DioPexy™ Probe

Operator Manual

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Introduction

The DioPexy™ Probe, when connected to an IRIDEX laser, is used for transscleral retinal photocoagulation (TSRPC).

The DioPexy Probe allows side-firing transscleral delivery of laser energy.

Indications for Use

The DioPexy Probe, used with the IRIDEX laser, is indicated for transscleral retinal photocoagulation and typically used for:

- Retina detachment
- Retinal tear
- Retinopathy of prematurity
- Proliferative diabetic retinopathy
- Photocoagulation through a scleral buckle

Contraindications

- Any situation where the target tissue cannot be adequately visualized or stabilized.
- Do not treat albino patients who have no pigmentation.

Clinical 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.
- Due to potential transient disruption of ciliary nerve function, exercise care in delivering excessive energy over ciliary nerves located at clock positions 3:00 and 9:00.
- Always keep the eye well hydrated at point of contact.
- Inspect the probe tip occasionally during treatment to ensure that the tip is free of debris and to avoid thermal damage at the site of application.

Precautions

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

Aiming Beam

To focus the aiming beam, place the probe tip perpendicular to the sclera and adjust the probe until the aiming beam is circular and sharply discrete. The aiming beam is coaxial with the treatment beam and only illuminates when the laser is in Treat mode.

Positioning

- Adjust the DioPexy Probe tip so that the face of the prism is parallel to the surface of the eye.
- Use the DioPexy Probe as a scleral depressor. After you indent the sclera with the probe and deliver the laser energy, release the pressure, move the probe to a new site, and re-indent.
- Avoid dragging the DioPexy Probe across the sclera as this may result in injury.
- Areas with subretinal fluid may NOT show whitening of the sensory retina during treatment. You may see immediate whitening of the retinal pigment epithelium (RPE), which is usually adequate for a chorioretinal adhesion to form. When treating areas with subretinal fluid, first treat an area where the retina and RPE are apposed, obtain the treatment parameters for a light blanching of the retina, and use these parameters to treat the area with subretinal fluid. Delayed whitening of the retina may take place.
- After delivering ten pulses at one setting, inspect the sclera to ensure there is no thermal effect. This is important at higher power settings, if the sclera is thin, or where there is little subretinal fluid. Decrease the power setting and exposure duration to avoid increased energy uptake.

Endpoint

Titrate the retinal reaction to a light-gray endpoint by releasing the footswitch at the first sign of graying of the overlying retina. Desired endpoints are achieved more quickly in areas of heavier pigmentation.

Too white **Desired light grey** **Too light**

Power and Duration

If uncertain of tissue response, start with the lower power settings and increase the power until satisfactory clinical lesions are observed.

Pigmentation	Starting Power	Starting Duration
Dark	750 mW	1500 ms
Moderate	1000 mW	1500 ms
Light	1250 mW	1500 ms

Warnings and Cautions

WARNINGS:

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.

To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth.

Always inspect the fiber-optic cable before connecting it to the laser to ensure that it has not been damaged. A damaged fiber-optic cable could cause accidental laser exposure or injury to yourself, your patient, or others in the treatment room.

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

Do not use the delivery device with any laser system other than an IRIDEX laser. Such use may void product warranties and threaten the patient, yourself, and others in the treatment room.

Tissue absorption is directly dependent upon presence of pigmentation; therefore, dark pigmented eyes will require lower energies to obtain equivalent results as compared to light pigmented eyes.

Inadequate clinical results or infection may result from improper cleaning and/or sterilization.

CAUTIONS:

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.

Turn off the laser before inspecting any delivery device components.

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

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

Sterilize with EtO or by using the STERRAD system. Do not autoclave.

Follow standard facility procedures for the handling of biohazardous material.

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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.

