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CE

Volk Optical Blumenthal Suturelysis Lens

ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE

The Volk Blumenthal Suturelysis Lens is 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 Design	Anti-Reflective Laser Coating
Blumenthal Suturelysis (VBSL)	2.0 – 3.0	0.50 – 0.33	Standard Fluid	None

NOTE: Depending on the distance from the suture, magnification and laser spot will vary.

INDICATIONS FOR USE

1. To be used by a licensed physician in a method consistent with other ophthalmic contact fundus lenses.
2. The Volk Blumenthal Suturelysis Lens is designed to allow smooth suturelysis in routine cases, as well as enhanced suture visibility in difficult situations.
3. The lens' novel design has a convex back surface (the surface facing the surgeon) that magnifies the suture appearance two to three fold.
4. The pointed tip provides a strong compressive force that increases visibility of the suture and adds to the stabilization of the treated area. This is a particular benefit to patients with a thick Tenon's layer or a subconjuctival.
5. The Volk Blumenthal Suturelysis Lens is uncoated and a slight reduction in efficiency may be experienced in comparison to a coated lens.
6. Suturelysis can usually be performed with laser settings in the range of 100 - 500 mW. Where higher settings are needed (usually secondary to thick Tenon's or somewhat older sutures that have partially blanched) the laser energy should be carefully increased. A 50-micron spot is the standard setting for suturelysis. In difficult cases larger spots can be used. Power should be increased accordingly.
7. Inspect the contacting surface(s) prior to use to ensure they are free from damage including chips or scratches.
8. Identify the suture area before placing the lens on the eye; aim the lens tip in that direction. The suture you wish to bisect should be centered on the lens tip.
9. Where the suture cannot be visualized well, apply the lens tip firmly against the area for 20-30 seconds. Compression will often reveal sutures that are hidden by a thick overlying Tenon-conjunctiva layer. Occasionally pressure, held up to 1 minute, may reveal deep-lying sutures.
10. After suturelysis is done the special design of the lens tip can be further utilized to compress the area of the flap to encourage filtration through the suture-lysed portions of the flap. As fluid filters out of the eye, conjunctiva will be seen inflating around the lens.

⚠ ***WARNING:***

1. DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW(S) ANY SIGNS OF DAMAGE.
2. 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 WITH ULTRASONIC CYCLE IS RECOMMENDED.
2. CORROSIVE CLEANING AGENTS (I.E. ACIDS, ALKALINES, ETC) ARE NOT RECOMMENDED. DETERGENT CLEANING AGENTS WITH NEUTRAL PH ARE RECOMMENDED.

REPROCESSING LIMITATIONS:

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

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 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.

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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-immerse. 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 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. Sterilize using the Steris V-Pro® 60 Low Temp Sterilization System, V-Pro® s2 Low Temp Sterilization System, V-Pro® maX Low Temp Sterilization System, or V-Pro® maX 2 Low Temp Sterilization System. Sterilize using the Non-lumen cycle or Fast cycle.
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.

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