IM-012 Rev. B Issue Date: 2021-06-21

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CE

Volk Optical Vitrectomy Contact Lenses

ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE

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

SPECIFICATIONS

Product	Part Numbers	Magnification
MiniQuad®	VMQVIT VMQVITSSV	0.39
MiniQuad® XL	VMQXLVIT VMQXLVITSSV	0.38
DynaView	VDVVIT	0.39
Central Retinal	VCRLVIT VCRLVITSSV	0.71
Super Macula®	VSMACVIT	1.03
HRX Vit	VHRXVIT VHRXVITSSV	0.43

INDICATIONS FOR USE

1. To be used by a licensed physician in a method consistent with other ophthalmoscopic contact surgical vitrectomy lenses
2. The contact design requires a viscous, sterile tear-like fluid (methylcellulose or similar interface solution) applied to the concave contact surface (patient side).
3. The standard contact style is designed to be used with standard size suture or stabilizing rings, the VitreoLens Handle®, or the Volk Infusion Handle.
4. The self-stabilizing (SSV®) contact style provides stable lens positioning on the eye without a suture-down ring.
5. 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.

⚠ *WARNINGS:*

1. DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW(S) 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.
5. 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:

3. New or used, contaminated lenses must be cleaned.
4. Body fluids should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids.
5. Universal precautions for handling contaminated materials should be observed.
6. Instruments should be cleaned as soon as possible after use to minimize the drying.

REPROCESSING LIMITATIONS:

Repeated cleaning, disinfection, and sterilization have minimal effect on Volk Indirect 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.

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. Do not use detergent with any type of Emollients.
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 insert in the ring. ***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. 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.

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⚠ *CAUTION:*

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

DISINFECTION:

1. Reusable surgical medical 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 (5.25% NaClO; household bleach)	9 parts water, 1 part bleach	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-immerse. Repeat rinse procedure two additional times using fresh water.
6. Dry with a soft, lint-free cotton cloth.

STERILIZATION:

1. Follow the *Method C* cleaning instructions from above.
2. Ethylene oxide sterilization is the preferred method of sterilization. Sterilize using a 2 hour cycle with a temperature of 130°F and a concentration of 600 mg/L, but not exceeding **150°F**.
3. Do not sterilize lenses within standard (black leatherette) lens cases as they are not meant for use in sterilization systems.

⚠ *CAUTION:*

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

INSPECTION, MAINTENANCE & TESTING

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 hospital is responsible for in-house procedures for inspection and packaging of the 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.

⚠ 📖 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