

G-Probe Illuminate® Device

ENGLISH INSTRUCTIONS FOR USE

INDICATIONS

The Iridex Cyclo G6® Laser System and Probe Delivery Devices (G-Probe® device, G-Probe Illuminate® device, and MicroPulse P3® device) are used to deliver laser energy in either CW-Pulse (CW) or MicroPulse (µP) treatment mode:

| | Treatment (Intended Use) | CW / µP |
|------------------------------|---|---------|
| MicroPulse P3 Device | Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes | µP |
| G-Probe & G-Probe Illuminate | 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 an Iridex Cyclo G6 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. It is essential that the probe tip is continuously immersed in fluid. 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 frequently.

G-Probe Illuminate Light Source

During use of G-Probe Illuminate probe, the light source will illuminate the targeted area of ciliary body and thus, will help determine the appropriate probe position.

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.

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 effectiveness 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 trabeculectomy blebs.

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

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Made in USA

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