G-Probe™

Operator Manual

G-Probe™ Operator Manual
13105-EN Rev D 2013-05

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Introduction

Indications for Use

The G-Probe, used with an IRIDEX laser, is indicated for transscleral photocoagulation (TSCPC) of the ciliary processes and is typically used when:

- The patient has failed prior filtration surgery and is expected to fail further filtration surgery.
- The patient has a secondary glaucoma in which failure is a likely outcome of filtration surgery (e.g., neovascular, inflammatory, postpenetrating keratoplasty, postscleral buckling).
- The patient has lost ambulatory level vision and is being treated with cyclophotocoagulation for comfort or to prevent further visual loss.
- The patient is not a surgical candidate for filtration surgery.

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 cause ciliary body hemorrhage.
- Excessive power delivered at short pulse durations may result in choroidal hemorrhage.
- Excessive energy may cause peripheral lens damage.
- Presence of heavy perilimbal conjunctival pigmentation can result in local absorption and burns; therefore, avoid areas of intense pigmentation.
- Keep the fiber-optic tip clean to avoid thermal damage at the site of application.
- More than slight conjunctival burns are not typical. If they occur, then replace the G-Probe.
- Avoid areas of significant scleral scarring, which may be thin and inelastic.
- Keep the conjunctiva well irrigated at all times.
- Do not drag or rotate G-Probe on the globe.

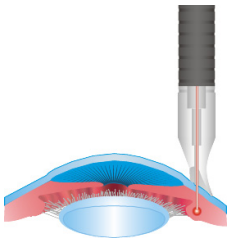
Precautions

- TSCPC should be approached cautiously in the region of a pigmented intraocular lens haptic located in the ciliary sulcus.
- Protect the fiber-optic tip from damage. If damage is suspected to the fiber tip, discard the G-Probe.

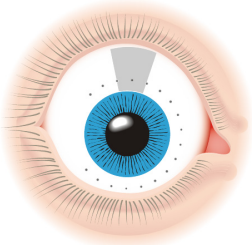
Recommended Procedure

The IRIDEX G-Probe is a fiber-optic laser delivery device used to selectively destroy ciliary processes in patients who require treatment for refractory glaucoma. Delivery is transscleral. Laser delivery is essentially parallel with the viewing axis of the eye, rather than perpendicular to the scleral surface. This technique reduces laser effects on adjacent structures, including the crystalline lens.

POSITIONING



Hold the handpiece parallel to the visual axis and mate the curved surface of the G-Probe with the sclera, keeping the smallest edge of the tip in close proximity to the limbus. Depress the G-Probe until the protruding fiber indents the sclera and the spherical surface of the G-Probe tip is in complete contact against the sclera. Maintain contact throughout laser delivery. During treatment, avoid dragging or rotating the G-probe over the conjunctiva.



Right eye shown

Space subsequent laser applications one-half the width of the G-Probe tip by aligning the trailing edge of the probe tip on the center of the indentation of the previous treatment lesion. Deliver laser application to 18–20 treatment sites over a 270° arc, as shown. Treat the right eye from the 10:30 position clockwise to the 7:30 position unless the area is scarred from previous operations. Treat the left eye from the 4:30 position clockwise to the 1:30 position (270°) unless the area is scarred from previous operations. Leave the most temporal 90° untreated to avoid hypotonous side effects.

Proper positioning of the G-Probe, as described above, automatically spaces the center of the fiber 1.0-1.2 mm posterior to the limbus and assures proper spacing between lesions. Each half of the G-Probe covers a 16° sector, with the fiber located in the center. Since the 600 µm fiber optic protrudes from the tip of the G-Probe by 0.75 mm, mating the curved surface of the G-Probe with the sclera ensures that the protruding fiber optic indents the sclera an equal distance at each treatment spot, and assures repeatable scleral indentation and reproducible scleral transmission. Keep the eye moist throughout the entire laser procedure, using ophthalmic saline or methylcellulose as needed.

SPOT SIZE

Therapeutic lesion size is larger than the theoretical spot size due to thermal conduction. A typical lesion size is approximately 2 mm in diameter.

POWER AND DURATION

Comparison of Original Approach to TSCPC With Dr. Gaasterland's Slow-Coagulation Technique				
Technique	**Iris Color**	**Power, mW**	**Duration, ms**	**Energy per Application, J**
Original[a,b]	Dark	1,500	2,000	3
	Light	1,750	2,000	3.5
Slow Coagulation[c]	Brown	1,250	4,000	5
	All Others	1,500	3,500	5.25

[a]Titrate to occasional "pops."

