EndoProbe®, OtoProbe™ and FlexFiber™
Operator Manual

IRIDEX
Contents

1 Introduction ................................................................. 1
   Indications for Use ....................................................... 1
   Precautions ............................................................. 1
   Recommended Procedure .............................................. 1
   Power and Duration .................................................... 1
   Warnings and Cautions ................................................. 2
   References ............................................................... 3
   Compatible IRIDEX Lasers ............................................ 4

2 Operation ................................................................. 5
   About the Components ................................................. 5
   EndoProbe Models ...................................................... 5
   OtoProbe Models ........................................................ 6
   FlexFiber Models ........................................................ 6
   Eye Safety Filters ....................................................... 6
   Connecting the Components ......................................... 7
   Laser Spot Size .......................................................... 7
   Treating Patients ....................................................... 7

3 Troubleshooting ....................................................... 9
   General Problems ....................................................... 9

4 Maintenance ............................................................ 11
   Cleaning Optical Components ...................................... 11

5 Safety and Compliance ............................................... 12
   Protection for the Physician ........................................... 12
   Protection for All Treatment Room Personnel .................... 12
   Safety Compliance ...................................................... 13
   Illuminating Probe Specifications .................................. 13
   Illumination Testing ................................................... 13
   Symbols (As Applicable) ........................................……….. 14
1
Introduction

IRIDEX probes come with a universal SMA connector that allows them to be used with validated compatible laser systems.

Indications for Use

The EndoProbe is indicated for use in performing ophthalmic laser treatments to deliver laser energy to the treatment area inside the eye. The EndoProbe is cleared for use for the particular indications of the compatible laser system to which it is attached.

The OtoProbe is intended for use in surgical procedures including incision, excision, coagulation, and vaporization of soft and fibrous tissue (including osseous tissue) in the medical specialty of Ear, Nose and Throat (ENT) surgery. The OtoProbe is cleared for use for the particular indications of the compatible laser system to which it is attached. The FlexFiber is intended for use in treatment of soft tissue/vascular lesions of the airway and larynx. The FlexFiber is cleared for use for the particular indications of the compatible laser system to which it is attached.

Precautions

Protect the fiber-optic tip from damage. If damaged, discard the probe.

Recommended Procedure

Qualified physicians should review the available literature presented in clinical papers before using the probe delivery device.

Power and Duration

If you are uncertain of tissue response, always start with a lower power setting and increase the power until you observe satisfactory clinical lesions.
Warnings and Cautions

**WARNINGS:**

US federal law restricts this device to sale by or on the order of a healthcare practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Use of controls or adjustments or performing of procedures other than those specified herein may result in hazardous radiation exposure.

Do not operate the equipment in the presence of flammables or explosives, such as volatile anesthetics, alcohol, and surgical preparation solutions.

Lasers generate a highly concentrated beam of light that may cause injury if improperly used. To protect the patient and the operating personnel, the entire laser and the appropriate delivery system operator manuals should be carefully read and comprehended before operation.

Never look directly into the aiming or treatment beam apertures or the fiber-optic cables that deliver the laser beams, with or without laser safety eyewear.

Never look directly into the laser light source or at laser light scattered from bright reflective surfaces. Avoid directing the treatment beam at highly reflective surfaces such as metal instruments.

Ensure that all personnel in the treatment room are wearing the appropriate laser safety eyewear. Never substitute prescription eyewear for laser safety eyewear.

Always handle the fiber-optic cables with extreme care. Do not coil the cable into a diameter less than 15 cm (6 in).

Turn off the laser before inspecting any delivery device components.

Keep the protective cap over the fiber-optic connector when the delivery device is not in use.

Follow standard facility procedures for the handling of biohazardous material after each use of the delivery device.

Always verify that the delivery device is properly connected to the console. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

When using an IRIDEX probe with a non-IRIDEX laser console, ensure that the proper eye safety filter is installed. Refer to your laser manual for specific eye safety filter information.

The IRIDEX eye safety filter (ESF) is designed to be used with an IRIDEX laser. Always ensure that the ESF is properly connected to the laser during use.

The relationship between spot size and resultant power density is not linear. Halving the spot size quadruples the power density. The physician must understand the relationships among spot size, laser power, power density, and laser/tissue interaction before using an Iridex probe.

Ophthalmic Warnings:

- Excessive treatment power may result in a retinal hole and a retinal hemorrhage.
- Excessive power delivered at short pulse durations may result in choroidal hemorrhage.

