

IRIDEX G-Probe™ Illuminate

Instructions for Use

INTENDED USE and INDICATIONS:

The Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm] [IRIDEX Cyclo G6 Laser System]) and the hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulse® or LongPulse™ mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

810nm (The IRIDEX Cyclo G6 Laser System)

Ophthalmology:

The IRIDEX® Cyclo G6™ Laser System and Probe Delivery Devices (G-Probe, G-Probe Illuminate, & MicroPulse® P3) are used to deliver laser energy in either CW-Pulse (CW) or MicroPulse (µP) treatment mode and indicated for the treatment of Glaucoma:

	Condition (Indicated for)	Treatment (Intended Use)	CW/µP
MicroPulse P3 Device	For the treatment of Glaucoma including: <ul style="list-style-type: none"> • Primary Open-Angle • Closed-Angle • Refractory 	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	µP
G-Probe & G-Probe Illuminate	For the treatment of Glaucoma including: <ul style="list-style-type: none"> • Primary Open-Angle • Closed-Angle • Refractory 	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	CW

DIRECTIONS FOR USE:

Remove probe from package and unwind with care. This product contains a glass optical fiber that can be damaged with improper handling.

Connect probe to a compatible IRIDEX laser console and light source.

Consult your operator manual for additional instructions, contraindications, warnings, and cautions.

Anesthesia

Administer local anesthetic block: Retrobulbar and/or peribulbar injections, or subconjunctival anesthesia with, for example, 2% mepivacaine, or equivalent agent.

Treatment may be done with patient supine or seated at the slit lamp.

G-Probe Illuminate and Eye Moistness

Keep the G-Probe Illuminate tip and the eye surface moist throughout TSCPC. Apply a drop of methylcellulose solution to the G-Probe Illuminate device's fiber optic tip, or close the patient's eyelids to ensure moisturizing with the natural tear film. If you use a lid speculum, apply artificial tears to the eye; repeat topical lubricant method of choice after every four laser applications.

Placement (Fig. 1)

Hold the G-Probe Illuminate parallel to the visual axis with the shorter edge of the footplate firmly between the anterior border and the middle of the limbus. Laser delivery is transscleral.



Fig. 1: Placement

Applications (Fig. 2)

Successive applications are spaced one-half the width of the G-Probe Illuminate footplate apart by aligning a side of the probe over the indented center of the adjacent application.



Fig. 2: Applications

Treatment (Fig. 3)

Administer 18-21 laser applications per treatment session over 270° (three quadrants, six or seven applications per quadrant), usually omitting the temporal quadrant.



Fig. 3: Treatment

G-Probe Illuminate treatment parameters are suggested by IRIDEX and are based on recommendations by experienced clinicians (Table 1). Ultimately, it is the physician's responsibility to determine appropriate treatment parameters for each case.

CAUTION: Federal law restricts this device to sale by or on the order of a physician

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Table 1

Iris Color	Power	Duration	Energy per Application
Dark Brown	1250 mW	4000 ms	5.00 joules
All other	1500 mW	3500 ms	5.25 joules

This array of treatment parameters has been called the "slow coagulation" technique and has proven effective for most eyes.

Response

Use of these parameters will typically result in no or few audible "pops."

Most doctors usually prescribe topical cycloplegics and corticosteroids in anticipation of secondary postoperative inflammation and possible discomfort.

Patient Repeat Treatment, if necessary

Begin retreatment 45° from the initial treatment. The second 270° treatment will cover a half of the untreated quadrant, plus two and a half quadrants from the earlier treatment.

G-Probe Illuminate Fiber Cleanliness

Keep the G-Probe Illuminate tip clean to minimize the risk of burns to the ocular surface. If the tip becomes dirty during the procedure, clean it gently with an alcohol swab. If dirt or discoloration on the tip cannot be removed by gentle cleaning, discard the G-Probe Illuminate. Scleral burns are not typical and may indicate contamination at the G-Probe Illuminate tip.

If a scleral burn occurs, discontinue use and replace the G-Probe Illuminate immediately. The G-Probe Illuminate is a Single-Use Product.

CAUTION:

Keep the G-Probe Illuminate tip and the eye surface moist throughout TSCPC treatment. Do not treat over sites of previous trabeculectomies.

WARNING:

Excessive treatment power may result in ocular surface burns or ciliary body hemorrhage. Contamination of the fiber optic tip by blood or tissue char may result in ocular surface burns. Excessive energy may cause equatorial burns. Heavy perilimbal conjunctival pigmentation may result in local absorption and burns; therefore, avoid areas of heavy perilimbal pigmentation.

Do not open sterile package prematurely. Open sterile package just prior to use to maintain sterility of contents.

This device must be used with appropriate laser safety filter or eyewear. Never look directly into the laser light source or at laser light scattered from reflective surfaces.

Inspect packaging prior to use: DO NOT USE IF THE PACKAGE IS DAMAGED OR IF THE STERILE BARRIER IS COMPROMISED.



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