Instructions for Use

Laser Probes, Illuminated Laser Probes, and Illumination Instruments

VS0110.23, VS0110.25, VS0110.27, VS0120.23, VS0120.25, VS0120.27, VS0125.23A, VS0125.23B, VS0125.23D, VS0125.25A, VS0125.25B, VS0125.25D, VS0130.23, VS0130.25, VS0140.23, VS0140.25, VS0140.27, VS0141.23, VS0141.25, VS0141.27

Indications for use - Vortex Surgical Laser Probes and Illuminated Laser Probes are indicated for use in laser endophotocoagulation procedures in the posterior segment of the eye during vitreoretinal surgery at 500nm to 1100nm. Vortex Surgical Illuminated Laser Probes, Endoilluminator, and Chandelier are indicated for illumination during vitreoretinal surgery with visible light.

Contraindications - None

Device Description - Vortex Surgical Laser Probes, Illuminated Laser Probes, Endoilluminators, and Chandeliers are intended as a single-use instruments used in ophthalmic surgery for posterior segment procedures. The devices do not conduct electrical energy. By design the device does not generate, intensify, or significantly reduce energy. All radiation emitted from this device was produced from a source. Detailed information regarding the nature, intensity, and distribution of emitted radiation can be found with the source's instructions for use or user manual. The clinical benefits of the Vortex Surgical Laser Probes and Illumination Devices when used in combination with a compatible source to transmit laser and illumination energy within the eye, include the support of the process of reattachment of retinal tears or detachments, treatment of abnormal blood vessels to mitigate vision loss, and reduction of the risk for disease progression. Absence of treatment of retinal tears/detachment may lead to permanent loss of vision.

Devices meet ISO 60601-2-22 laser output requirement and will not deviate more than ±20% of calibrated source reading.

VS01XX.2XA - For use with the Alcon Constellation; VS01XX.2XB- For use with the Bausch and Lomb Stellaris PC; VS01XX.2XD- For use with the DORC EVA.

Known Complications - Choroidal or retinal detachment, tears, holes and contusions, bleeding, inflammation, and infection. These complications are statistically rare and it is assumed that the user is adequately trained in the treatment of these known complications and methods of avoidance.

Precaution - Laser probes: Excessive treatment power may result in a retinal hole, a retinal hemorrhage, and/or foveal burns. Start with low power and slowly increase power until desired treatment level is achieved.

Precaution - Illumination devices: The light emitted from this instrument is potentially hazardous. Avoid concentrating the illumination output on a small area of the retina for prolonged periods of time due to the potential for photoretinitis and serious permanent patient injury. Set the illumination level to the minimum needed to perform the surgical procedure.

Caution - Federal (USA) law restricts this device sale by, or on the order of, a physician. Devices are to be handled by adequately trained personnel.

Instructions for use: (Electronic Copy of IFU can be found at https://www.vortexsurgical.com/instructionsforuse)

1) Determine package integrity. **Warning** - Do not use product if package integrity has been breached, or product is damaged. Do not modify instruments.
2) Affect sterile transfer of the product to the sterile field.
3) Remove the product from the tray.
4) Attach connector to appropriate laser source and/or light source. Verify the device is compatible with the ophthalmic system with which it is used. Vortex Surgical laser probes and illuminated laser probes are tested to be compatible with the Alcon Pure Point Laser and Constellation, Bausch and Lomb Stellaris, Iridex GL Laser, Ellex Solitaire laser, and DORC EVA.
5) The instrument is now prepared for specified use.
6) When using the Illuminated and standard MAXReach laser probes, ensure the probe is in the straight position before entering the cannula or removing the probe from the eye.
7) Follow established surgical procedures.

Warnings - This device must be used with the appropriate laser and illumination filters. Do not look directly into or at the laser beam or its reflections.
- Do not sterilize. Single Use only - Discard after use. Turn off the laser before inspecting any laser probe device.
- Keep the laser probe in the protective tray when not in use. Always handle the fiber optic cables with extreme care. Do not coil the cable into a diameter less than 3 inches.
- There is a risk when using unapproved sources that could result in unexpected power levels and/or treatment sizes. >1W of power may damage probe.
- Use of a probe with a damaged tip could result in unexpected treatment size or direction; Use aiming beam quality as an indication of tip/fiber condition.
- The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Vortex Surgical Illumination Instruments can be used with calibrated illumination sources including: B&L Stellaris®, Alcon Constellation®, and DORC EVA®. Check source manufacturers for safe operating times according to ISO 15752. >100mW of power may damage probe.

Device Storage - Vortex Surgical Inc. recommends that the product is stored in a clean, dry and well ventilated area at room temperature 15-37°C (59-98.6°F) away from direct sunlight.

Sterilization—This product is sterilized by ethylene oxide gas (EtO) and provided with an EtO indicator. Verify indicator status color prior to use.

Reuse - This product is sterilized by Ethylene Oxide Gas. Vortex Surgical Inc. has not validated the reprocessing/re-sterilization of this product and will not be responsible for product that is re-sterilized.

Device Disposal - This single use surgical instrument should be considered clinical waste and should be disposed in accordance with clinical waste laws applicable in your country.

Reporting - Report serious incidents to Vortex Surgical and your regulatory body.

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Manufacturer

Sterilized using ethylene oxide

Manufactured in USA/ Date of Manufacture


Do not use if damaged

Do not reuse

Do not resterilze

Temperature limit


Keep away from sunlight

Not made with natural rubber latex

Medical Device

Prescription Use only


Consult Instructions for Use

EMERGO EUROPE
Westervoortsedijk 60, 6827 AT Amhem
Authorized representative in the European Union


Keep dry


Use By

Quantity

Catalog number

Lot number

Issue Date: 9-29-23

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