ENT Warnings:

- Excessive treatment may cause swelling (edema) in the area treated by the laser.
Anesthesia Considerations:

One of the main concerns during otolaryngeal and bronchial procedures is the substantial risk of endotracheal fires. The following sections provide information and safety guidelines, which can greatly decrease the risks, associated with these procedures. Information is also provided on what to do if such a fire does occur.

IRIDEX Corp. recommends the safety guidelines of American National Standards ANSI Z136.3-2007 as follows:

- Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
- Use the lowest possible oxygen concentration to support the patient;
- Use the venturi ventilation technique when possible;
- Use intravenous anesthetic agents rather than inhalation techniques;
- Use non-flammable laser-safe endotracheal tubes; and
- Protect the endotracheal tube cuff with wet cottonoids.

References

Reference material and additional information regarding laser safety and the prevention of endotracheal fires may be obtained from the following U.S. sources:


Care must be taken to protect endotracheal tubes from laser radiation. Ignition or perforation of endotracheal tubes by the laser beam could result in serious or fatal patient complications.
Compatible IRIDEX Lasers

<table>
<thead>
<tr>
<th>Laser System</th>
<th>EndoProbe</th>
<th>OtoProbe</th>
<th>FlexFiber</th>
</tr>
</thead>
<tbody>
<tr>
<td>GL</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLx</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>TX</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>SL</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SLx</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IQ 810</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IQ 532</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>IQ 577</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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The Netherlands
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Warranty and Service. This device carries a standard factory warranty. This warranty is void if service is attempted by anyone other than certified IRIDEX service personnel.

NOTE: This Warranty and Service statement is subject to the Disclaimer of Warranties, Limitation of Remedy, and Limitation of Liability contained in IRIDEX’s Terms and Conditions.

Should you require assistance, please contact your local IRIDEX Technical Support representative or our corporate headquarters.
2 Operation

About the Components

After unpacking the contents of your IRIDEX laser probe, ensure that you have all of the components ordered. Check the components carefully before use to ensure that no damage occurred during transit.

Ensure that the appropriate eye safety filter is installed prior to using a probe.

EndoProbe Models

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard (straight or angled)</td>
<td>Provides intraocular laser delivery.</td>
</tr>
<tr>
<td>Illuminating</td>
<td>Provides light illumination and laser delivery.</td>
</tr>
<tr>
<td>Aspirating (active or passive)</td>
<td>Permits fluid aspiration and laser delivery. Active connects to vitrectomy system. Passive utilizes intraocular pressure.</td>
</tr>
<tr>
<td>Stepped 45° angled</td>
<td>Provides laser delivery; probe designed for use with a trochar.</td>
</tr>
<tr>
<td>Adjustable and Intuitive</td>
<td>Provides laser delivery; probe designed for manual adjustment of angle.</td>
</tr>
</tbody>
</table>
OtoProbe Models

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Model</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14320</td>
<td>Short-angled*</td>
<td>Angle at the distal end of the needle</td>
</tr>
<tr>
<td>14310</td>
<td>Long-angled*</td>
<td>Angle at the proximal end of the needle</td>
</tr>
</tbody>
</table>

* Also available with RFID connector

FlexFiber Models

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>15702</td>
<td>200 μm Laser Fiber</td>
</tr>
<tr>
<td>15703</td>
<td>300 μm Laser Fiber</td>
</tr>
<tr>
<td>15704</td>
<td>400 μm Laser Fiber</td>
</tr>
<tr>
<td>15706</td>
<td>600 μm Laser Fiber</td>
</tr>
</tbody>
</table>

Eye Safety Filters

<table>
<thead>
<tr>
<th>Eye Safety Filter</th>
<th>532 nm</th>
<th>577 nm</th>
<th>810 nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Two-Position</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

Fixed Eye Safety Filter

Eye protection for physician is fixed and always in place.

Two-Position Eye Safety Filter

Filter position is adjusted manually. SmartKey® provides feedback to laser to ensure no laser emission when filter is out of position.

**WARNING:** For use with IRIDEX laser systems only.
Connecting the Components

**NOTE:** Use the eye safety filter appropriate for the laser in use. If you are using a two-position eye safety filter, you may need to configure your laser before installing the filter. Follow the configuration instructions in your laser manual.

**WARNINGS:**

If you are using a beam splitter on your operating microscope, you must install the fixed eye safety filter before installing the beam splitter.

