END UP PERMANENTLY DISABLED. MY PRESCRIPTION HAS NEVER STOPPED DRIFTING. PRESCRIPTIONS HAVE BEEN CHANGED EVERY FEW MONTHS FOR NEARLY 5 YEARS. I AM WEARING GLASSES BECAUSE CONTACTS WERE VERY UNCOMFORTABLE WITH DRY EYE. THEY DO NOT WORK VERY WELL OR VERY LONG CAUSING ME HORRIBLE HEADACHES AND NAUSEA FROM STRAIN. BESIDES THIS MY EYES ARE NEVER COMFORTABLE AND BURN CONSTANTLY. I HAVE ECTASIA AND MAY NEED A CORNEAL TRANSPLANT EVENTUALLY. I'VE BEEN DIAGNOSED WITH BINOCULARITY PROBLEMS AND LATE ONSET NYSTAGMUS WHICH SEEMS TO INCREASE WITH REFRACTIVE ERROR. THE LASER WAS A BAUSCH AND LOMB. THIS WAS NEVER REPORTED AND THE DOCTOR NEVER EVEN EXAMINED ME AGAIN, BUT TOLD ME IT WASN'T LASIK RELATED.

Concomitant Medical Products:

Mfr Name: BAUSCH AND LOMB
Address:

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
23-JUN-2009:

Recd: 1,059
Page: 2,135
Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** BAUSCH AND LOMB
- **Device Type:** LASER
- **Catalog:**
  - **Serial:** (*confidential*)
  - **Lot:**
- **Other ID:**

- **Reprocessed & Reused:** N/A
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5011663
Mfr Name: CUTERA, INC.

Event Date (B3): 06-Mar-2009
Report Date (B4): 09-Jun-2009
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): 305 - PATIENT
Device Operator: HEALTH PROFESSIONAL

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 29-JUN-2009: THIS LASER WAS USED ON A CONSULTATION OFFICE VISIT. I WAS DRUGGED BY THE PHYSICIAN AND THE DOCTOR USED THE LASER ALL OVER MY FACE HANDS, FEET, LEGS JOINTS AND SEXUALLY ABUSED ME WITH IT. I HAVE SCARRING ON MY FACE PERMANENT DAMAGE, ON MY ANKLES, AND POSSIBLE PERMANENT DAMAGE TO MY FACE, EVEN USED IT ON MY HEAD. THE SCARS ARE VERY PAINFUL, MY SKIN IS WAVY AND MY ANKLES AND LEGS ARE SKINNY VAPORIZED. THEY LOOK AND FEEL BAD. DATES OF USE: 2009. EVENT REAPPEARED AFTER REINTRODUCTION: YES.

Concomitant Medical Products:

Mfr Name: CUTERA, INC.
Address:

Device Available for Evaluation:
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
29-JUN-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** CUTERA, 2790 NM WAVE LENGTH
- **Device Type:** LASER, CUTERA INC
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Email:** (b) (6)
- **Phone:** (b) (6)
- **International:**
- **Fax:**

Health Professional: No

Occupation: 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5012030</th>
<th>Mfr Name:</th>
<th>MICRON CORP.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Jul-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>16-Jul-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(GU)-LASER FOR GASTRO-UROLOGY USE (LNK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**
Volun 24-JUL-2009: MD USING A 1000 MICRON PERIPHERAL FIBER, HOLMIUM REUSEABLE LASER FIBER TO DO PROCEDURE. UPON SECOND ENTRY WITH CYSTOSCOPE THE MD PASSED THE FIBER THROUGH THE SCOPE AND NOTED THAT HET TIP WAS BROKEN. FIBER TIP EXCHANGED FOR ANOTHER DEVICE, PROCEDURE CONTINUED.

**Concomitant Medical Products:**

**Mfr Name:** MICRON  
**Address:** 7620 NORTH HARTMAN LANE #184  
TUCSON, AZ 85743  
UNITED STATES  
**Device Available for Evaluation:** R  
**Device Evaluated by Manufacturer (H3):** No Answer  
**Remedial Action (H7):**  
**Correction/Removal No (H9):**  
**Additional Mfr Narrative (H10 & H11):** 24-JUL-2009:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** MICRON
- **Device Type:** LASER FIBER
- **Device Type:** 10853
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** Yes
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 002 - NURSE
Voluntary Report No: MW5012097  
Mfr Name: DORNIER MEDTECH AMERICA, INC.  