[b]Data adapted from Kosoko O, Gaasterland DE, Pollack IP, Enger CL. Long-term outcome of initial ciliary ablation with contact diode laser transscleral cyclophotocoagulation for severe glaucoma. The Diode Laser Ciliary Ablation Study Group. *Ophthalmology*. 1996;103(8):1294-1302.

[c]No-pop technique described by Gaasterland. Gaasterland DE. Diode laser cyclophotocoagulation. Technique and results. *Glaucoma Today*. March 2009;7(2):35-38.

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.

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.

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.

Always keep the IRIDEX laser in Standby mode when you are not treating a patient. Maintaining the IRIDEX laser in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.

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.

Always keep the fiber-optic tip / eye interface well irrigated to minimize risk of overheating and of burning tissue onto fiber face. Significant scleral burns are not typical and may indicate contamination at the G-Probe tip. Replace immediately. Do not continue to use; a full thickness or near full thickness burn or sclerostomy may result.

If there is an audible "pop" or "snap" during treatment, this may indicate intraocular tissue disruption; reduce power and leave the duration unchanged.

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.

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

IRIDEX Corporation Contact Information

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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.

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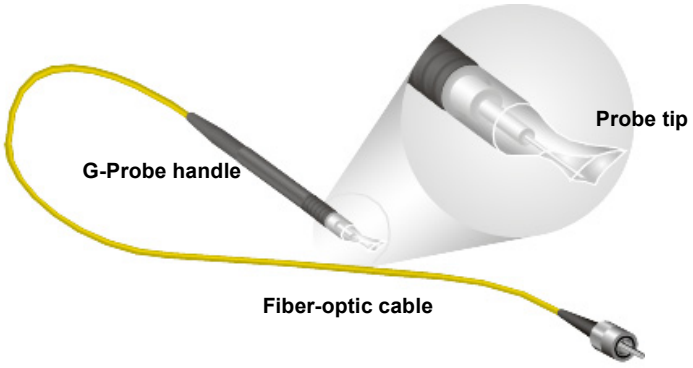
Operation

About the Components

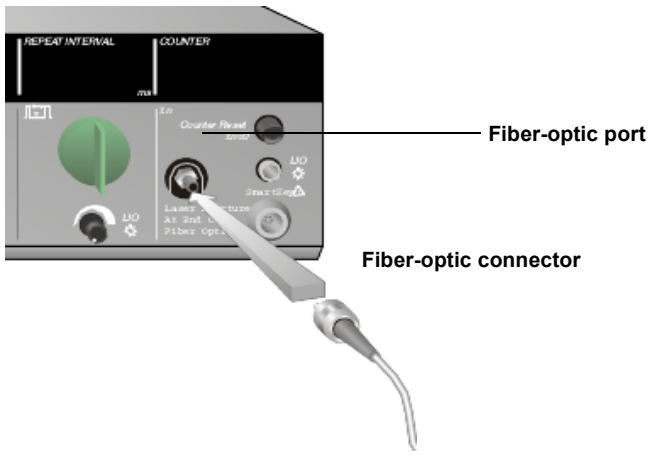
The G-Probe is a single-use, fiber-optic delivery device that consists of a hemispheric probe tip, a handle, and a fiber-optic cable. It delivers laser energy through its fiber-optic tip. The probe tip allows precise placement around the circumference of the limbus.

Check the G-Probe carefully before use to ensure that no damage occurred during transit.

NOTE: *Ensure eye safety. Use 810 nm laser safety glasses or eye safety filter. An 810 nm filter may be part of an SLA, LIO, or operating microscope system.*



Connecting the G-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

The G-Probe is a single-use, disposable delivery device. When finished with a procedure, dispose of the G-Probe. Do not reuse or resterilize.

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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 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.

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.

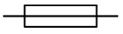
Safety Compliance

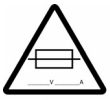
Complies with FDA performance standards for laser products, except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

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	Σ_n Pulse Count
$\Sigma_n = 0$ Pulse Count Reset	 No-ionizing Electromagnetic Radiation	 Read Information
 Remote Control	 Remote Interlock	SN 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				

G-Probe Specifications

Specification	Definition
Probes	Standard handle: 10.30 cm (4.05 in.)
Laser compatibility	OcuLight SL OcuLight SLx IQ 810
Treatment wavelength	Laser diode, 810 nm
Fiber diameter	600 µm
Sterile condition