EndoProbe® Handpiece, OtoProbe™ Device and FlexFiber™ Device

Operator Manual

IRIDEX®

EndoProbe® Handpiece, OtoProbe™ Device and FlexFiber™ Device Operator Manual
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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® Handpiece 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™ Device 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™ Device 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 uncertain of tissue response, start with the lower power settings and increase the power until satisfactory clinical lesions are observed.

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.*

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.

References

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

- **ANSI Z136.3, The Safe Use of Lasers in Health Care Facilities**, American National Standards 2007.
- **Recommended Practices: Laser Safety in the Practice Setting**, *AORN Journal*, March 1993, Vol. 57 No. 3, Pg. 720-727.
- **Safety Considerations for the Use of Medical Lasers, The Nursing Spectrum of Lasers,** Pfister, Kneedler, Purcell, *Education Design*, 1988, Pg. 70-72.
- **Prevention of Fires and Protection of Non-Target Tissues, Airway Precautions**, *Plan for Success: A Practical Guide for Your Carbon Dioxide Laser Surgery Program*, Lewis, Coherent 1989, Pg. 16-17.
- **Laser Resistant Stainless Steel Endotracheal Tube: Experimental and Clinical Evaluation**, *Lasers in Surgery and Medicine*, Fried, Marvin P., MD, 11:301-306 (1991).
- **Evaluation & Discussion: Issues in Using and Selecting Laser Resistant Endotracheal Tubes (LRETTs) and Wraps**, *ECRI, Health Devices,* July-August 1991, Vol. 20 Nos. 7-8.
- **Diffuse Reflections, Endoscopic Surgery: Is Laser Safety Eyewear Really Needed?**, *Radiant Resources Newsletter*, Winter 1992, Rockwell Laser Industries.

Compatible Iridex Lasers

Laser System	EndoProbe	OtoProbe	FlexFiber
GL	✓		
GLx	✓	✓	✓
TX	✓	✓	✓
SL	✓		
SLx	✓		
IQ 810	✓		
IQ 532	✓	✓	✓
IQ 577	✓		

Iridex Corporation Contact Information

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2514 AP The Hague
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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.

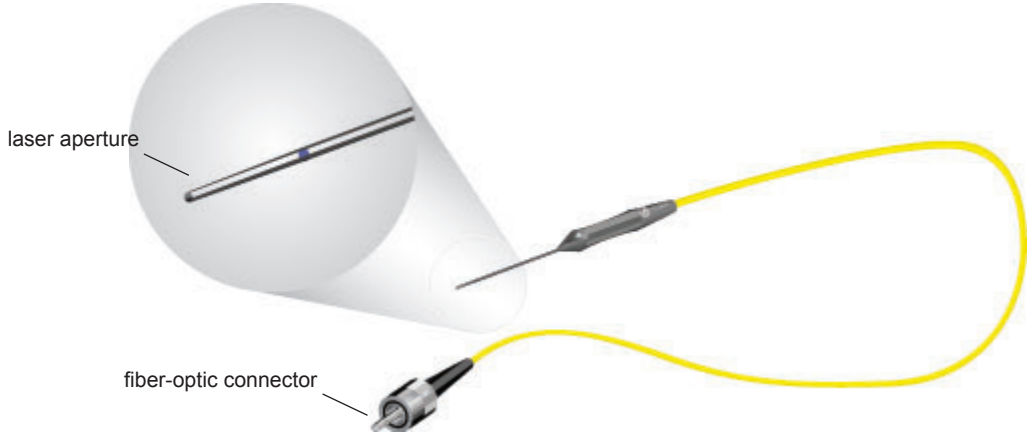
2
Operation

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



Model	Description
Standard (straight or angled)	Provides intraocular laser delivery.
Illuminating	Provides light illumination and laser delivery.
Stepped 45° angled	Provides laser delivery; probe designed for use with a trochar.
Adjustable and Intuitive	Provides laser delivery; probe designed for manual adjustment of angle.

OtoProbe Models

Part Number	Model	Description
14320	Short-angled*	Angle at the distal end of the needle
14310	Long-angled*	Angle at the proximal end of the needle

* Also available with RFID connector

FlexFiber Models

Part Number	Description
15702	200 µm Laser Fiber
15703	300 µm Laser Fiber
15704	400 µm Laser Fiber
15706	600 µm Laser Fiber

Eye Safety Filters

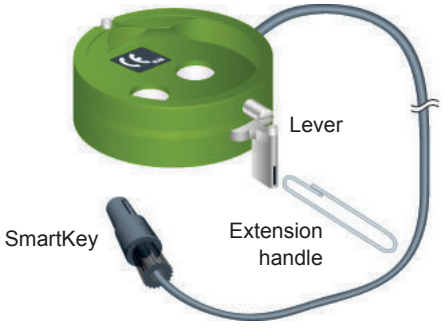
Eye Safety Filter	532 nm	577 nm	810 nm
Fixed	✓	✓	✓
Two-Position	✓	✓	

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.

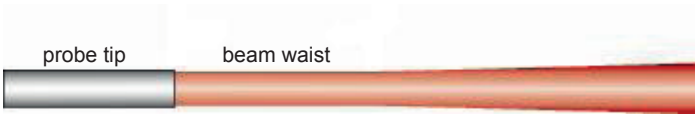
If the pouch is open or damaged, do not use the probe.

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.

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Troubleshooting

General Problems

Problem	User Action(s)
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.
The aiming beam is large or out of focus on the patient's 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.

Problem	User Action(s)
The treatment lesions are variable or intermittent (LIO only)	• The LIO may be slightly out of focus. This decreases power density. Readjust your working distance to obtain the smallest spot size. • 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. • 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.
Does not fit on the mounting plate (OMA only)	• Inspect and clean the mounting plate. • Verify that the mounting plate corresponds to your microscope.
Laser and viewing systems are not focussed at the same point (OMA* only)	• Verify installation of a 175 mm microscope objective lens on the microscope. • Turn on the aiming beam to determine focus position and adjust as necessary.
View is blocked or partially blocked by OMA (OMA* only)	Set magnification to 10X or more.
*Operating microscope adapter compatible with Iridex IQ 810 and SLx Systems.	

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Maintenance

These probes are single-use, disposable delivery devices. The device is intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. No reuse processes have been validated by the manufacturer. The reuse of a single-use medical device can compromise the safety and health of patients, users or third parties. Reuse risks the introduction of contaminants and/or microbes and may lead to patient injury and/or infection.

Store probe package under normal storage conditions - in a dry, clean, well ventilated area at room temperature, between 15º-25ºC (59-77ºF).

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.

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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 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. Refer to laser console Operator Manual for laser safety eye wear minimum OD, it is specific per each laser console wavelength and maximum power output.

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

Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

CE-marked 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.

Feature	Specification
Effective Aperture	0.5 mm
Numerical Aperture	0.5 - 0.8
Light Guide Materials	PMMA or Silica

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
	Date of manufacture		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		Waste Electrical and Electronic Equipment (WEEE)		Pattern is Activated

	Temperature Limitations	**IPX4**	Protections Against Splash Water Coming from all Directions	**IPX8**	Protections Against Continuous Immersion
	Refer to Instruction Manual/Booklet (in blue)		Initial Power (PowerStep)		Interval between Groups
	Number of Pulses (Group)		Number of Steps (PowerStep)		Power (MicroPulse)
	Power Increment		Power Increment (PowerStep)		Parameter is Locked
	USB		Port Indicators		Laser Firing
	Laser Preparing		Speaker		Screen
	System Brightness		Latex Free		Prescription
	Warning, Replace with fuses as indicated				