Event Date (B3): 24-Jun-2009  
Report Date (B4): 27-Jul-2009  
Report Date (F8):  
Date Mfr Rec'd (G4):  
Product Code: (GU)-LASER FOR GASTRO-UROLOGY USE (LNK)  
Device Operator: HEALTH PROFESSIONAL  

Event Report Type: INJURY  
Event Outcome (B2): HOSPITALIZATION  
Reporter Occupation (E3): OTHER  
Report Source (G3): HEALTH PROFESSIONAL  

Adverse Event (B1): Y  
Problem (B1): N  
Event Location (F12):  
Report Date (F8): OTHER  

Event Description (B5): 
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Concomitant Medical Products:
NA

Mfr Name: DORNIER MED TECH AMERICA
Address: 1155 ROBERTS BLVD
KENNESAW, GA 30144
UNITED STATES

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
31-JUL-2009:

DEVICE INFORMATION:

Brand: DORNIER MEDLITE 20WATT
Device Type: LASER (LASER TRIPTER)
Device Type: MEDLITE 20
Catalog: NA
Serial: (*confidential*)
Lot: NA
Other ID: NA

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [redacted]
Address: [redacted]

Health Professional: Yes

EMAIL: [redacted]
Phone: [redacted]
International: [redacted]
Fax:

Occupation: OTHER
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5012167</th>
<th>Mfr Name:</th>
<th>AMS INNOVATIVE CENTER-SAN JOSE</th>
<th>Date Received</th>
<th>23-Jul-2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>10-Jul-2009</td>
<td>Event Report Type:</td>
<td>MALFUNCTION</td>
<td>Adverse Event (B1):</td>
<td>Problem (B1):</td>
</tr>
<tr>
<td>Report Date (B4)</td>
<td>23-Jul-2009</td>
<td>Event Outcome (B2):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>500 - RISK MANAGER</td>
<td>Event Location (F12):</td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>AMERICAN MEDICAL SYSTEMS, INC.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td>SAN JOSE, CA</td>
<td></td>
<td></td>
<td></td>
<td>UNITED STATES</td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10-AUG-2009:</td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: GREENLIGHT HPS-BPH FIBER OPTIC
Device Type: LASER FIBER
Device Type: 10-2090
Catalog: 
Serial: (*confidential*)
Lot: 10-2090-923U
Other ID: 

Reprocessed & Reused: N

REPORTER INFORMATION:

Name: [b] (6) [b] (6) [b] (6) [b] (6)
Address: [b] (6) [b] (6) [b] (6) [b] (6)

Health Professional: Yes

EMAIL: [b] (6) [b] (6) [b] (6) [b] (6)
Phone: [b] (6) [b] (6) [b] (6) [b] (6)
International: 
Fax: 

Occupation: 500 - RISK MANAGER
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Voluntary Report No: MW5012233
Mfr Name: CUTERA, INC.

Event Date (B3): 27-Feb-2009
Report Date (B4): 04-Aug-2009
Report Date (F8):
Date Mfr Rec'd (G4):

Event Report Type: INJURY
Event Outcome (B2): DISABILITY OR PERMANENT DAMAGE
Reporter Occupation (E3): 001 - PHYSICIAN
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Report Date (B4): 04-Aug-2009
Event Outcome (B2):
Event Location (F12):
Report Source (G3):

Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)
Device Age (F9):
Expiration Date:
Device Usage (H8):

Event Description (B5):
Volun 10-AUG-2009: PT UNDERWENT TREATMENT WITH CUTERA TITAN LASER FOR FACE BY A NURSE. NOTED SIGNIFICANT PAIN AFTER A FEW PASSES. TREATMENT WAS STOPPED BY THE TREATING NURSE. SHE DEVELOPED SEVERE SECOND AND THIRD DEGREE BURNS ON THE TREATED CHEEK, WHICH THEN REQUIRED SKIN GRAFTING TO SOME AND HAVE LEFT PERMANENT HYPERTROPHIC ERYTHEMATOUS SCARS -TOTAL # = 7 SCARS-. ACCORDING TO THE PT, THE TREATING PHYSICIAN NOTIFIED THE MANUFACTURER, CUTERA AND THE DEVICE WAS INSPECTED BY THE MANUFACTURER. SHE WAS SEEN IN OUR OFFICE IN 2009 WITH SEVEN PERMANENT LINEAR ERYTHEMATOUS AND HYPERTROPHIC SCARS ON THE CHEEK. DATES OF USE: 2009. DIAGNOSIS OR REASON FOR USE: SKIN LAXITY. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED: YES.

Concomitant Medical Products:

Mfr Name: CUTERA
Address: BRISBANE, CA
UNITED STATES

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):
Additional Mfr Narrative (H10 & H11):
10-AUG-2009:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** TITAN
- **Device Type:** LASER/LIGHT DEVICE
- **Reprocessed & Reused:** N
### Event Description (B5):


### Concomitant Medical Products:

- **Mfr Name:** SPECTRANETICS CORPORATION
- **Address:** 91 TALAMINE COURT
  COLORADO SPRINGS, CO 80907
  UNITED STATES

- **Device Available for Evaluation:** Y
- **Device Evaluated by Manufacturer (H3):** No Answer

- **Remedial Action (H7):**
- **Correction/Removal No (H9):**
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):

17-AUG-2009:

**DEVICE INFORMATION:**

- **Brand:** SPECTRANETICS LASER
- **Device Type:** LASER SURGICAL EXCIMER
- **Device Type:** CVX-300
- **Catalog:** *
- **Serial:** (*confidential*)
- **Lot:** *
- **Other ID:** *

