IM-010 Rev. C Issue Date: 2025-06-13

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Volk Optical Contact Laser & Diagnostic Lenses (Direct Contact)

ENGLISH (EN): INSTRUCTIONS FOR USE

INTENDED USE

Contact Laser & Diagnostic Lenses are indicated for use as diagnostic contact lenses for eye fundus examinations and use in the therapy of intraocular abnormalities.

SPECIFICATIONS

Product	Magnification	Laser Spot Magnification Factor	Available Contact Designs	Anti-Reflective Laser Coating
Centralis Direct® (VCD, VCDANF+)	0.90	1.11	Standard Fluid ANF+ (no fluid)	BBAR
Volk Fundus Laser (VFUNDUS)	1.25	0.80	Standard Fluid	BBAR
Volk Fundus 20mm Laser (VFUNDUS20)	1.44	0.70	Standard Fluid	BBAR
Volk Capsulotomy (VCAPS)	1.57	0.63	Standard Fluid	BBAR
Volk MagPlus Iridectomy (VMPIRID)	1.60	0.63	Standard Fluid	BBAR
Volk Iridectomy (VIRID)	1.70	0.58	Standard Fluid	BBAR
Volk Blumenthal Iridotomy (VBIRID)	1.54	0.65	Standard Fluid	BBAR

INDICATIONS FOR USE

1. To be used by a licensed physician in a method consistent with other direct image ophthalmic contact laser & diagnostic lens.
2. Inspect the contacting surface(s) to make sure they are free from any damage (e.g. chips, scratches, etc.).
3. Standard Fluid and No Flange (NF) contact lenses require methylcellulose or other similar interface solution be applied to the concave contact surface.
4. ANF+ contact lenses require a normal tear solution be applied to the concave contact surface.
5. 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).
6. When calculating the spot size at the retina, 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.
7. When using MagPlus Iridectomy lens, the best results are obtained when working in reference to the silver machine mark along the outer housing which indicates the apex of the lens.
8. When using Blumenthal Iridotomy lens, the best results are obtained when working between the two reference marks within the anterior of the lens.

WARNING:

1. DO NOT USE THE DEVICE IF THE CONTACTING SURFACE SHOWS ANY SIGN OF DAMAGE.
2. DO NOT USE THE DEVICE IF IT SHOWS ANY SIGN OF DAMAGE.
3. 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.
4. 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:

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 that 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 Direct Contact 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:

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 - 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. 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) 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.

⚠ *CAUTION:*

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

DISINFECTION:

1. Follow the ***Method A*** cleaning instructions.
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 (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

3. 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.
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 THAT THE DEVICE IS COMPLETELY SUBMERGED IN THE DISINTECTANT 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. 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.
3. Do not sterilize lenses within standard lens cases, as they are not meant for use in sterilization systems.

⚠ *CAUTION:*

TO AVOID PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL LENSES OR ADAPTERS.

STORAGE:

Devices should be stored at room temperature. 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

Manufacturer

EC REP Authorized representative in the European Community

Date of manufacture

MD Medical Device