LASER PROBE, STERILE, SINGLE USE (*REFER TO LABEL FOR PATENT PROTECTION)

STERILE EO

DESCRIPTION/INDICATION FOR USE (by physicians in the operating room)

This probe is used during surgical interventions with laser at operating wavelength of 500 to 1,100 nm, and is indicated for use to perform endo-ocular laser photocoagulation treatments inside the eye during trans-plana vitrectomy. It is made out of 8ft fiberoptic cable that is covered by a flexible plastic jacket along its length for protection against damages.
It is terminated on one end with a handpiece for holding and manipulation during surgery, having a distal end that is 20 gauge or smaller outer diameter (i.e., larger gauge numerical value).
It allows to safely and effectively transmit laser energy from the laser source to the surgical site, facilitated by the aiming beam that is provided by the laser source, transmitted via the laser connector terminated on the other end of the probe.
For Bending* laser probes, when the sliding button on the handle is advanced, an internal straightening tube advances into the distal pre-curved PEEK memory tube, thus causing a reduction of the angle of the pre-curved PEEK memory tube, down to zero degrees (straight position) at the maximum sliding position, allowing the selection of the desired angle during surgery.
For information on the power settings, duty cycle(s), ranges and increments of timing and intervals, please refer to the Directions for Use of the laser source.
In case of added illumination functionality, the illumination branch is terminated with an illumination connector to allow connection to the illumination machine.
This device does not include any lenses, and there is no focal distance to define.
Refer to the label for specific device details including functionalities and connectors.

CAUTION: FEDERAL (U.S.A) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

INSTRUCTIONS FOR USE:

- Prior to unpacking, inspect the device package for integrity
- Unpack the laser probe in a sterile environment
- Release the probe from pouches and remove mini-tray
- The laser source should be in the OFF position prior to attaching the laser probe.
- Insert the laser connector into the laser source.
- In case of illuminated laser probe, insert the illumination connector into the illumination machine
- Follow the recommendations of the laser source manufacturer (e.g.: calibration of the laser source as well as the need for protective eye wear for the corresponding wavelength of the laser model used), and -if applicable- the illumination source manufacturer
- In case of bending* probes, fully slide button forward to straighten the tip prior to penetration or withdrawal; sliding the button all the way forward straightens the tip while sliding the button backward incrementally curves the tip, as illustrated below:

- To test the performance for the safe use of the laser probe, inspect the image of the aiming beam before the start of the laser procedure. For this purpose, point the tip of the probe straight to a bright (white) surface at a distance of about 20 cm (8”). Activate the aiming beam. When the image is circular and evenly illuminated, the performance of the laser probe is acceptable. If the image is faint or unequal, the laser probe should not be used.
- If the expected tissue effect cannot be obtained regardless of increased power output, the tip of the laser probe may be soiled or the probe itself may have deteriorated or be broken and may require replacement.

- **WARNINGS**
  THIS DEVICE MUST BE USED WITH AN APPRORIATE FILTER. Use appropriate filter when using this device.
  Do not look directly into or at the laser beam or its reflections. Direct and reflected laser light can cause permanent eye injury.
  Typical laser power is few hundred milli Watts, with the limit not to exceed 1 Watt.

- **WARNING - IN CASE OF ILLUMINATED LASER PROBE:**
  Due to the potentially hazardous effects of phototoxicity to the retina from prolonged endoillumination, this device should be used with an illumination source with filters that eliminate UV radiation (<400nm) and whenever possible, with filters that eliminate short wavelength blue light (<420nm). Care should be taken not to focus this device on a single point of the retina for prolonged, unnecessary periods of time.

REORDER CODES:

Refer to the product label to determine type and corresponding reorder product REF code.

FEATURES:

- Ergonomic and non-slip handpiece design.
- Different connectors that suit most laser source and illumination source models available on the market.
- Sterilized by Ethylene Oxide, single-use, latex-free.
- 20g tip laser probe tapered tip for ease of insertion through the sclerotomy sites during the surgical procedure.
- 23g and smaller sizes are available for faster patient post-operative recovery.

- Bending* pre-curved flexible distal tip that straightens when sliding the button on the handle.

CAUTION:

This device is to be used only by qualified physicians trained on the procedure and the laser machine.
Follow medical operating procedures during surgery.
Single use only. Do not re-sterilize. Do not reuse. Material fatigue decreases performance.
For bending probes, straighten tip before insertion and withdrawal.

PRECAUTION:

- Do not use if package is open, damaged or wet.
- Do not use if expiry date shown on the label (format: yyyy-mm-dd) is exceeded.
- This device is to be used only by qualified physicians trained on the procedure and the laser machine. Follow medical operating procedures during surgery.
- Single use only. Do not re-sterilize. Do not reuse. Material fatigue decreases performance.
- Avoid contact of the laser probe tip with other instruments, because of the risk of uncontrolled scatter or damage to the laser probe.
- Do not apply excessive stress (i.e. kinks or bends) to the laser probe as to avoid product damage.
- Positioning the laser probe closer to its intended target will provide a decreased laser spot size. Backing probe away from its intended target will result in a larger laser spot size.
- Do not fire the laser when the laser probe is in direct contact with tissue.
- Keep the tip of the probe free of debris during use.
- Use appropriately sized trocar to suit the tip of the probe

ADVERSE REACTIONS:

Potential complications specific to retinal photocoagulation include inadvertent foveal burns, choroidal neovascularization, paracentral scotomata, subretinal fibrosis, photocoagulation scar expansion, Bruch's membrane rupture, choroidal detachment, exudative retinal detachment, pupillary abnormalities from damage to the ciliary nerves, and optic neuritis from treatment directly or adjacent to the disc.

CONTRAINDICATIONS:

There are no contraindications associated with the use of this product other than those related to the specific procedure being performed (to be assessed by the physician).

RECOMMENDED STORAGE CONDITIONS:

- No exposure to rain or water
- No exposure to direct sunlight or ultraviolet rays
- A clean and dry location with nothing loaded on the delivery unit
- No chemicals, organic solvents, or corrosive gas present
- No poisonous gas, sulfur, salt, or large amount of dust contained in the air
- Level and stable without vibration and shock

COMPATIBILITY WITH OTHER DEVICES:

Refer to the product label to determine connector type and the machine(s) that this device may be connected to.
Refer to catalog located at http://www.ophthalmed.com/Products.html or http://www.ophthalmed.com/Ophthalmed-catalog.pdf

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