**Reprocessed & Reused:** N

**REPORTER INFORMATION:**

<table>
<thead>
<tr>
<th>Name:</th>
<th>[b] (6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>[b] (5)</td>
</tr>
</tbody>
</table>

- **Health Professional:** Yes
- **Occupation:** 500 - RISK MANAGER
### MAUDE EVENT REPORT (FOI)

#### SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name:</th>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Event Outcome (B2):</th>
<th>Event Location (F12):</th>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW5013081</td>
<td>NONE</td>
<td>02-Jul-1999</td>
<td>INJURY</td>
<td>Y</td>
<td>OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)</td>
<td>HEALTH PROFESSIONAL</td>
<td>17-Oct-2009</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>17-Oct-2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
<td>Volun 23-OCT-2009: LASIK SURGERY IN BOTH EYES TO CORRECT VISION OF -7.0/-7.5. RESULTS : SEVERE DRY EYE, PAIN AND INFECTION THAT WOULD NOT CLEAR. REQUIRED 3 ROUNDS OF ANTIBIOTIC EYE DROPS. CORRECTION REGRESSED 1.5 DIOPTERS IN BOTH EYES BY 3 MONTHS. LEFT EYE RETREATED FOR &quot;MONOVISION&quot; CORRECTION. THIS CLEARED UP THE STUBBORN INFECTION SUSPICION THAT THE ORIGINAL SURGERY IN LEFT EYE -WITH A TORN FLAP, ABRASION- HAD SOMEHOW CAUSED BACTERIA TO ENTER EYE OR ANOTHER FOREIGN OBJECT WAS LEFT UNDER THE FLAP- NO MORE INFECTIONS. TEN MORE YEARS OF HEADACHES, DRY EYE, INCREASED ALLERGIC CONJUNCTIVITIS, VISION CORRECTION FLUCTUATIONS AND CORRECTION REGRESSION TOWARD INCREASED MYOPIA. THE &quot;MONOVISION&quot; CORRECTION PROMPTED HEADACHES AD FUSION PROBLEMS. SINCE GLASSES HAVE BEEN REQUIRED FOR VISION SINCE 3 MONTHS AFTER THE SURGERY, THE FUSION PROBLEM IS CORRECTED WITH GLASSES. HOWEVER, SINCE THE CORRECTION FLUCTUATES AND REGRESSES, NEW GLASSES WERE REQUIRED EVERY FEW MONTHS IN THE FIRST 5 YEARS. CURRENTLY, I SWITCH BACK AND FORTH BETWEEN GLASSES PRESCRIPTION APPROX. 4 TIMES A YEAR. I HAVE NOT HAD A CONSISTENT CORRECTION IN 10 YEARS.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td></td>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>23-OCT-2009:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Recd: 1,066  
Page: 2,149  
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand:
Device Type: LASER LASIK

Device Type:
Catalog:
Serial: (*confidential*)
Lot:
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name: [b] (6)
Address: [b] (6)

EMAIL: [b] (6)
Phone: [b] (6)
International: [b] (6)
Fax:

Health Professional: No

Occupation: 305 - PATIENT
<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>01-Jan-2007</th>
<th>Event Report Type:</th>
<th>INJURY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>306 - PATIENT FAMILY MEMBER OR FRIEND</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td>Report Source (G3):</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td>Volun 27-OCT-2009: A FAMILY MEMBER OF MINE HAS HAD THE CORRECTIVE LASER EYE SURGERY IN BOTH OF HER EYES. SINCE THE SURGERY, HER MAIN EYE DOCTOR HAS REMOVED HER FROM THAT DOCTOR'S CARE AND SHE IS UNABLE TO SEE AT NIGHT WELL ENOUGH TO DRIVE.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concomitant Medical Products:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfr Name:</td>
<td>UNSURE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Available for Evaluation:</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Evaluated by Manufacturer (H3):</td>
<td>No Answer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remedial Action (H7):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction/Removal No (H9):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Mfr Narrative (H10 &amp; H11):</td>
<td>27-OCT-2009:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:** UNSURE
- **Device Type:** LASER EYE SURGERY
- **Reprocessed & Reused:** N
Event Description (B5):
Volun 15-DEC-2009: LEFT STONE RETRIEVAL LITHOTRIPSY WITH LASER URETEROSCOPY BEGAN AT 1227 AND WAS ABORTED AT 1330 DUE TO MALFUNCTION OF THE LEASED LASER. PT DID NOT SUSTAIN INJURY AND WAS BROUGHT BACK FOR COMPLETION OF PROCEDURE 2 DAYS LATER. LASER REP WITH FACILITY PRESENT AND OPERATING LASER TOOK LASER OUT OF SERVICE AND BACK TO COMPANY FOR CHECK. DATES OF USE: 2009 - 1 HOUR. DIAGNOSIS OR REASON FOR USE: UROLITHIASIS.