If the pouch is open or damaged, do not use the probe.

Always inspect the fiber-optic cable before connecting it to the console. A damaged fiber-optic cable could cause accidental laser exposure or injury to you, your patient, or others in the treatment room.

**CAUTION:** Gently finger-tighten the connector to the port. Do not overtighten.

Laser Spot Size

To change the spot size, move the probe farther from or closer to the target.

Treating Patients

**BEFORE TREATING A PATIENT:**

- Ensure that the eye safety filter (as appropriate) is properly installed and that the SmartKey®, if used, is selected.
- Ensure that the laser components and delivery device(s) are properly connected.
- Post the laser warning sign outside the treatment room door.

**NOTE:** Refer to Chapter 5, “Safety and Compliance,” and your delivery device manual(s) for important information about laser safety eyewear and eye safety filters.

**TO TREAT A PATIENT:**

1. Turn on the laser.
2. Reset the counter.
3. Set the treatment parameters.
4. Position the patient.
5. If required, select an appropriate contact lens for the treatment.
6. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
7. Select Treat mode.
8. Position the aiming beam on the treatment site.
9. Focus or adjust the delivery device as applicable.
10. Press the footswitch to deliver the treatment beam.

**TO CONCLUDE PATIENT TREATMENT:**

1. Select Standby mode.
2. Record the number of exposures and any other treatment parameters.
3. Turn off the laser and remove the key.
4. Collect the safety eyewear.
5. Remove the warning sign from the treatment room door.
6. Disconnect the delivery device(s).
7. Disconnect the SmartKey, if used.
8. If the delivery device is single-use, dispose of it properly. Otherwise, inspect and clean the delivery device(s) as instructed in your delivery device manual(s).
9. If a contact lens was used, handle the lens according to the manufacturer’s instructions.
10.
## 3 Troubleshooting

### General Problems

<table>
<thead>
<tr>
<th>Problem</th>
<th>User Action(s)</th>
</tr>
</thead>
</table>
| No display | • Verify that the keyswitch is on.  
• Verify that the components are properly connected.  
• Verify that the electrical service is on.  
• Inspect the fuses.  
If there is still no display, contact your local IRIDEX Technical Support representative. |
| Inadequate or no aiming beam | • Verify that the delivery device is properly connected.  
• Verify that the console is in Treat mode.  
• Turn the aiming beam control fully clockwise.  
• Verify that the fiber-optic connector is not damaged.  
• If possible, connect another IRIDEX delivery device and place the console in Treat mode.  
If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative. |
| No treatment beam | • Verify that the remote interlock has not been activated.  
• Verify that the aiming beam is visible.  
• Verify that the fiber switch is in the correct position for the laser system and wavelength you are using.  
• Verify that the eye safety filter is in the closed position.  
If there is still no treatment beam, contact your local IRIDEX Technical Support representative. |
| No illumination light (LIO only) | • Verify that the illumination connector is connected to the console.  
• Verify that the special function control is not between detents.  
• Check the bulb and replace it (if necessary). |
| Illumination light is too dim (LIO only) | • Verify that the special function control is not between detents.  
• Adjust the console illumination intensity control. |
<p>| The aiming beam is large or out of focus on the patients’ retina (LIO only) | Readjust your working distance between the LIO headset and the examination lens. The aiming beam should be sharply defined and at its smallest diameter when in focus. |</p>
<table>
<thead>
<tr>
<th>Problem</th>
<th>User Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The treatment lesions are variable or intermittent (LIO only)</td>
<td>• The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size.</td>
</tr>
<tr>
<td></td>
<td>• A poorly centered laser beam may be clipping on the examination lens or on the patient’s iris. Adjust the laser beam in the illumination field.</td>
</tr>
<tr>
<td></td>
<td>• The laser treatment parameters may be too close to the tissue response threshold for consistent response. Increase the laser power and/or exposure duration, or select a different lens.</td>
</tr>
<tr>
<td>Does not fit on the mounting plate (OMA only)</td>
<td>• Inspect and clean the mounting plate.</td>
</tr>
<tr>
<td></td>
<td>• Verify that the mounting plate corresponds to your microscope.</td>
</tr>
<tr>
<td>Laser and viewing systems are not focussed at the same point (OMA* only)</td>
<td>• Verify installation of a 175 mm microscope objective lens on the microscope.</td>
</tr>
<tr>
<td></td>
<td>• Turn on the aiming beam to determine focus position and adjust as necessary.</td>
</tr>
<tr>
<td>View is blocked or partially blocked by OMA (OMA* only)</td>
<td>Set magnification to 10X or more.</td>
</tr>
</tbody>
</table>

*Operating microscope adapter compatible with IRIDEX IQ 810 and SLx Systems.
4 Maintenance

These probes are single-use, disposable delivery devices. When finished with a procedure, dispose of the probe. Do not reuse or resterilize.

