

Instructions for Use

Backflush (VS27X.2X)

Indications for use – Vortex Surgical Backflush and Retractable Backflush devices are intended to inject, irrigate, or remove fluids during vitreoretinal surgery. **Contraindications** - None

Device Description - Vortex Surgical Backflush and Retractable Backflush are vitreoretinal cannulas with polyurethane tips and reflux bulb within the handle. The cannulas are available in three gauges: 23ga (Orange), 25ga (Blue) and 27ga (Purple). Retractable Backflush products can retract the polyurethane tip for passage through valved trocar cannula systems. 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: (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 tip protector and the instrument is now prepared for specified use.
4. Connect to standard irrigation/aspiration tubing sets.
5. Follow established surgical procedures.

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.

Device Storage - Vortex Surgical, Inc. recommends that the product is stored in a clean, dry and well-ventilated area at room temperature 15-25 °C (59-77 °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. 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 Drive, Suite 124, St. Charles, MO 63304, USA

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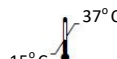
Manufacturer



Authorized representative
in the European Union



Sterilized using
ethylene oxide



Temperature
limit



Keep
dry



Keep away
from sunlight



Do not
resterilize



Do not
reuse



Do not use if
damaged



Prescription
use only



Medical
Device



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Issue Date: 2024-12-06

2200024 rev B



Consult
Instructions
for Use



Lot
number



Catalog
number



Quantity



Use
By



Manufactured
in USA/Date of
Manufacture



Not made with
natural rubber
latex

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Manufacturer



Authorized representative
in the European Union



Sterilized using
ethylene oxide



Temperature
limit



Keep
dry



Keep away
from sunlight



Do not
resterilize



Do not
reuse



Do not use if
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Prescription
use only



Medical
Device



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Use
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Manufactured
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