Instructions for Use

I2 Injection Kit (VS050XX)

Indications for use - The I2 Injection Kit is intended as a single-use kit used in ophthalmic surgery for posterior segment procedures.

Contraindications - None.

Known complications - Retinal detachment, tears and holes and/or scleral abrasions

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:

2) Determine package integrity.
3) Affect sterile transfer of the product to the sterile field.
4) Visually inspect the speculum and scleral marker for damage.
5) The device is now prepared for specified use.
6) 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:

- Do not use if package integrity has been compromised.
- Do not use if products are damaged.
- 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.

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 serious incidents to Vortex Surgical and your regulatory body

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.

Symbol glossary available on website (www.vortexsurgical.com/symbols)

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