



DISPOSABLE LASER PROBES

Indications for Use

Vitreoq Disposable Laser Probes, 90° Directional Laser Probes and (90°) Directional Illuminated Laser Probes are intended for use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelengths of 500nm to 900nm.

The (90°) Directional Illuminated Laser Probes, Light Fibers and Chandelier are for illumination during ophthalmic surgery and should only be used with the light wavelength range of 425nm to 700nm.

Instructions for Use

The Laser Probe can only be used in combination with compatible ophthalmic laser equipment approved for intraocular endo-photocoagulation. Please verify that the Laser Probe is compatible with the ophthalmic laser equipment, which is used in the specific market. The maximum power output of the used ophthalmic laser equipment is up to 3 Watts. The Vitreoq Laser Probe does not conduct electric energy.

Europe Market (EMEA)			
Ophthalmic surgical system, including Laser generator	Compatible Vitreoq Directional (Illuminated) Laser Probes		
	Alcon® Style	Iridex® Style	DORC® Style
ALCON Constellation® ALCON PUREPOINT®	✓	✗	✗
Ellex Medical Solitaire™ Meridian Merilas 532α Oertli OS4™	✓	✗	✗
Bausch & Lomb Stellaris® PC Bausch & Lomb Stellaris® Elite	✗	✓	✗
Iridex OcuLight GL, GLx or TX Iridex IQ 532™	✗	✓	✗
DORC EVA® DORC LaserStar	✗	✗	✓

USA Market			
Ophthalmic surgical system, including Laser generator	Compatible Vitreoq Directional (Illuminated) Laser Probes		
	Alcon® Style	Iridex® Style	DORC® Style
ALCON Constellation® (K101285) ALCON PUREPOINT® (K062624)	✓	✗	✗
DORC EVA® (K142877) DORC LaserStar (K072823)	✓	✗	✗
Meridian Merilas 532α (K072823)	✓	✗	✗
Bausch & Lomb Stellaris® PC (K133486) Bausch & Lomb Stellaris® Elite (K170052)	✗	✓	✗
Iridex OcuLight GL, GLx (K050562) Iridex OcuLight TX (K062369) Iridex IQ 532™ (K071687)	✗	✓	✗

Caution:

-Rx only: "Federal law restricts this device to sale by or on order of a licensed physician."

Japan Market			
Ophthalmic surgical system, including Laser generator	Compatible Vitreo Directional (Illuminated) Laser Probes		
	Alcon® Style	Iridex® Style	DORC® Style
ALCON Constellation® 22200BZX00923000	✓	✗	✗
DORC EVA® 23000BZX00103000	✓	✗	✗
IRIS Medical OcuLight GL 20900BZY00835000 IRIS Medical OcuLight GLx 21000BZY00690000 Iridex IQ 532™ 22500BZX00168000	✗	✓	✗

Packaging

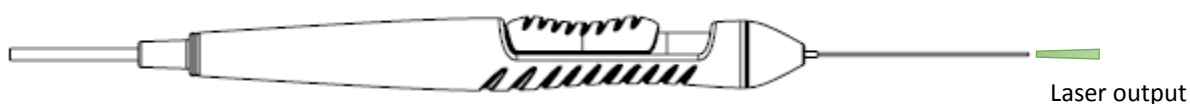
The Laser Probes are supplied sterile. The Laser Probes are ethylene oxide gas sterilized and guaranteed to be sterile until the expiration date stated on the product label. Each Laser Probe is packaged in a peel pouch for ease of introduction into the sterile field.

Preparation

- Please visually inspect the packaging of the sterile Laser Probe for possible damages and expiration date. Probes from previously opened or damaged packaging must be deemed unsterile.
- Unpack the Laser Probe for introduction into a sterile environment.
- Set the medical laser equipment in a safe setting following the instructions of the ophthalmic laser equipment.
- Remove the Laser Probe from the protection tray and uncoil with care.
- Insert the laser probe connector into the receptor port of the ophthalmic laser equipment following the instructions of the ophthalmic laser equipment.
- The laser power is released from the instrument tip.

Directions for Use

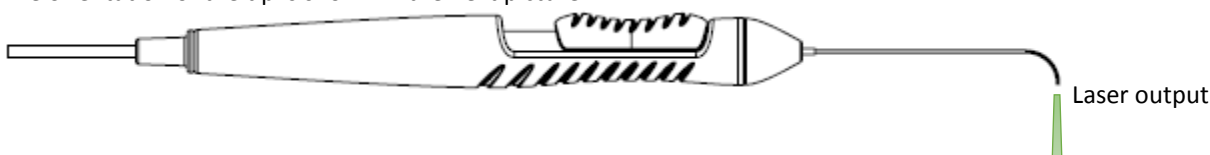
Insert the laser probe in the posterior segment of the eye through the entry port or incision in the following retracted position:



Inside the eye the curved instrument tip can be extended by sliding the button forward.

CAUTION: The rigid inner tube extends towards the retina when using this product and moving from a straight to a curved configuration. To avoid retina contact, the hand piece must be simultaneously withdrawn.

The orientation of the tip is shown in the next picture:



Positioning the Laser Probe closer to its intended tissue target will provide a decreased laser spot size as well as a focused light field. Backing the Laser Probe away from its intended tissue target will result in a larger laser spot size and wider illuminating field.

Vitreoq a company of:



Known complications of endophotocoagulation:

- Edema at the site of treatment
- Inflammation
- Choroidal detachment
- Infection
- Corneal burn
- Increased bleeding

Occurrence of the complications is statistically rare. The user is adequately trained in the use of ophthalmic laser surgery and in the treatment of the known complications.

Contraindications

- Use of this product if package integrity has been breached or compromised;
- Use of the product after the expiration date.

Warnings

The laser probe is NOT intended for use with CO₂ laser systems.

Proper eye protection should be worn at all times, when the laser equipment is switched on.

Please read carefully the instructions for full clinical use provided by the manufacturer of the ophthalmic laser equipment.

Do not apply excessive stress to the Laser Probe as to avoid product damage.

Avoid contact of the Laser Probe tip with other instruments, because of the risk of uncontrolled scatter or damage to the Laser Probe.

The use of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided. Some materials, for example cotton or wool when saturated with oxygen, may be ignited by the high temperatures produced in normal use of the laser equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Do not re-use

The design and the materials used do not allow cleaning and re-sterilization of the Vitreoq Laser Probes. Reprocessing will decrease the performance of the device and correct function and sterility cannot be guaranteed.

Symbols



Do not re-use



Keep away from heat



Use-by date YYYY-MM



Keep dry



Batch code



Manufacturer



Sterilized using ethylene oxide



Do not use if pack is damaged



Catalogue number



Consult instruction for use



Store at temperature range 15 to 30°C
(59 to 86°F)

Liability statement

Vitreoq makes no warranty, neither expressed nor implied, relating to sales of Laser Probes and disclaims warranty liability with regard to merchantability or suitability of use. Vitreoq will not be liable for injury or damage resulting from surgeon's method or technique.

Vitreoq will not be liable for injury or damage resulting from selection and use of any Laser Probe for any particular patient or any patient's condition.

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