Concomitant Medical Products:

### Device Evaluated by Manufacturer (H3):

- **Device Available for Evaluation:** R
- **Device Evaluated by Manufacturer:** No Answer
- **Remedial Action (H7):**
- **Correction/Removal No (H9):**
- **Additional Mfr Narrative (H10 & H11):**

15-DEC-2009:

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name: NEW STAR LASERS, INC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3): 23-Nov-2009</td>
<td>Event Report Type: OTHER</td>
</tr>
<tr>
<td>Report Date (B4): 08-Dec-2009</td>
<td>Event Outcome (B2):</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td>Reporter Occupation (E3): 002 - NURSE</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td>Device Operator: OTHER</td>
</tr>
<tr>
<td>Product Code: (SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td>Report Source (G3):</td>
</tr>
<tr>
<td>Device Code:</td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td>Manufacture Date (H4):</td>
</tr>
<tr>
<td>Expiration Date:</td>
<td>Single Use (H5):</td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
</tr>
<tr>
<td>Event Description (B5):</td>
<td></td>
</tr>
<tr>
<td>Volun 15-DEC-2009: LEFT STONE RETRIEVAL LITHOTRIPSY WITH LASER URETEROSCOPY BEGAN AT 1227 AND WAS ABORTED AT 1330 DUE TO MALFUNCTION OF THE LEASED LASER. PT DID NOT SUSTAIN INJURY AND WAS BROUGHT BACK FOR COMPLETION OF PROCEDURE 2 DAYS LATER. LASER REP WITH FACILITY PRESENT AND OPERATING LASER TOOK LASER OUT OF SERVICE AND BACK TO COMPANY FOR CHECK. DATES OF USE: 2009 - 1 HOUR. DIAGNOSIS OR REASON FOR USE: UROLITHIASIS.</td>
<td></td>
</tr>
</tbody>
</table>
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** HOLMIUM/ND:YAG LASER
- **Device Type:** LASER
- **Device Type:** NEW STER TFF04
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N

REPORTER INFORMATION:

- **Name:**
- **Address:**
- **Health Professional:** Yes

**EMAIL:**

**Phone:**

**International:**

**Fax:**

**Occupation:** 002 - NURSE
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>Mfr Name:</th>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW5013996</td>
<td>NONE</td>
<td>14-Dec-2009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event Date (B3):</th>
<th>Event Report Type:</th>
<th>Adverse Event (B1):</th>
<th>Problem (B1):</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-Nov-2009</td>
<td>INJURY</td>
<td>Y</td>
<td>N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report Date (B4):</th>
<th>Event Outcome (B2):</th>
<th>Event Location (F12):</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-Dec-2009</td>
<td>REQUIRED INTERVENTION</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reporter Occupation (E3):</th>
<th>Device Operator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>305 - PATIENT</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Device Age (F9):</th>
<th>Expiration Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(SU)-POWERED LASER SURGICAL INSTRUMENT (GEX)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Manufacture Date (H4):</th>
<th>Single Use (H5):</th>
