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## Volk Optical High Resolution Direct Image Vitrectomy ACS® Lenses

### ENGLISH: INSTRUCTIONS FOR USE

#### 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

Product	Product Code	Magnification	Field of View	Available Contact Designs	Suture Ring
HR Direct 1X ACS®	VHRD1XACS	1.00	30°	Standard Fluid	Required
HR Direct 20° Prism ACS®	VHRD20PACS	0.50	40°	Standard Fluid	Required
HR Direct Bi-Concave ACS®	VHRDBCACS	1.00 (air); 0.50 (fluid)	30° / 45°	Standard Fluid	Required
HR Direct High Mag ACS®	VHRDHMACS	1.40	20°	Standard Fluid	Required
HR Direct 1X NSR ACS®	VHRD1XNSRACS	1.00	30°	Standard Fluid	Not Required
HR Direct High Mag NSR ACS®	VHRDHMNSRACS	1.40	20°	Standard Fluid	Not Required

#### INDICATIONS FOR USE

- To be used by a licensed physician in a method consistent with other direct-image vitreo-retinal surgical lenses.
- Volk High Resolution Direct Image Vitrectomy ACS® Lenses are indicated for steam sterilization.
- 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.
- 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.
- 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.
- Sterilized lenses should be allowed to stabilize to the ambient air temperature of the operating room; this reduces unintended fogging during surgery.
- The contact design requires a viscous, sterile tear-like fluid (methylcellulose or similar interface solution) applied to the concave contact surface (patient side). Apply a drop of sterile viscous, tear-like coupling fluid to the concave contact surface at the point of use.
- Inspect the contacting surface(s) prior to use to ensure they are free from damage including chips or scratches.

#### **WARNING:**

- DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW(S) ANY SIGNS OF DAMAGE.
- 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.
- CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PRESSURE ON THE CORNEA AS IT MAY AFFECT AQUEOUS DYNAMICS.
- DO NOT ATTEMPT TO USE THE LENS IF, FOR ANY REASON, THE RETINAL IMAGE IS UNCLEAR OR UNFOCUSED.
- 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

#### **WARNING:**

- A THOROUGH, MANUAL CLEANING PROCESS IS RECOMMENDED.
- 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:**

- New or used, contaminated lenses must be cleaned.
- Body fluids should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids.
- Universal precautions for handling contaminated materials should be observed.
- Instruments should be cleaned as soon as possible after use to minimize the drying of contaminants to the surface.
- 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:**

Repeated 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.



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## CLEANING, DISINFECTION, STERILIZATION

### CLEANING:

Select the desired method of cleaning:

<b>Method A:</b>	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).
<b>Method B:</b>	Volk Precision Optical Lens Cleaner (POLC) is not recommended for this device.
<b>Method C:</b>	<ol style="list-style-type: none"> <li>1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water.</li> <li>2. Soak each device in solution for 20 minutes.</li> <li>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.</li> <li>4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.</li> <li>5. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.</li> <li>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.</li> <li>7. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.</li> </ol>



### CAUTION:

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

### 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:

DISINFECTANT	CONCENTRATION	MIN SOAK TIME	MAX SOAK TIME
Glutaraldehyde	2% aqueous solution	25 minutes	N/A
Sodium hypochlorite (5000 ppm NaClO)	9-parts water:1-part household bleach (5.25% NaClO)	25 minutes	25 minutes
Cidex OPA	See Manufacturer's Instructions	12 minutes	N/A

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-immerses. 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.

### 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 Vitrectomy 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.  
- or -
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.

### 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.



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Consult the Instructions for Use for important cautionary information



Lot number



Reference number



Manufacturer



Authorized representative in the European Community



Date of manufacture



Medical Device