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

<table>
<thead>
<tr>
<th>Product</th>
<th>Part Numbers</th>
<th>Magnification</th>
<th>Laser Spot Magnification Factor</th>
<th>Anti-Reflective Laser Coating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idrees MidVitreous Lens</td>
<td>VMV</td>
<td>1.11</td>
<td>0.90</td>
<td>BBAR</td>
</tr>
<tr>
<td>Singh MidVitreous Lens</td>
<td>VSMV</td>
<td>1.16</td>
<td>0.86</td>
<td>BBAR</td>
</tr>
</tbody>
</table>

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 DISINFECTED 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.

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 added by not allowing contamination to dry on the lens surface. When possible place the lenses in water or cover them with a damp cloth.
CLEANING, DISINFECTION, STERILIZATION

CLEANING:
Select the desired method of cleaning:

<table>
<thead>
<tr>
<th>Method A:</th>
<th>Method B:</th>
</tr>
</thead>
</table>
| Clean with a mild detergent and a clean soft cotton cloth or swab. Do not use detergent with any type of Emollients (moisturizers). | Clean the glass element with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®.

Method B:
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:

<table>
<thead>
<tr>
<th>DISINFECTANT</th>
<th>CONCENTRATION</th>
<th>MIN SOAK TIME</th>
<th>MAX SOAK TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calutaride ®️️</td>
<td>2% aqueous solution</td>
<td>25 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium hypochlorite (5.25% NaClO; household bleach)</td>
<td>9 parts water, 1 part bleach</td>
<td>10 minutes</td>
<td>25 minutes</td>
</tr>
<tr>
<td>Cortex OP®️️</td>
<td>See Manufacturer’s Instructions</td>
<td>12 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Revital-O®️️ Resert®️️ XL HLD</td>
<td>≥ 1.5% aqueous solution</td>
<td>8 minutes</td>
<td>16 minutes</td>
</tr>
</tbody>
</table>

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-immers. 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 ENTIRETY 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 Arclight®️️ V-Pro®️️ 1 Low Temp Sterilization System, V-Pro®️️ 1 Plus Low Temp Sterilization System, or V-Pro®️️ maX Low Temp Sterilization System. Sterilize for a minimum of 28 minutes using a non-lumen cycle, with a 12 minute sterilant injection and 2.1g sterilant injection per pulse (~59% H2O2) at 0.4 ±0.1 Torr pre-injection pressure, and at 90°C chamber temperature.
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 isoflurene) 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.