

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Laser Probes
Manufactured by SterilMed, Inc.
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Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed laser probes from various original equipment manufacturers (OEM). Reprocessed laser probes are part of a laser delivery system and are used in ophthalmic procedures where laser energy is the mode of treatment.

Each OEM provided an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

Laser probes are an accessory used in laser surgery in conjunction with a laser delivery system. The probe consists of the probe hand piece, strain relief, fiber optic cable, and laser connector. It is the laser probe that delivers the energy to the treatment site through the opening at the probe tip.

Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

Reprocessed laser probes have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from an owner, reprocessed, and returned to the owner for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor and ensure the number of times reprocessed.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

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CONTRAINDICATIONS

1. These instruments are not intended for use when optical procedures or laser techniques are contraindicated.
2. Laser surgery should be performed only by persons having adequate training and familiarity with such techniques. Consult literature relative to techniques, complications, and hazards prior to performing any procedure.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of laser surgery and the techniques required for safety.
2. Inspect the packaging and product prior to use. Do not use the package/product if sterility appears to be compromised or the package appears to be damaged.
3. Equipment may vary with each manufacturer. Verify appropriate compatibility of all equipment and accessories prior to use.
4. Never substitute prescription eyewear for the appropriate laser safety eyewear as severe eye damage could occur. Prescription eyewear can concentrate the laser light to the eye and/or can be shattered by a high power density beam, possibly causing severe eye damage.
5. Severe and irreversible eye damage and scarring may occur from direct or indirect exposure to the treatment beam. The predominant ocular structures at risk are dependent on the laser wavelength in use. Visible and near-infrared wavelengths are most damaging to the retina, while ultraviolet or infrared wavelengths are most damaging to the cornea and sclera. Severity of injury depends on how concentrated or diffused the treatment beam is and the length of exposure. A thorough understanding of the specific ocular risks and safety precautions for each laser wavelength is necessary to ensure the safety of the patient and operating personnel.
6. Never look directly into any optical lens, except for therapeutic purposes, nor any optical fiber, probe, or laser system aperture while the laser is energized. Severe eye damage could occur. Turn off the laser before inspecting any delivery system or laser components.
7. Verify the integrity of the aiming beam before beginning a procedure. Verifying the aiming beam integrity is extremely important for the safe operation of the laser equipment. Do not use the laser or delivery system if the aiming beam is not visible. Operating the laser without the aiming beam may result in laser exposure to non-targeted tissue and possible injury.
8. A damaged fiber optic cable may cause accidental laser exposure to the treatment personnel or patient and/or fire in the treatment room.
9. Minimize the light intensity and duration of exposure to the retina to reduce risk of retinal photic injury.

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10. Power density may vary slightly from system to system. Laser power should initially be set at a low level and then be increased gradually until the desired tissue effect is obtained.
11. Do not clamp the cable with a hemostat or other instruments. If sterile tape is used, always remove the tape before lifting the cable.
12. When adjusting the distance to the target tissue, be careful not to actually touch the retina with the probe tip. Touching could tear or damage the retina.
13. Make sure the fiber optic cable is not kinked, punctured, fractured or damaged in any way. A damaged fiber optic cable may cause accidental laser exposure to the treatment room personnel or patient and/or fire in the treatment room.
14. Do not use the delivery system if the aiming beam is set to high intensity and is still weak or not visible; the fiber optic cable may be damaged.
15. The laser clinician must understand the relationships between spot size, laser power, power density, and thermal interaction of the laser beam with living tissue before using the laser system and the laser delivery system
16. 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.
17. Do not focus light on a single point of the retina for prolonged, unnecessary periods of time.

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with laser surgery. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Damage to the optical area, e.g., tears
2. Infection
3. Burns
4. Phototoxicity.

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies, individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely on training and practical experience.

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If additional reprocessing of the product is desired, wipe the device with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, routine sterilization, and functional testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

** Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:*

** Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.*

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

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