Volk Optical High Resolution Direct Image Vitrectomy ACS® Lenses

INTENDED USE
Volk High Resolution Direct Image Vitrectomy ACS® 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 Code</th>
<th>Magnification</th>
<th>Field of View</th>
<th>Available Contact Ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR Direct 1X ACS®</td>
<td>VHRD1XACS</td>
<td>1.00</td>
<td>30°</td>
</tr>
<tr>
<td>HR Direct 20° Prism ACS®</td>
<td>VHRD20PACS</td>
<td>0.50</td>
<td>40°</td>
</tr>
<tr>
<td>HR Direct Bi-Concave ACS®</td>
<td>VHRDBCACS</td>
<td>1.00 (air); 0.50 (fluid)</td>
<td>30° / 45°</td>
</tr>
<tr>
<td>HR Direct High Mag ACS®</td>
<td>VHRDHMACS</td>
<td>1.40</td>
<td>20°</td>
</tr>
<tr>
<td>HR Direct 1X NSR ACS®</td>
<td>VHRD1XNSRACS</td>
<td>1.00</td>
<td>30°</td>
</tr>
<tr>
<td>HR Direct High Mag NSR ACS®</td>
<td>VHRDHMNSRACS</td>
<td>1.40</td>
<td>20°</td>
</tr>
</tbody>
</table>

INDICATIONS FOR USE:

1. To be used by a licensed physician in a method consistent with other direct-image vitreoretinal surgical lenses.
2. Volk High Resolution Direct Image Vitrectomy ACS® Lenses are indicated for steam sterilization.
3. The Standard Fluid contact style is designed to be used with standard size sutures or stabilizing rings, the VitreoLens Handle®, or the Volk Infusion Handle.
4. It is suggested that an appropriate diffusion or bullet-type fiberoptic light pipe and a high intensity light source be used to provide illumination of the retina.
5. Refer to the Specifications table to determine if your lens requires a stabilizing ring. If needed, place the lens in a stabilizing ring or in the Volk VitreoLens Handle®. If corneal irrigation is desired place the lens in the Volk Infusion Handle.
6. Sterilized lenses should be allowed to stabilize to the ambient air temperature of the operating room; this reduces unintended fogging during surgery.
7. The contact design requires a viscous, sterile tear-like fluid (methylcellulose or similar interface solution) applied to the concave contact surface.
8. Inspect the contacting surface(s) prior to use to ensure they are free from damage including chips or scratches.

WARNING:

1. DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW ANY SIGNS OF DAMAGE.
2. DO NOT ATTEMPT TO USE THE LENS UNLESS AN ADEQUATE TYPE AND AMOUNT OF COUPLING FLUID IS PRESENT BETWEEN THE CORNEA AND THE CONTACTING LENS SURFACE.
3. CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PRESSURE ON THE CORNEA AS IT MAY AFFECT AQUEOUS DYNAMICS.
4. DO NOT ATTEMPT TO USE THE LENS IF, FOR ANY REASON, THE RETINAL IMAGE IS UNCLEAR OR UNFOCUSED.

REPROCESSING

WARNING:

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.

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 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.

REPROCESSING LIMITATIONS:

Repealed cleaning, disinfection, and sterilization have minimal effect on Volk HR Direct Image Vitrectomy ACS™ Lenses when processed according to instructions. End of the product’s life cycle is normally determined by wear and damage due to use.

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:

<table>
<thead>
<tr>
<th>Method A</th>
<th>Description</th>
<th>Glutaraldehyde</th>
<th>Sodium hypochlorite</th>
<th>Cidex OPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clean with a mild detergent and a clean soft cotton cloth or swab. Clean lens surface in a clockwise direction to prevent loosening of the retaining ring within the housing. Do not use detergents containing Emollients (moisturizers).</td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method B</th>
<th>Description</th>
<th>Glutaraldehyde</th>
<th>Sodium hypochlorite</th>
<th>Cidex OPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water.</td>
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</tr>
<tr>
<td>2. Soak each device in solution for 20 minutes.</td>
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</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.</td>
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<td></td>
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</tr>
<tr>
<td>5. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.</td>
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</tr>
<tr>
<td>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.</td>
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<td></td>
</tr>
<tr>
<td>7. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.</td>
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</tbody>
</table>

### 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 SOLUTION</th>
<th>CONCENTRATION</th>
<th>MIN SOAK TIME</th>
<th>MAX SOAK TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde (2% aqueous solution)</td>
<td>25 minutes</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Sodium hypochlorite (5000 ppm NaClO)</td>
<td>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 tap water bath (minimum of 20°C). Rinse by immersing device completely for a minimum of 10 minutes.
6. Dry with a soft, lint-free cotton cloth.

### 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 HR Direct Image Vitreoscopy ACS™ Lenses. 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.

### 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.

### 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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**Volk Optical Inc**
7893 Enterprise Drive
Mentor, OH 44060 USA
Tel: 440-942-6161
Fax: 440-942-2257
Email: volk@volk.com

EU Representative:
Keeler Limited
Clew Hill Road
Windsor
Berkshire SL4 4AA U.K.
+44 (0) 1753 857177

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

**DISINFECTANT SOLUTION:**

- **Glutaraldehyde:** 2% aqueous solution
- **Sodium hypochlorite:** 5 parts water:1-part household bleach (5.25% NaClO)
- **Cidex OPA:** See Manufacturer’s Instructions

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**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 HR Direct Image Vitreoscopy ACS™ Lenses. 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.