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CE

Volk Optical Suture Ring

ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE

The Volk Suture Ring is an ophthalmic ring device and is intended to aid in manual ophthalmic surgical procedures.

INDICATIONS FOR USE

1. To be used by a licensed physician in a method consistent with other accessories for contact vitreo-retinal surgery.
2. The Volk Suture Ring is to be used in conjunction with Volk Vitrectomy Contact lenses and is indicated for steam sterilization.
3. The suture ring design features two tabs that are positioned to provide an easy and stable location for the sutures.
4. After the suture ring is securely in place, set a Volk Vitrectomy Contact Lens in the ring. Hold your Volk lens by the lens ring housing or by the lens edge to avoid touching the lens surface. To remove the lenses after use simply grasp and lift up.
5. Inspect the contacting surface(s) prior to use to ensure they are free from damage.

⚠ *WARNINGS:*

1. Do not use the suture ring 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 AND AUTOMATED CLEANING PROCESS WITH AN AUTOMATED DISHWASHER IS RECOMMENDED.
2. CORROSIVE CLEANING AGENTS (I.E. ACIDS, ALKALINES, ETC) ARE NOT RECOMMENDED. NON-IONIC DETERGENTS WITH NEUTRAL PH ARE RECOMMENDED.

REPROCESSING LIMITATIONS:

Repeated cleaning, disinfection, and sterilization have minimal effect on the Volk Suture Ring 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 devices 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 device surface. When possible, place the instrument in water or cover them with a damp cloth.

CLEANING, DISINFECTION, STERILIZATION

CLEANING:

1. Choose an enzymatic detergent recommended for metallic surgical instruments (e.g. Lancerzyme).
2. Following the detergent manufacturer's instructions, fully submerge and vigorously brush the device in the detergent solution for at least 1 minute.
3. Remove the device from the detergent bath and rinse with clean water (~ 30°C) a minimum of 3 times.
4. Dry the device and place it in a basket suitable for an automated dishwasher cycle.
5. Wash the device using an automated dishwasher cycle consisting of a 2-minute prewash, a 3-minute detergent wash at 93°C, and a drying stage to ensure complete removal of all moisture.

DISINFECTION:

1. Reusable surgical devices require full sterilization. Disinfection is only acceptable as an optional step, next to full sterilization.
2. Follow the 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. Immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C).
5. Rinse thoroughly in a room temperature water bath (minimum of 20°C). Rinse by immersing device completely for a minimum of one minute. 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 cleaning instructions.
2. Steam sterilization is the preferred method of sterilization. Steam sterilize using a pre-vacuum cycle for a minimum of 5 minutes at a temperature of 127°C and a maximum temperature of 137°C. Volk recommends using distilled water for steam sterilization. The use of distilled water will increase the lifetime of your product. 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.

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 suture ring, 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 instruments 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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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