CLEANING

INDICATIONS FOR USE

Volk Optical recommends using anti-reflective coated BIO Lenses to optimize laser throughput. Please check with Volk Optical for additional information on other BIO Lenses, coating styles, and laser treatments.

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 device prior to cleaning. Remove excess body fluids.
3. Universal precautions for handling contaminated materials should be observed.

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.

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. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. Do not use detergents containing Emollients (moisturizers).

Method B: Clean the glass element with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. 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 °C) tap water.
2. Soak each device in solution for 20 minutes.
3. After soaking, brush knurled surface on device ring with a soft cloth.
4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) for 10 minutes until all visible cleaner has been removed.
5. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 10 minutes.
6. After sonication, thoroughly rinse device(s) 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.

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ENGLISH: INSTRUCTIONS FOR USE

The Volk Optical ACS™ PermaView BIO Lenses are designed for steam sterilization and are intended for use in the operating room. The optical components of these lenses are anti-reflective coated BIO Lenses. Reductions in efficiency have been experienced in comparison to an anti-reflective coated BIO Lens. Volk Optical recommends using anti-reflective coated BIO Lenses to optimize laser throughput. Please check with Volk Optical for additional information on other BIO Lenses, coating styles, and laser treatments.

REPROCESSING LIMITATIONS:

Repeated cleaning, disinfection, and sterilization have minimal effect on Volk ACS™ PermaView BIO 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 device 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 contaminants to the surface.
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.

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3. After soaking, brush knurled surface on device ring with a soft cloth.
4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) for 10 minutes until all visible cleaner has been removed.
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CLEANING:

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Method A: Clean with a mild detergent and a clean soft cotton cloth or swab. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. Do not use detergents containing Emollients (moisturizers).

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Method C:

1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 °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. Clean lens surface in a clockwise direction. 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) for 10 minutes until all visible cleaner has been removed.
5. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.
6. After sonication, thoroughly rinse device(s) 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.
DISINFECTION:
1. Reusable surgical devices require full sterilization. Disinfection is only acceptable as an optional step, next to full sterilization.
2. Follow the Method A or Method C cleaning instructions.
3. 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>Glutaraldehyde</td>
<td>2% aqueous solution</td>
<td>25 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium hypochlorite</td>
<td>(5000 ppm NaClO) 9 parts water:1 part household bleach (5.25% NaClO)</td>
<td>10 minutes</td>
<td>25 minutes</td>
</tr>
<tr>
<td>Cidex OPA</td>
<td>See Manufacturer’s Instructions</td>
<td>12 minutes</td>
<td>N/A</td>
</tr>
</tbody>
</table>

4. Position the lens on its side, and then 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.
5. 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.
6. 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. Steam sterilization is the preferred method of sterilization. Steam sterilize using a pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). Volk recommends using distilled water for steam sterilization. The use of distilled water greatly increases the lifetime of your Volk ACS™ PermaView BIO Lens. Where the use of distilled water is not practical, the use of a reverse osmosis (RO) filter is recommended just prior to the autoclave water intake.
3. Ethylene oxide sterilize at an exposure time of 120 minutes, sterilant concentration of 700 - 750 mg/L, a humidity of 50 +/- 20%, and a temperature of 52 - 60°C.
4. Steris System 1 – follow the manufacturer’s recommendations.

CAUTION:
DO NOT STERILIZE LENSES WITHIN STANDARD (BLACK LEATHERETTE) LENS CASES AS THEY ARE NOT MEANT FOR USE IN STERILIZATION SYSTEMS.

INSPECTION & MAINTENANCE
1. Carefully check to ensure that all visible debris has been removed. If any contamination is visible, repeat the cleaning procedure.
2. Visually check for damage and/or wear.
3. If damage or wear is apparent that may interfere with the performance of the lens, contact Volk Optical or your distributor for return.
4. No maintenance activities are necessary.
5. Volk ACS™ BIO Lenses should not be disassembled.

PACKAGING & STORAGE
1. The user facility is responsible for in-house procedures for inspection and packaging of lenses in a method that will allow adequate sterilization.
2. If applicable, use standard double wrap method.
3. Sterile instruments should be stored in an area that provides protection from loss of sterility.

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