Instructions for Use

Subretinal Injection Cannula (VS0220.25)

Indications for use - Vortex Surgical Cannula devices are intended to inject, irrigate, or remove fluids during vitreoretinal surgery into the subretinal space

Contraindications - None

Device Description - Vortex Surgical Subretinal Injection Cannula is a vitreoretinal cannula with polyimide tip connected to a standard luer hub. The cannula is only available in 25ga (Blue) gauge. Cannulas are compatible with their corresponding gauge trocar cannula system.

Known complications - Retinal Detachment, tears, holes, contusions, bleeding, inflammation, infection, and partial loss of vision. 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.

Caution - Federal (USA) law restricts this device sale by, or on the order of, a physician.

Instructions for use:

1. Determine package integrity.
2. Affect sterile transfer of the product to the sterile field.
3. Remove the tip protector and the instrument is now prepared for specified use.
4. Connect to standard irrigation/aspiration tubing sets.
5. Follow established surgical procedures.

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. **Re-sterilization:** Do not re-sterilize instrument

Warnings:

- Use with valved cannulas may result in damage to the product.
- Do not use if package integrity or product compromised.
- Do not use if product exposed to conditions outside of indicated range.
- Do not use if EtO indicator does not show exposure to sterilization gas.

Reuse: Do not reuse or reprocess instrument. Reuse could lead to cross contamination, infection, or device failure.

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 any serious incident that has occurred in relation to the device to Vortex Surgical and your regulatory body including the competent authority of the Member State in which the user and/or patient is established.

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info@vortexsurgical.com 636-778-4350 www.vortexsurgical.com

Manufacturer

EC REP — EMERGO EUROPE Westervoortsedijk 60, 6827 AT Arnhem The Netherlands — Authorized representative in the European Union

STERILE EO — Sterilized using ethylene oxide

15°C – 37°C — Temperature limit

Keep dry | Keep away from sunlight | Do not resterilize | Do not reuse | Do not used if damaged | Rx Only — Prescription use only | MD — Medical Device

Consult Instructions for Use | LOT — Lot number | REF — Catalog number | QTY — Quantity | Use By | USA — Manufactured in USA/Date of Manufacture | LATEX — Not made with natural rubber latex

Issue Date: 2024-12-06
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Vortex Surgical, Inc. excludes all warranties, whether expressed, implied, or otherwise, to matters beyond the direct control of Vortex Surgical, Inc and the end result of this device's use. This would include, but not be limited to handling, shipment and storage of the device and patient diagnosis and treatment. The fitness and merchantability of this device are as specified. Implied factors are specifically excluded. Vortex Surgical, Inc. is not liable for loss, whether incidental or consequential, damage and/or expense, arising directly or indirectly from the use of this device. There is no additional liability or responsibility assumed, other than that specified. All additional liability or responsibility is specifically disclaimed.

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