<th>Device Usage (H8):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Volun 22-DEC-2009: DR USED LEVULAN KERASTICK ON ME FOR APPROX 15 KERATOSIS ON MY FOREHEAD. I HAD BEEN GIVEN A PAMPHLET RE THE TREATMENT AND DISCUSSED THE TREATMENT WITH DR. THE TREATMENT WAS TO APPLY A TOPICAL MEDICATION TO THE KERATOSIS, AND THEN TO TREAT THEM WITH PHOTODYNAMIC BLU LIGHT -PER THE INFORMATION IN THE PAMPHLET PROVIDED BY THE DOCTOR.- GOT BUSY?!- HAD AN ASSISTANT- SHE SAYS A NURSE; I NEVER MET THE WOMAN- DO THE PROCEDURE. AFTER TWO OTHER OFFICE ASSISTANTS CAME IN -- ONE GAVE ME TWO VICODIN AND TWO VALIUM, THE OTHER PUT THE KERASTICK ON MY FOREHEAD. I WAS WHEELED INTO ANOTHER ROOM WHILE WAITING FOR THE SOLUTION TO WORK PRIOR TO HAVING THE LIGHT TREATMENT. -NOTE: LEVULAN'S BROCHURE AND THE DOCTOR -- NEITHER STATED THAT THIS IS A "TWO VISIT" PROCEDURE, SO I WAS NOT AWARE THAT "IT" WAS BEING DONE WRONG BY HAVING IT DONE IN ONE OFFICE VISIT. DURING THE COURSE OF THE TREATMENT, APPARENTLY THEY WERE SUPPOSED TO HAVE LIGHTS OFF AS THEIR OFFICE LIGHTS WERE THOSE REALLY BRIGHT "INSTITUTIONAL" LIGHTS, AND NO LIGHT BRIGHT/HARSH LIGHT -FOUND OUT LATER- SHOULD BE ON THE TREATED AREAS -- SO I AM NOT SURE IF IS THEIR LACK OF PROCEDURE - THIS PART - THAT CAUSED WHAT HAS TURNED OUT TO BE PERMANENT DAMAGE, OR IF IT IS THE ACTUAL DRUG -- THOUGH THAT WAS NOT PUT ON ANY PART OF MY FACE EXCEPT THE 15 LESIONS ON MY FOREHEAD, OR THE FACT THAT DR'S OFFICE USED A LASER INSTEAD OF THE PRESCRIBED BLU-U LIGHT -- AND THE DISASTER THAT HAPPENED IS JUST BECAUSE THEY BURNED MY SKIN SO BADLY WITH A LASER -I WAS TOLD IT WAS TO BE PASSIVE-, BUT THAT LEVULAN KERASTICK WITH THE LASER, BURNT MY SKIN SO SEVERELY THAT MY FACE SWELLED AND WAS ACTIVELY BURNING FOR OVER THREE MONTHS WITH MULTIPLE INFECTIONS, SWOLLEN TISSUE AND SCARS, AND THE LASER WAS USED AROUND MY EYES -NO KERASTICK WAS USED ANYWHERE BUT MY FOREHEAD, SO THIS IS WHAT IS CONFUSING; WHY THE KERASTICK WOULD DO THIS TO MY "WHOLE FACE" -- I HAVE LOST MY EYELIDS AND HAVE SEVERE WRINKLING NOT ONLY ON MY EYELIDS, BUT ALSO THROUGHOUT MY FACE, AND TWO EDEMAS DIRECTLY CAUSED BY BURNS THAT CONTINUE TO CAUSE PAIN/SWELLING. ALSO ENLARGED PORES, BROKEN BLOOD VESSELS, SAGGING SKIN, AND SWOLLEN TISSUE IN ONE OF MY NOSTRILS -- I'M A MESS. LEVULAN'S PAMPHLET SAID THE COSMETIC RESULTS WERE EXCELLENT WITHOUT SCARRING; MY FACE IS A MESS. I AM CONFUSED BY THEIR CLAIM -- AND WOULD NOT HAVE HAD THE "VERY SMALL" KERATOSIS REMOVED FROM MY FOREHEAD IF I HAD KNOWN WHAT THEIR PRODUCT WOULD DO TO ME. I DO NOT UNDERSTAND HOW USING THE PRODUCT ON MY FOREHEAD ALLOWED "SPREADING" TO ALL AREAS OF MY FACE, INCLUDING -- AS ABOVE -- MY EYELIDS ARE COMPLETELY RUINED AND I NEED PLASTIC SURGERY TO FIX -ONE EDEMA/BURN MARK INSIDE MY CHEEK/MOUTH EVEN- AND ALL THE OTHER PROBLEMS LISTED ABOVE - I AM CONFUSED -AND HEART-BROKEN - AND THIS NEEDS TO BE TOLD WITHIN THEIR LITERATURE THAT RANDOM "SPREADING" OF THE DRUG TO OTHER AREAS NOT BEING TREATED IS A POSSIBLE DISASTROUS OUTCOME. THE DOCTOR SAID THAT HER STAFF'S USE OF A LASER WAS NOT THE CAUSE OF MY DISFIGUREMENT, SO IT MUST BE THE KERASTIC THAT WAS USED. DOSE OR AMOUNT: ONE APPLICATION. FREQUENCY: ONCE. ROUTINE: TOP. DATES OF USE: 2008. DIAGNOSIS OR REASON FOR USE: MILD KERATOSIS. EVENT ABATED AFTER USE STOPPED OR DOSE REDUCED?: NO.