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

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.*

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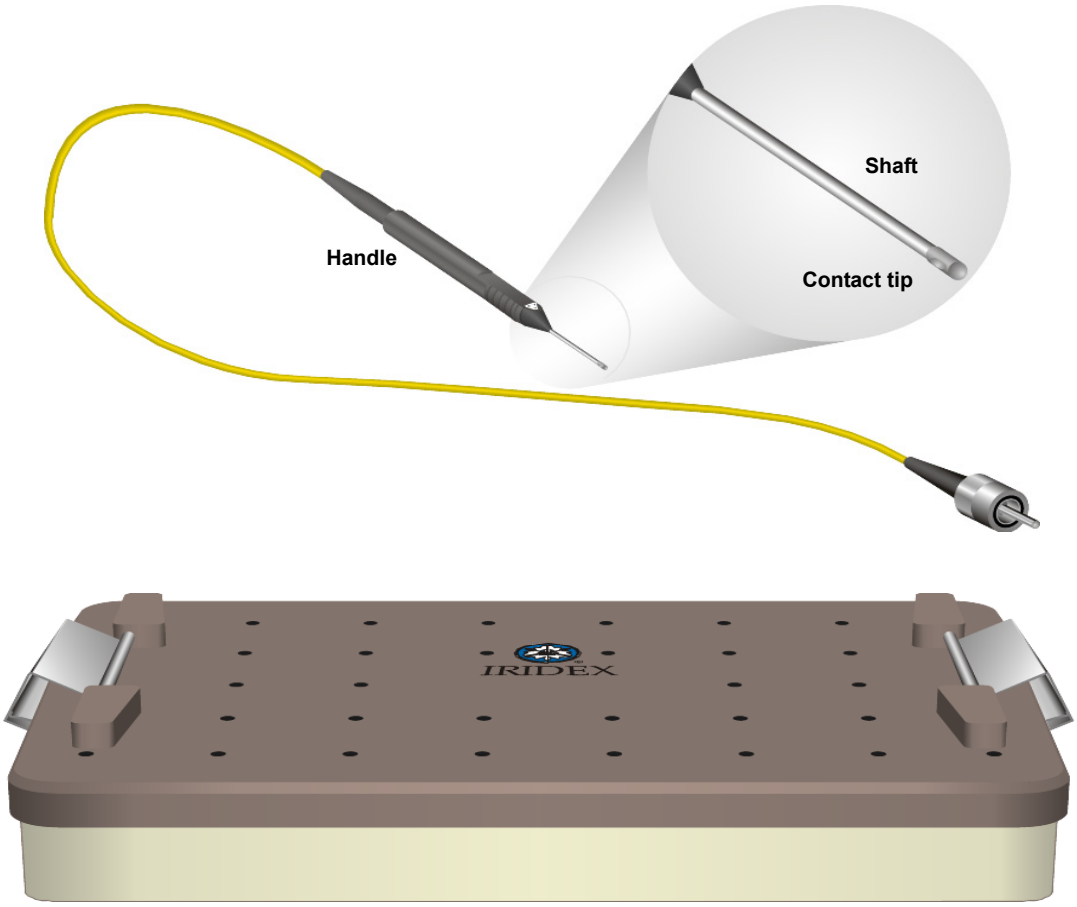
Operation

About the Components

Verify that you have received all of the components in the DioPexy Probe package, and check the components carefully before use to ensure that no damage occurred during transit. The DioPexy Probe is shipped non-sterile, single-bagged inside a plastic tray.

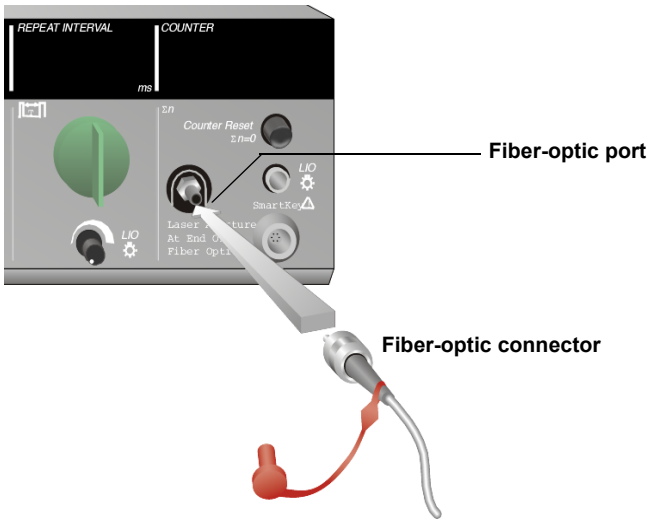
The shape of the tip automatically enables easy scleral indentation for efficient and consistent transmission through tissue.

The sterilization tray is used for ethylene oxide (EtO) or STERRAD® sterilization of the DioPexy Probe.



