

# MicroPulse P3® Device

## ENGLISH INSTRUCTIONS FOR USE

### INDICATIONS

Indications for this device include, but are not limited to transscleral cyclophotocoagulation.

### DIRECTIONS FOR USE

The following directions are intended to provide guidance only for treatment settings which are not prescriptive for any condition. The operative needs of each patient should be individually evaluated based on the specific indication, treatment location, and patient-specific characteristics. If uncertain of expected clinical response, always start with conservative settings and increase laser power and/or duration settings in small steps.

1. 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. Consult your operator manual for additional instructions, contraindications, warnings, and cautions.
2. The device may be used with or without a speculum.
3. Use laser safety glasses with a minimum optical density (OD) of 4.
4. Keep the probe tip and the eye surface moist throughout the procedure. It is essential that the probe tip is continuously immersed in fluid. Apply a drop of methylcellulose gel or equivalent to the undersurface of the MicroPulse P3 device's footplate. Repeat topical lubricant method of choice frequently.
5. Place the curved end of the footplate at the limbal margin. Be sure to view from directly above to avoid placement error because of parallax. Maintain the footplate of the probe flat against the conjunctiva throughout the treatment with constant, gentle pressure, see **Figure 1**. Note, the device will align the internal fiber-optic tip at approximately 3mm posterior to the limbus.

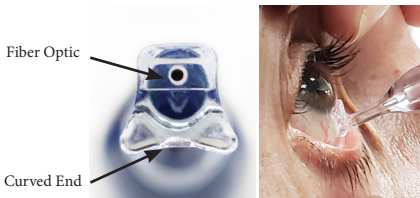
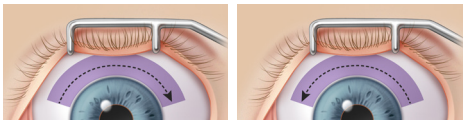


Figure 1. Placement

6. Treat the superior hemisphere. Press the footswitch to activate the laser. If you interrupt the treatment, release the footswitch and reactivate the footswitch when you are ready to resume.

Sweep the MicroPulse P3 probe along the limbus in an arc of 150 degrees for 10 seconds. Reverse the direction and repeat for a total of 5 passes for a total of 50 seconds, see **Figure 2**. Avoid the 3 and 9 o'clock positions.

Based on recommendations of experienced clinicians, use MicroPulse mode at an average power of 2000 mW and a duty cycle of 31.3% (0.5 ms on 1.1 ms off).<sup>1</sup>



A single pass is 150° in one direction

Figure 2. Sweep Technique

7. If the device snags on conjunctiva, momentarily stop laser

treatment to release the caught conjunctiva and replace the device.

8. After treatment of a hemisphere, inspect the probe footplate for debris or "charring" and confirm gel is adequately present. If the probe tip accumulates debris or "charring" during the procedure, clean it gently with sterile gauze and a saline solution. Keep the device tip clean to minimize the risk of burns to the ocular surface. After cleaning tip, re-apply a drop of methylcellulose gel and continue treatment. If the "charring" or discoloration on the tip cannot be removed by gentle cleaning, discard the device. Scleral burns are not typical and may indicate contamination at the device tip.

If a scleral burn occurs, discontinue use and replace the device immediately.

9. To treat the inferior hemisphere, repeat steps 4-8.

The device is a Single-Use Product. 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 on the eye of a patient and may lead to patient injury and/or infection.

### CAUTION

Keep the device tip and the eye surface moist throughout treatment. Do not treat over sites of previous trabeculectomy blebs, scleral thinning, or directly over tubes and shunts.

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

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

Store package under normal storage conditions – in a dry, clean, well ventilated area at room temperature, between 15°-25°C (59°-77°F).

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

**REFERENCE:** 1. Tan A, et al. Micropulse Transscleral Diode Laser Cyclophotocoagulation in the Treatment of Refractory Glaucoma. *Clin Experiment Ophthalmol*, 2010;38(3):266-72.

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



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