Instructions for Use

T.I.D. Todorich Illuminated Depressor Pharos (VS0801X)

Indications for use – The Vortex Surgical Todorich Illuminated Depressor Pharos is intended as a single-use instrument used in ophthalmic surgery for posterior segment procedures.

Contraindications - Reprocessing/re-sterilization of product, repair of damaged product by customer, use of product if package integrity has been breached, use of damaged product

Known complications - Retinal detachment, tears, holes and contusions, burns, bleeding, inflammation, and infection.

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. Visually inspect depressor surface.
4. Insert the device connector into appropriate light source. Chart below.
5. The instrument is now prepared for use.
6. Follow established surgical procedures.

Connector Chart:

VS0801A - For use with the Alcon Constellation

VS0801B - For use with the Bausch and Lomb Stellaris PC

VS0801D - For use with the DORC EVA

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 product is damaged.
- Do not use if sharp edges or imperfections are present on depressor surfaces.
- 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

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

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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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