Cleaning Optical Components

1. Wrap a lens tissue around one end of a cotton-tipped swab.
2. Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
3. Wipe the lens gently with the swab to remove all dust and debris.
4. If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe it again.

Optical components refer to eye safety filters, output prism of DioPexy handpiece, mirrors on slit lamp adapters, operating microscope adapters, etc.
5 Safety and Compliance

To ensure safe operation and prevent hazards and unintended exposure to the laser beams, read and follow these instructions:

- To prevent exposure to laser energy, except as a therapeutic application from either direct or diffusely reflected laser beams, always review and observe the safety precautions outlined in the operator manuals before using the device.
- This device is intended for use only by a qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility.
- Do not use any device if you think it is not functioning properly.
- Laser beams reflected from specular surfaces can harm your eyes, the patient’s eyes, or others’ eyes. Any mirror or metal object that reflects the laser beam can constitute a reflection hazard. Be sure to remove all reflection hazards near the laser. Use non-reflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

**CAUTION:** Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Protection for the Physician

Eye safety filters protect the physician from backscattered treatment laser light. Integral eye safety filters are permanently installed in every compatible Slit Lamp Adapter (SLA) and Laser Indirect Ophthalmoscope (LIO). For endophotocoagulation or for Operating Microscope Adapter (OMA) use, a separate discrete eye safety filter assembly must be installed into each viewing path of the operating microscope. All eye safety filters have an optical density (OD) at the laser wavelength sufficient to permit long-term viewing of diffuse laser light at Class I levels. When using the dermatology handpieces, always wear the appropriate laser safety eyewear.

Always wear appropriate laser safety eye wear when performing or observing laser treatments with the unaided eye.

Protection for All Treatment Room Personnel

The Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for each of the delivery devices used with the laser system, as well as the configuration of the treatment room. For additional information, refer to ANSI Z136.1, ANSI Z136.3, or European Standard IEC 60825-1.
Safety Compliance


CE-labeled devices comply with all requirements of the European Medical Device Directive MDD 93/42/EEC.

Illuminating Probe Specifications

The following information on the illumination capabilities of this device is provided in accordance with ISO 15752, Section 6.2.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Aperture</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>Numerical Aperture</td>
<td>0.5 - 0.8</td>
</tr>
<tr>
<td>Light Guide Materials</td>
<td>PMMA or Silica</td>
</tr>
</tbody>
</table>

Illumination Testing

The following information on the illumination capabilities of this device is provided in accordance with ISO 15752, Section 4.4.2.

Measurement of the aphakic weighted irradiance of an illuminating EndoProbe may be made under sterile conditions. Follow the instructions provided by the manufacturer of your EndoIlluminator light source. Drape the EndoProbe handpiece with a sterile sleeve, or grip the EndoProbe with a sterile clamp, forceps, or gloves. Do not compromise the sterile tip.
Symbols (As Applicable)

- Aiming Beam
- Angle
- Aspirating Probe
- Caution
- Audible Signal
- CE Mark
- Connector Type
- Do Not Use if Package is Damaged
- Duration
- Duration with MicroPulse
- Emergency Stop
- ETL Mark
- EtO Sterile
- EU Authorized Representative
- Expiration Date
- Footswitch
- Footswitch In
- Footswitch Out
- Fuse
- Gauge
- Protective Earth (Ground)
- Illuminating Probe
- Decrease/Increase
- Interval
- Interval with MicroPulse
- Laser Aperture at End of Fiber
- Laser Warning
- Illumination
- LOT
- Manufacturer
- Manufacture Date
- Off
- On
- Part Number
- Power
- Pulse Count
- Pulse Count Reset
- No-ionizing Electromagnetic Radiation
- Read Information
- Remote Control
- Remote Interlock
- Serial Number
- Single Use
- Standby
- Treat
- Type B Equipment
- WEEE Guidance. Contact IRIDEX or your distributor for disposal information.