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## Volk®1 Single Use Indirect Wide Field Vitrectomy Lens

- 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: INSTRUCTIONS FOR USE

#### INDICATIONS FOR USE

The Volk®1 Single Use Indirect Wide Field Vitrectomy Lens is indicated for use as a diagnostic lens 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 Indirect Wide Field Vitrectomy SSV with Handle	VVITSSVDH	0.55x	106°



#### WARNINGS

1. Do not immerse the device in a decontaminating product before use. Do not spray the device with any liquid before or during use.
2. 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.
3. 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.
4. 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

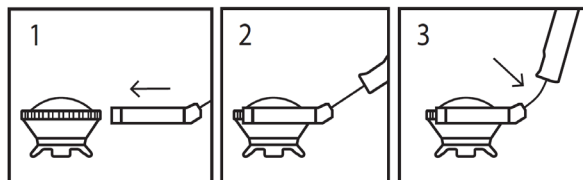
1. Do not attempt to use the Volk®1 Single Use Indirect Wide Field Vitrectomy Lens prior to completely reading and understanding these instructions for use.
2. To be used by a licensed physician in a method consistent with other indirect image ophthalmic vitrectomy lenses.
3. The sterile packaging and lens should be inspected prior to use. Do not use the device if the packaging is open or damaged, including holes, seal damage, loose components, or particulates inside the pouch.
4. The Volk®1 Single Use Indirect Wide Field Vitrectomy Lens is intended for single patient use only.
5. Bend the VVITSSVDH handle to your preferred angle prior to lens installation on the cornea. Do not bend the handle more than 5 times. Do not bend the handle past 20° from vertical. Do not twist the handle.
6. Do not resterilize and reuse.
7. This device is packaged and sterilized for single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization 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

1. Remove the lens from its package and place it in a sterile work area.
2. All lens designs require methylcellulose or other similar viscous interface solution be applied to the concave contact surface (i.e., between the cornea and the device).
3. The VVITSSVDH handle is optional to use. To assemble the lens and handle, hold the lens by the base of the black lens ring. Keep the lens and handle parallel. Slide the handle clip around the top scalloped ridge of the black lens ring.



4. The Volk®1 Single Use Indirect Wide Field 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 of 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