Concomitant Medical Products:

2008/11/21 LEVULAN KERASTICK

Mfr Name: UNKNOWN
Address: 

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9):

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
22-DEC-2009:

DEVICE INFORMATION:

- **Brand:** UNKNOWN
- **Device Type:** LASER
- **Catalog:** (*confidential*)
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:** UNK

Reprocessed & Reused: N

REPORER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Email:** [redacted]
- **Phone:** [redacted]
- **International:** [redacted]
- **Fax:** [redacted]
- **Occupation:** 305 - PATIENT

Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5014432</th>
<th>Mfr Name:</th>
<th>VISX, INCORPORATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>21-Feb-2002</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>15-Jan-2010</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (B8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-EXCIMER LASER SYSTEM (LZS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Operator:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Event Description (B5):
Volun 25-JAN-2010: FOLLOWING LASER SURGERY FOR CORRECTION OF NEARSIGHTEDNESS, PT IMMEDIATELY BEGAN TO SEE DOUBLE WHEN READING OR DOING OTHER CLOSE-UP WORK. A SECOND LASER SURGERY WAS DONE ON THE LEFT EYE ON (B) (6) 2002, BUT THE DOUBLE VISION PROBLEM WAS NOT CORRECTED. PT DECLINED FURTHER LASER SURGERIES. EYE TESTS INDICATE PT'S VISION IS FINE, ALBEIT WITH SOME DOUBLE-SIGHTEDNESS. IF THE PT READS A BOOK FOR A WHILE BEFORE THE EYE TEST, THE RESULTS ARE GREATLY REDUCED, HOWEVER, AS THE DOUBLE VISION IN MORE SEVERE. THIS DOUBLE VISION IS NOT THE RESULT OF POOR TRACKING BETWEEN THE TWO EYES; EACH EYE INDEPENDENTLY SEES DOUBLE, WITH THE RIGHT EYE BEING MORE EXTREME. THE DOCTOR WHO DID THE LASER SURGERY COULD FIND NO REASON FOR THE DOUBLE VISION, ALTHOUGH ONE OF HIS ASSISTANTS TOLD THE PT THERE WAS MORE ASTIGMATISM PRESENT FOLLOWING THE LASER SURGERY THAN BEFORE. SEVERAL YEARS LATER, ANOTHER DOCTOR SAID THE PROBLEM WAS DRY EYE AND COULD BE CORRECTED WITH TEAR DUCT PLUGS. PT ALLOWED TEMPORARY PLUGS TO BE PLACED IN THE TEAR DUCTS, BUT THEY DID NOT STAY LONG ENOUGH TO SEE IF THERE WAS ANY BENEFIT. USE OF ARTIFICIAL TEARS DOES NOT CLEAR UP THE DOUBLE VISION. AS A RESULT OF THIS COMPLICATION OF THE LASER SURGERY, PT HAS DIFFICULTY READING FOR RELATIVELY LONG PERIODS, AND CAN DO SO ONLY BE GRADUALLY SQUINTING MORE AND MORE AT THE PAGE AND TRYING TO IGNORE THE SHADOWS OF THE DOUBLE IMAGES. DATES OF USE: LENGTH OF SURGERY ON EYES, (B) (6) 2002, LENGTH OF SURGERY ON EYE, (B) (6) 2002. DIAGNOSIS OR REASON FOR USE: NEARSIGHTEDNESS.

Concomitant Medical Products:

Mfr Name: VISX
Address: 

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 

Date Last Updated: 11/2/2010 9:17 AM
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Additional Mfr Narrative (H10 & H11):
25-JAN-2010:

<table>
<thead>
<tr>
<th>DEVICE INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand:</strong> STAR 3</td>
</tr>
<tr>
<td><strong>Device Type:</strong> LASER FOR EYE SURGERY FOR VISION CORRECTION</td>
</tr>
<tr>
<td><strong>Device Type:</strong> STAR 3</td>
</tr>
<tr>
<td><strong>Catalog:</strong></td>
</tr>
<tr>
<td><strong>Serial:</strong> (<em>confidential</em>)</td>
</tr>
<tr>
<td><strong>Lot:</strong></td>
</tr>
<tr>
<td><strong>Other ID:</strong></td>
</tr>
</tbody>
</table>

Reprocessed & Reused: N

<table>
<thead>
<tr>
<th>REPORTER INFORMATION:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name:</strong> [REDACTED]</td>
</tr>
<tr>
<td><strong>Address:</strong> [REDACTED]</td>
</tr>
<tr>
<td><strong>Health Professional:</strong> No</td>
</tr>
<tr>
<td><strong>Email:</strong> [REDACTED]</td>
</tr>
<tr>
<td><strong>Phone:</strong> [REDACTED]</td>
</tr>
<tr>
<td><strong>International:</strong></td>
</tr>
<tr>
<td><strong>Fax:</strong></td>
</tr>
</tbody>
</table>

Occupation: 305 - PATIENT
Event Description (B5):
Volun 08-MAR-2010: COMPLICATIONS FROM LASIK SURGERY IN 2005. PRIOR TO SURGERY IN 2004, I WAS DIAGNOSED WITH AN AUTOIMMUNE DISEASE - THYROID EYE DISEASE. I WAS TREATED WITH RADIATION THERAPY IN 2004 TO CONTROL INFLAMMATION IN EYES. I WAS TOLD I WAS A CANDIDATE FOR SURGERY WITH WORSE CASE SENARIO BEING I MAY HAVE TO WEAR GLASSES OR CONTACTS TO GET 20/20 VISION. VISION DETERIORATED OVER TIME AND I HAD 2 REFLOAT PROCEDURES TO TRY TO IMPROVE THE SITUATION. I HAD 12 SUTURES PLACED IN MY LEFT EYE ON THE SECOND REFLOAT PROCEDURE, TO HELP HOLD THE FLAP IN PLACE. MY VISION POST LASIK IS 20/200 IN MY LEFT EYE AND 20/70 IN MY RIGHT EYE. GLASSES DO NOT CORRECT THE PROBLEM AND CONTACTS ARE NOT AN OPTION BECAUSE I AM INTOLERANT TO THEM. I SPENT 6 MONTHS WITH A LENS SPECIALIST AT THE (B) (6) WITH NO SUCCESS. DUE TO THE LASIK SURGERY, I SUFFER FROM VISION LOSS, DOUBLE VISION, HALOS, IRREGULAR ASTIGMATISM, ANASOMETROPIA AND DRY EYE SYNDROME. I LOST MY JOB OF 16 YEARS DUE TO THE COMPLICATIONS.

