Instructions for Use

E.D.D. - External Drainage and Depression (VS0290X)

Indications for use – Vortex Surgical E.D.D. External Drainage and Depression devices are intended to remove subretinal fluids during vitreoretinal surgery. **Contraindications** - Injection of any substance through the device into the eye

Device Description – Vortex Surgical E.D.D. External Drainage and Depression devices is a device with an acrylic depressor head containing a retractable 28ga hypodermic needle designed to be inserted directly through the sclera and provide a self-sealing scleral incision for the drainage of subretinal fluids. Curved E.D.D. depressor is at a 45° angle from the handle.

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

1. Determine package integrity. 2. Affect sterile transfer of the product to the sterile field. 3. Remove product from tip protector. 4. Visually inspect depressor surface. Do not use if sharp edges or imperfections are present. 5. Actuate the slide button to expose the needle. Visually inspect the needle prior to use. Do not use if tip is damaged. 6. Prime the device utilizing a 3cc syringe of BSS (Balanced Salt Solution). Slowly prime the device using minimum pressure on the syringe until the BSS fills the device and is seen through the end of the needle. 7. The instrument is now prepared for use. 8. Follow established surgical procedures.

Surgical Recommendations for use during Vitrectomy:

- When positioning the needle for ***active*** drainage/aspiration in the subretinal space, clamp the infusion line and plug the trocar/cannulas to ensure the eye remains pressurized during depression and stable. Connect the device to the extrusion line after priming with BSS. After needle is appropriately positioned in the subretinal space, unclamp the infusion line and use the foot pedal for ***active extrusion*** to remove subretinal fluid. Recommended vacuum setting of 200-400mmHg depending on consistency of subretinal fluid.

- When positioning the needle for ***passive*** drainage in the subretinal space, clamp the infusion line and plug the trocar/cannulas to ensure the eye remains pressurized during depression and stable. Ensure the device is primed with BSS. After the needle is appropriately positioned in the subretinal space, unclamp the infusion line and raise the intraocular pressure gradually (>+35mmHg) to start ***passively*** removing subretinal fluid until the desired flow of subretinal fluid drainage is attained. Drainage can be expedited by (1) slowly increasing the infusion pressure in the eye or (2) manually depress the globe while infusion is clamped to raise intraocular pressure.

Warnings - Avoid contact with instrument tip while not in surgical use as damage to the tip could occur. 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. **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 **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.

Vortex Surgical, Inc. 4 Research Park Suite 124, Saint Charles, MO 63304, USA
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

℞ 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

Vortex Surgical Inc., 2024

Issue Date: 2024-12-06

2200010 rev D

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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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