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Volk®1 Single Use Vitrectomy Lenses

- STERILE. STERILIZED WITH ETHYLENE OXIDE GAS.
- FOR SINGLE USE ONLY.
- DO NOT USE IF THE PACKAGE IS OPEN OR DAMAGED.
- FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

ENGLISH (EN): INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The Volk®1 Single Use Vitrectomy Lenses are indicated for use as diagnostic lenses for eye fundus examinations and use in the therapy of intraocular abnormalities. The devices are sterile, single use, disposable lens systems.

SPECIFICATIONS

Product	Product Code	Magnification	Field of View
Volk®1 Single Use Flat Vitrectomy	VFD	1.00x	36°
Volk®1 Single Use 1.5x Magnifying Vitrectomy	VMD	1.50x	30°
Volk®1 Single Use Wide Field Vitrectomy	VWFD	0.50x	48°
Volk®1 Single Use 30° Prism Vitrectomy	V30PD	0.80x	33° (offset 30°)
Volk®1 Single Use Biconcave Vitrectomy	VBCD	1.00x	25°
Volk®1 Single Use Flat SSV	VFLATSSVD	0.92x	30°



WARNINGS

- Do not immerse the device in a decontaminating product before use.
- Inspect the device(s) to make sure it is free from any damage (e.g. chips, scratches, etc.). Do not use or repair if the device is damaged.
- Inspect the contacting surface(s) to make sure it is free from any damage (e.g. chips, scratches, etc.). Do not use or repair if the device is damaged.
- ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO THE DEVICE SHOULD BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED.



PRECAUTIONS

- Do not attempt to use the Volk®1 Single Use Vitrectomy Lens prior to completely reading and understanding these instructions for use.
- To be used by a licensed physician in a method consistent with other direct image ophthalmic vitrectomy lenses.
- The sterile packaging and lens should be inspected prior to use.
- The Volk®1 Single Use Vitrectomy Lens is intended for single patient use only.
- Do not resterilize and reuse.
- This device is packaged and sterilized for single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or reesterilization may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

EXPIRATION DATE

Use the device prior to the Expiration Date on the package label.

SUGGESTED DIRECTIONS FOR USE

- Remove the lens from its package and place it in a sterile work area.
- All lens designs require methylcellulose or other similar viscous interface solution to be applied to the concave contact surface (i.e., between the cornea and the device).
- The Volk®1 Single Use Vitrectomy Lens is a surgical lens device that is placed on the cornea and helps improve accuracy and clarity of images of the posterior and peripheral retina and of the vitreous body during surgical intervention.

STORAGE

Devices should be stored at room temperature. Sterile instruments should be stored in an area that provides protection from loss of sterility.

DEVICE DISPOSAL

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Do not dispose the lens as unsorted municipal waste. When disposing of this product, please follow the procedure which conforms with the laws and regulations applicable to your area.



Sterilized using ethylene oxide



Do not re-use



Consult the Instructions for Use for important cautionary information



Do not use if package is damaged or open



Expiration Date



Lot number



Reference number



Manufacturer



Authorized representative in the European Community



Medical Device