Concomitant Medical Products:
2006/01/01 CONTACT LENS THERAPY FAILURE

Remedial Action (H7):

Correction/Removal No (H9):

Additional Mfr Narrative (H10 & H11):
08-MAR-2010:
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

Brand: NA
Device Type: LASER SURGERY
Device Type:
Catalog:
  Serial: (*confidential*)
  Lot: NA
Other ID:

Reprocessed & Reused: N/A

REPORTER INFORMATION:

Name:
Address:

EMAIL: [b] (6)
Phone: [b] (6)
International:
Fax:

Health Professional: No

Occupation: 305 - PATIENT
CDRH
MAUDE EVENT REPORT (FOI)

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

Date Received
MW5015089
Mfr Name: NONE

Event Date (B3): 16-Oct-2005
Report Date (B4): 08-Mar-2010
Report Date (F8): 
Date Mfr Rec'd (G4): 

Event Report Type: INJURY
Event Outcome (B2): REQUIRED INTERVENTION
Reporter Occupation (E3): 305 - PATIENT
Device Operator: HEALTH PROFESSIONAL

Adverse Event (B1): Y
Problem (B1): N

Event Location (F12): 
Report Source (G3): 

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Age (F9): 
Expiration Date: 01-Jan-2000

Device Evaluated by Manufacturer (H3): No Answer

Remedial Action (H7):
Correction/Removal No (H9): 
Additional Mfr Narrative (H10 & H11): 16-MAR-2010:

Concomitant Medical Products:

Mfr Name: NA
Address: NA

Device Available for Evaluation: Y
Device Evaluated by Manufacturer (H3): 

Volun 16-MAR-2010: MY LEFT EYE HAD BAD CORNEA SCARRING AND I NEED A CORNEA TRANSPLANT WHICH COSTS (B) (6) THAT I DON'T HAVE. I HAVE TO CLOSE MY LEFT EYE WHILE I SEE WITH MY RIGHT ONE OR THE BAD SIGHT OVERLAPS WITH MY RIGHT EYE. I NOW HAVE ONE GOOD EYE ... AND GLASSES DON'T HELP. CONTACTS HURT AFTER 4 HOURS IN MY LEFT EYE, SO I CAN'T WEAR THEM ALL DAY. ALSO MY LEFT EYE IS 20/100 WITH DOUBLE VISION AND VERY BAD LIGHT STREAKS AT NIGHT. I JUST WANT MY LEFT EYE TAKEN OUT; IT BOTHERS ME WHEN I TRY TO SEE WITH MY OTHER 20/30 RIGHT EYE. I GOT LAID OFF TWO MONTHS AGO, AND IT PROBABLY WILL BE HARDER WITH ONE EYE TO KEEP ANY DECENT JOB. I HAD FOUR OPERATIONS -ENHANCEMENTS- THAT CAUSED TRAUMA TO MY LEFT EYE AND STARTED (B) (6) SIMPLEX WHICH CAUSED DAMAGE TO MY LEFT EYE. THE PLACE WHERE I HAD OPERATIONS WILL NOT HELP ME AT ALL WITH MONEY BECAUSE THEY SAY I CAN'T PROVE THAT THE LASERS CAUSED THE VIRUS. I AM VERY MAD, BUT CAN'T DO ANYTHING ABOUT IT. BY THE WAY, I DID NOT HAVE (B) (6) BEFORE THE OPERATION.

Recd: 1,072
Page: 2,162
Date Last Updated: 11/2/2010 9:17 AM
MAUDE EVENT REPORT (FOI)

SORTED BY

This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** NA
- **Device Type:** LASER
- **Catalog:** NA
- **Serial:** (*confidential*)
- **Lot:** NA
- **Other ID:** NA
- **Reprocessed & Reused:** N/A

REPORTER INFORMATION:

- **Name:** [Redacted]
- **Address:** [Redacted]
- **Health Professional:** Yes
- **EMAIL:** [Redacted]
- **Phone:** [Redacted]
- **International:** [Redacted]
- **Fax:** [Redacted]
- **Occupation:** 305 - PATIENT
Event Date (B3): 05-Dec-2007
Report Date (B4): 17-Mar-2010

Adverse Event (B1): Y
Problem (B1): N
Event Report Type: INJURY
Event Outcome (B2): OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
Reporter Occupation (E3): Device Operator:

Device Available for Evaluation: N
Device Evaluated by Manufacturer (H3): No Answer
Remedial Action (H7):
Correction/Removal No (H9): 25-MAR-2010:

Event Description (B5):
Volun 25-MAR-2010: LASIK SURGERY RUINED MY VISION QUALITY. DOCTOR VISITS.