Sterilization Tray (optional)

Connecting the DioPexy Probe



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.

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Maintenance

With proper care and handling, in accordance with these inspection and cleaning instructions, the DioPexy Probe may be reused and resterilized up to 50 times.

TO PROVIDE ROUTINE CARE:

- Do not kink or bend the fiber-optic cable.
- When connected to the laser, the fiber-optic cable must be located away from high traffic areas.
- Do not bend the probe needle during use or storage.
- Do not strike the tip against hard surfaces.
- Keep the optical components free of fingerprints.
- Keep the SLA attached to the slit lamp, except when you need to move it or attach it to another delivery device.
- When not in use, cover the slit lamp with the provided cover to keep the slit lamp free of dust, and store all accessories in suitable storage boxes.

Tip Integrity Test

Using latex gloves, confirm the integrity of the probe tip prior to each use by gripping the tip alongside the final prism/optic and pulling axially with a gentle (1.0 lb/0.5 kg) force. Tip/optic and adhesive should form an integral assembly, with no sign or feeling of looseness. Do not use any probe failing this test.

Cleaning the Probe Handle and Tip

After each use:

1. Immerse the distal 3 cm end of the DioPexy probe shaft thoroughly in a solution of protein solubilizing soap (i.e., Enzol®) and lukewarm tap water. Do not use hot water as it may make any organic material more difficult to remove.
2. Scrub the probe with a soft brush to loosen and remove debris.
3. If desired, wipe the probe handle and fiber-optic jacket with a protein solubilizing soap.
4. Rinse the probe shaft thoroughly in warm tap water. Blot dry with a sterile towel.
5. Wipe the probe with 70% isopropyl alcohol (IPA).

Sterilizing the Probe

Ensure that the probe has been inspected and cleaned. Sterilize the probe using the STERRAD system. The STERRAD system is a low-temperature sterilization method using proprietary equipment and processes manufactured by the Advanced Sterilization Products®, a division of Johnson & Johnson Medical, Inc.

STERRAD resterilization parameters:

Phase	Function	Time
Vacuum phase	Evacuation of sterilization chamber to 300 mTorr	5-20 minutes
Injection phase	Automatic injection of 1.8 mL of aqueous solution of H_2O_2 and vaporization	6 minutes
Diffusion phase	Diffusion of H_2O_2 in sterilization chamber throughout load	44 minutes
Plasma phase	Low temperature gas plasma with 400 W power at 500 mTorr pressure	15 minutes
Vent phase	Return of sterilization chamber to atmospheric pressure	5 minutes
Total cycle time		Approximately 75 minutes

EtO

Variations in chamber size, gas mixture, pressure, and temperature influence the sterility outcome of devices; follow individual or hospital sterilization instructions to ensure proper results.

Recommended parameters:

VACUUM

Initial evacuation: 76 mmHg to 78 mmHg
54° C to 55° C
30 minutes

PRESSURE

Gas Type: Ethylene Oxide
Oxyfume 2000, (8.6% EtO)/ 91.4% HCFC-124

Operating Temperature: 55° C to 60° C

Exposure Time: 2 hours

Humidity: 30% to 80%

Pressure: 1.3 bar to 1.4 bar (20 psi to 21 psi)

Aeration: 8 hours @ 55° C to 61° C

Chamber load density: 0.35 g/cm^3

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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 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

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

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

Feature	Function
Eye safety filter	The eye safety filter ensures that all laser radiation returned to the physician and any co-observers is below Class I limits.
Laser emission indicator	Illumination of the green Treat light on the laser provides a visible warning that laser radiation may be emitted.
Safety interlock	The delivery device's protective housing and the laser fiber connector cannot be opened without the use of special tools. The delivery device is also safety-interlocked at the fiber-optic port on the laser.

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

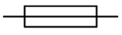
EU Authorized Representative


Expiration Date


Footswitch


Footswitch In


Footswitch Out


Fuse


Gauge


Protective Earth (Ground)


Illuminating Probe


Decrease/Increase


Interval


Interval with MicroPulse

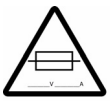

Laser Aperture at End of Fiber


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.	 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		

DioPexy Probe Specifications

Specification	Definition
Laser compatibility	OcuLight SL OcuLight SLx IQ 810
Treatment wavelength	Laser diode, 810 nm
Fiber diameter	600 µm