Instructions for Use

Straight and Curved NANO SubRet Gateway Device (VS0225X)

Indications for use - Vortex Surgical Straight and Curved Nano Subretinal Gateway Devices are intended to inject, irrigate, or remove fluids during vitreoretinal surgery .

Contraindications - None

Device Description - Vortex Surgical Straight and Curved Nano Subretinal are vitreoretinal cannulas with retractable polyimide tip and 28ga hypodermic needle designed to be inserted directly through the sclera and provide a self-sealing scleral incision. Curved Nano SubRet Gateway Device polyimide needle exits at a 40° angle as it is extended.

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 the instrument from the tray. 4. Visually inspect tip for damage. If damaged, do not use. 5. Connect to standard irrigation/aspiration tubing sets. 6. The instrument is now prepared for specified use. 7. 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.

Warnings:

The device is designed to be utilized without cannulas. However, if cannulas are used, ensure the polyimide tip is fully retracted into the front needle prior to insertion through the valved or non-valved cannulas. Ensure the polyimide tip is fully retracted into the front needle prior to making the incision in the sclera. 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.

Re-sterilization: Do not re-sterilize instrument

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. 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.

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

Issue Date: 2024-12-06

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