Concomitant Medical Products:

Mfr Name: NONE
Address: DURHAM, NC
UNITED STATES
Device Age (F9):
Expiration Date:
Device Usage (H8):

Product Code: (OP)-EXCIMER LASER SYSTEM (LZS)
Device Operator:

Date Mfr Rec'd (G4):
Report Source (G3):

Event Location (F12): Reporter Occupation (E3):

Date Last Updated: 11/2/2010 9:17 AM
Recd: 1,073 Page: 2,164

Recd: 1,073 Page: 2,164
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:
- **Brand:** LASIK SURGERY
- **Device Type:** LASER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

Reprocessed & Reused: N/A

REPORTER INFORMATION:
- **Name:**
- **Address:**
- **Health Professional:** No
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**
- **Occupation:** 305 - PATIENT
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5015628</th>
<th>Mfr Name:</th>
<th>NONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Date (B3):</td>
<td>19-Apr-2010</td>
<td>Event Report Type:</td>
<td>INJURY</td>
</tr>
<tr>
<td>Report Date (B4):</td>
<td>19-Apr-2010</td>
<td>Event Outcome (B2):</td>
<td>REQUIRED INTERVENTION</td>
</tr>
<tr>
<td>Report Date (F8):</td>
<td></td>
<td>Reporter Occupation (E3):</td>
<td>305 - PATIENT</td>
</tr>
<tr>
<td>Date Mfr Rec'd (G4):</td>
<td></td>
<td>Device Operator:</td>
<td>HEALTH PROFESSIONAL</td>
</tr>
<tr>
<td>Product Code:</td>
<td>(OP)-LASER, OPHTHALMIC (HQF)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Age (F9):</td>
<td></td>
<td>Manufacture Date (H4):</td>
<td></td>
</tr>
<tr>
<td>Expiration Date:</td>
<td></td>
<td>Single Use (H5):</td>
<td></td>
</tr>
<tr>
<td>Device Usage (H8):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Event Description (B5):**

Volun 26-APR-2010: DEVELOPED ECTASIA KERATOCONUS FROM LASIK. WAS NOT DIAGNOSED UNTIL 3 YRS AFTER SURGERY. ONE EYE CANNOT BE CORRECTED BETTER THAN 20/80 AND THAT IS WITH HORRIBLE VISION, NEVER CLEAR, ALWAYS FUZZY. TRIED PIGGY BACK CONTACTS LENS, HARD LENSES WITH SOFT SKIRT. COULD NOT READ WITH THESE LENSES IN. CAN NO LONGER BEAR WEARING THESE. PRESENTLY USING A SOFT CONTACT LENS, ALTHOUGH VISION NOT CLEAR. STRUGGLING TO READ. NIGHTMARE TO DRIVE AT NIGHT. ONE LIGHT MULTIPLIES AT A DISTANCE, CANNOT JUDGE DISTANCE. THERE DOESN'T SEEM TO BE ANYTHING YOU CAN DO! MY DAUGHTER HAD THE SAME SURGERY AND HAS THE SAME CONDITION. SHE HAD A CORNEAL TRANSPLANT (B) (6) 2008 AND SEES WORSE NOW THAN BEFORE THE TRANSPLANT.

**Concomitant Medical Products:**

<table>
<thead>
<tr>
<th>Mfr Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
</tr>
</tbody>
</table>

**Device Available for Evaluation:**

| Device Evaluated by Manufacturer (H3): | No Answer |

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**

26-APR-2010:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

DEVICE INFORMATION:

- **Brand:** LASIK MACHINE
- **Device Type:** LASER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:** UNK
- **Other ID:**

Reprocessed & Reused: Y

REPORTER INFORMATION:

- **Name:** [redacted]
- **Address:** [redacted]
- **Health Professional:** No
- **Occupation:** 305 - PATIENT

- **EMAIL:** [redacted]
- **Phone:** [redacted]
- **International:**
- **Fax:** [redacted]
The output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

<table>
<thead>
<tr>
<th>Voluntary Report No:</th>
<th>MW5016345</th>
<th>Mfr Name:</th>
<th>NONE</th>
<th>Date Received:</th>
<th>03-Jun-2010</th>
</tr>
</thead>
</table>

**Event Date (B3):** 01-Sep-2009  
**Report Date (B4):** 31-May-2010  
**Event Report Type:** INJURY  
**Event Outcome (B2):** REQUIRED INTERVENTION  
**Reporter Occupation (E3):** 305 - PATIENT  
**Device Operator:**  
**Product Code:** (OP)-EXCIMER LASER SYSTEM (LZS)  
**Device Usage (H8):**  

**Event Description (B5):**  
Volun 18-JUN-2010: RIGHT EYE, STILL BLEEDING, HAD 3 LASER SURGERIES BY: DR (B) (6), FROM: (B) (6) 2009 TO (B) (6) 2010.

**Concomitant Medical Products:**  
- Mfr Name:  
- Address:  

**Device Available for Evaluation:** Y  
**Device Evaluated by Manufacturer (H3):** No Answer  

**Remedial Action (H7):**

**Correction/Removal No (H9):**

**Additional Mfr Narrative (H10 & H11):**  
18-JUN-2010:
This output contains the medical device adverse event reports currently available to the public, in accordance with the Freedom of Information Act and the requested search criteria. Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

**DEVICE INFORMATION:**

- **Brand:**
- **Device Type:** LASER
- **Catalog:**
- **Serial:** (*confidential*)
- **Lot:**
- **Other ID:**

**Reprocessed & Reused:** N/A

**REPORTER INFORMATION:**

- **Name:** (b) (6)
- **Address:** (b) (6)
- **Health Professional:** No Answer
- **Occupation:** 305 - PATIENT
- **EMAIL:**
- **Phone:**
- **International:**
- **Fax:**