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Volk Vold Surgical Gonio Lens

ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE

The Volk Vold Surgical Gonio Lens is a reusable ophthalmic instrument used for general and surgical gonioscopy.

SPECIFICATIONS

Product	Magnification	Field of View	Lens Contact Diameter	Cleat Ring Diameter	Handle Length
Volk Vold Surgical Gonio Lens (VTSVVG)	1.2x	90°	10.2 mm	15.2 mm	98 mm

INDICATIONS FOR USE

1. The device is a single handed instrument that is intended to enhance the surgeon's ability to simultaneously articulate the device, stabilize the eye, and to obtain anterior chamber angle visualization during surgical and non-surgical procedures.
2. The device may be indirectly interfaced with surgical microscopes to enhance the user's ability to position, stabilize, and obtain anterior chamber angle visualization.
3. The lens component of the device is placed directly on the cornea and the cleat ring is positioned on the conjunctiva.
4. Outcomes can be affected by the user's level of experience. It is highly recommended that the user is adequately trained in this procedure prior to actually using the lens.
5. The lens should be cleaned and sterilized prior each use.
6. The Volk Vold Surgical Gonio Lens, including its handle, are sterilizable using steam sterilization.
7. A lubricant such as Ophthalmic Viscoelastic Device (OVD) agents or Ophthalmic Balanced Salt Solution (BSS) must be applied onto the cornea during use.

⚠ *WARNINGS:*

1. CAREFULLY EXAMINE THE DEVICE FOR DAMAGE PRIOR TO EACH USE. DO NOT USE THE DEVICE IF ANY SURFACE(S) SHOW(S) ANY EVIDENCE OF DAMAGE, OR PATIENT INJURY COULD RESULT.
2. CONTACTING SURFACE OF THE LENS ELEMENT INTERACTS WITH THE CORNEA, IN PART, TO EFFECT GLOBE SUPPORT AND MANIPULATION. CARE SHOULD BE USED TO CONSISTENTLY CONTROL THE AMOUNT OF THE MANUAL FORCE EXERTED BY THE SURGEON ON THE PATIENT'S EYE WITH THE VOLK VOLD SURGICAL GONIO LENS.
3. THE FIXATION RING HAS SHARP FEATURES THAT ARE DESIGNED TO GRIP THE CONJUNCTIVA OF THE PATIENT'S EYE TO EFFECT GLOBE SUPPORT AND MANIPULATION. CARE SHOULD BE USED TO CONSISTENTLY CONTROL THE AMOUNT OF THE MANUAL FORCE EXERTED BY THE SURGEON ON THE PATIENT'S EYE WITH THE VOLK VOLD SURGICAL GONIO LENS.

⚠ *CAUTION:*

1. THE DEVICE SHIPS NON-STERILE AND MUST BE CLEANED AND STERILIZED PRIOR TO USE. SEE CLEANING AND STERILIZATION PROCEDURES BELOW.
2. ALLOW THE DEVICE TO COOL TO ROOM TEMPERATURE BEFORE GENERAL OR SURGICAL USE.
3. 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.

REPROCESSING LIMITATIONS:

Repeated cleaning and sterilization have minimal effect on the Volk Vold Surgical Gonio Lens when processed according to instructions. End of life is normally determined by wear and damage due to use.

PREPARATION AT THE POINT OF USE:

1. A new or used contaminated lens must be cleaned.
2. Body fluids and/or tissue should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids and tissue immediately after use.
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.
5. The device should always be handled in an appropriate method to ensure contamination is not introduced to a recently cleaned and sterilized device.

PREPARATION BEFORE CLEANING:

The following cleaning and sterilization instructions are aided by not allowing contamination to dry on the lens following use. When possible, rinse the lens immediately after use, place the lens in water, or cover them with a damp cloth.

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CLEANING, DISINFECTION, STERILIZATION

CLEANING:

1. Prepare fresh enzymatic cleaner (e.g., Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water.
2. Soak the device in solution for 20 minutes.
3. After soaking, brush the components of the device 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 a soft cloth.
4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) for at least 1 minute and until all visible cleaner has been removed.
5. Transfer the devices to an ultrasonic cleaner with freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.
6. After sonication, using freshly distilled or deionized water that is sterile or controlled for bacterial endotoxins, thoroughly rinse the device in a room temperature water bath (not under running water) for at least 1 minute and until all visible cleaner has been removed.
7. Dry with a soft, sterile, lint-free cotton cloth or tissue.
8. Inspect each device for remaining soils or debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.
9. Visually check for damage and/or wear. If damage or wear is apparent that may interfere with the performance of the lens, contact Volk Optical, or your distributor for evaluation.

DISINFECTION:

Reusable surgical devices require full sterilization. The Volk Vold Surgical Gonio lens is not rated for disinfection.

STERILIZATION:

1. Follow cleaning instructions before sterilizing.
2. Steam sterilization is the preferred method of sterilization.
   a. **For sterilization in the US:** Steam sterilize, using a sterilization wrap (or pouch) under a pre-vacuum cycle for at least 4 minutes at a minimum temperature of 132°C (270°F). Allow dry time of at least 20 minutes following the cycle. Volk recommends using distilled water for steam sterilization; the use of distilled water greatly increases the lifetime.
   b. **For sterilization in the EU/UK:** Steam sterilize, using a sterilization wrap (or pouch) under a pre-vacuum cycle for at least 3 minutes at a minimum temperature of 134°C (273°F). Allow dry time of at least 20 minutes following the cycle. Volk recommends using distilled water for steam sterilization; the use of distilled water greatly increases the lifetime.

INSPECTION, MAINTENANCE, & TESTING

No maintenance activities are necessary.

PACKAGING & STORAGE

1. The hospital is responsible for in-house procedures for inspection and packaging of the device in a method that will allow adequate sterilization.
2. If applicable, use standard medical grade steam sterilization wrap following the double wrap method of your Volk Vold Surgical Gonio lens. 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.
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

SN
Serial Number

REF
Reference number

Manufacturer

EC REP
Authorized representative in the European Community

Date of manufacture

MD
Medical Device