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Volk Optical Vitreolysis Lenses

ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE
Vitreolysis Lenses are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.

SPECIFICATIONS

Product	Part Numbers	Magnification	Laser Spot Magnification Factor	Anti-Reflective Laser Coating
Idrees MidVitreous Lens	VIMV	1.11	0.90	BBAR
Singh MidVitreous Lens	VSMV	1.16	0.86	BBAR

INDICATIONS FOR USE
1. To be used by a trained, licensed physician in a method consistent with other vitreolysis lenses in laser therapy for lysis of organized vitreous membranes.
2. Inspect the contacting surface(s) before each use and after reprocessing to make sure they are free from any damage (e.g. chips, scratches, etc.)
3. This lens requires methylcellulose or other similar interface solution be applied to the concave contact surface.
4. Volk's BBAR Anti-Reflective Laser Coating is optimized for diagnostic imaging, as well as visible and near-infrared wavelength laser procedures (e.g. argon & diode).
5. When calculating the spot size the laser spot setting should be multiplied by the appropriate Laser Magnification Factor. Refer to the Specifications table to find the appropriate Laser Magnification Factor for the lens you are using.

⚠ *WARNINGS:*

1. CAREFULLY EXAMINE THE DEVICE FOR DAMAGE PRIOR TO EACH USE. DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW(S) ANY SIGNS OF DAMAGE.
2. ENSURE THERE IS NO AIR BUBBLE IN THE COUPLING FLUID BETWEEN THE CONTACT LENS AND THE CORNEA.

⚠ *CAUTION:*

1. THE DEVICE SHIPS NON-STERILE AND MUST BE CLEANED AND DISENFECTED OR STERILIZED PRIOR TO USE. SEE CLEANING AND DISINFECTION OR STERILIZATION PROCEDURES BELOW.
2. ALLOW THE DEVICE TO COOL TO ROOM TEMPERATURE BEFORE GENERAL OR SURGICAL USE.
3. 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.

REPROCESSING

⚠ *WARNINGS:*

1. A THOROUGH, MANUAL CLEANING PROCESS IS RECOMMENDED.
2. CORROSIVE CLEANING AGENTS (I.E. ACIDS, ALKALINES, ETC) ARE NOT RECOMMENDED. DETERGENT CLEANING AGENTS WITH NEUTRAL PH ARE RECOMMENDED.

REPROCESSING LIMITATIONS:
Repeated cleaning, disinfection, and sterilization have minimal effect on Volk Vitreolysis Lenses when processed according to instructions. End of the product's life cycle is normally determined by wear and damage due to use.

PREPARATION AT THE POINT OF USE:
1. New or used, contaminated lenses must be cleaned.
2. Body fluids should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids.
3. Universal precautions for handling contaminated materials should be observed.
4. Instruments should be cleaned as soon as possible after use to minimize the drying of any fluids on their surfaces.
5. Devices should always be handled in an appropriate method to ensure contamination is not introduced to a recently cleaned, disinfected, and /or sterilized device.

PREPARATION BEFORE CLEANING:
The following cleaning, disinfection, and sterilization instructions are aided by not allowing contamination to dry on the lens surface. When possible, place the lenses in water or cover them with a damp cloth.

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CLEANING, DISINFECTION, STERILIZATION

CLEANING:

Select the desired method of cleaning:

Method A:	Clean with a mild detergent and a clean, soft cotton cloth or swab. Do not use detergent with any type of Emollients (moisturizers).
Method B:	Clean the glass element with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®. ***CAUTION:*** Do not use Volk's POLC or the Volk LensPen® on surfaces that contact the eye.
Method C:	1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water. 2. Soak each device in solution for 20 minutes. 3. After soaking, brush knurled surface on device ring with a soft-bristle brush and wipe lens portion with a soft cloth until all traces of cleaner and soil are removed. Pay special attention to all crevices and other hard-to-reach areas. Note: Do not brush lens portion to avoid scratching; use soft cloth. 4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. 5. Transfer the devices to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes. 6. After sonication, thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. 7. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.

⚠ ***CAUTION:***

TO AVOID LENS SURFACE DAMAGE, NEVER CLEAN THE CONTACT ELEMENT WITH ALCOHOL, PEROXIDE, OR ACETONE.

DISINFECTION:

1. Follow the ***Method A*** or ***Method C*** cleaning instructions from above.
2. Select **one** of the solution types from the table below:

DISINFECTANT	*CONCENTRATION*	*MIN SOAK TIME*	*MAX SOAK TIME*
Glutaraldehyde	2% aqueous solution	25 minutes	N/A
Sodium hypochlorite (5.25% NaClO; household bleach)	9 parts water, 1 part bleach	25 minutes	25 minutes
Cidex OPA	See Manufacturer's Instructions	12 minutes	N/A
Revital-Ox™ Resert® XL HLD	≥ 1.5% aqueous solution	8 minutes	16 minutes

3. Immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C). Ensure to fill all lumens, hard-to-reach areas, and eliminate air pockets.
4. Rinse thoroughly in a room temperature water bath (minimum of 20°C). Rinse by immersing device completely for a minimum of one minute. Manually flush all lumens or other hard-to-reach areas with water. Agitate device under water, bring above water level, then re-immerse. Repeat rinse procedure two additional times using fresh water.
5. Dry with a soft, lint-free cotton cloth.

⚠ ***CAUTION:***

1. ENSURE THE DEVICE IS COMPLETELY SUBMERGED IN THE DISINFECTANT SOLUTION FOR THE ENTIRITY OF THE RECOMMENDED OR DESIRED SOAK TIME. DO NOT ALLOW THE DEVICE TO BECOME UNSUBMERGED FROM THE DISINFECTANT SOLUTION.
2. EXTENDED EXPOSURE AND/OR EXPOSURE TO HIGHER CONCENTRATIONS OF SODIUM HYPOCHLORITE WILL RESULT IN ACCELERATED DEGRADATION OF THE PRODUCT.

STERILIZATION:

1. Follow the ***Method C*** cleaning instructions.
2. Sterilize using the Steris V-Pro® 60 Low Temp Sterilization System, V-Pro® s2 Low Temp Sterilization System, V-Pro® maX Low Temp Sterilization System, or V-Pro® maX 2 Low Temp Sterilization System. Sterilize using the Non-lumen cycle or Fast cycle.
3. Ethylene oxide sterilization is the preferred method of sterilization. Sterilize using a 2 hour cycle with a recommended temperature of 130°F (not exceeding **150°F)** and a concentration of 600 mg/L.
4. Do not sterilize lenses within standard (black leatherette) lens cases as they are not meant for use in sterilization systems.

⚠ ***CAUTION:***

1. TO AVOID PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL LENSES.
2. TO AVOID PRODUCT DAMAGE, NEVER SUBJECT VOLK VITREOUS LENSES TO STERRAD STERILIZATION.

INSPECTION, MAINTENANCE, & TESTING

No maintenance activities are necessary.

PACKAGING & STORAGE

1. The hospital is responsible for in-house procedures for inspection and packaging of the device in a method that will allow adequate sterilization.
2. 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.

⚠ 📖 Consult the Instructions for Use for important cautionary information

LOT Lot number

REF Reference number

MD Medical Device

Manufacturer

EC REP Authorized representative in the European Community

Date of manufacture