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Volk Optical Vitrectomy Lens Accessories

ENGLISH: INSTRUCTIONS FOR USE

VITREOLENS® HANDLE

INTENDED USE

The Volk VitreoLens® Handle is an ophthalmic forceps device and is intended to aid in manual ophthalmic surgical procedures.

INDICATIONS FOR USE

- To be used by a licensed physician in a method consistent with other accessories for contact vitreo-retinal surgery.
- The Volk VitreoLens® Handle is to be used in conjunction with Volk Vitrectomy Contact lenses.
- To install the lens, push the Gripping Fingers into the recess of the lens' ring.
- To remove the lens, securely hold the lens with one hand and pull off the handle.
- The spring quality of the stainless steel allows the Lens Holder to be adjusted.
 - To increase the grip tension, carefully squeeze the Gripping Fingers together.
 - To decrease the grip tension, carefully push the Gripping Finger apart.
 - To adjust the handle angle, bend the Holder Extension to the desired angle.
- At the point of use, follow the instructions provided in the appropriate instruction manual of your Volk Vitrectomy Contact Lenses.

REPROCESSING

NOTE:

Refer to the appropriate instruction manual for the cleaning, disinfection, and sterilization procedures for your Volk Vitrectomy Contact Lenses.



WARNING:

- A THOROUGH, MECHANICAL CLEANING WITH ULTRASONIC CYCLE PROCESS IS RECOMMENDED.
- 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 Vitrectomy Lens Accessories 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:

- New or used, contaminated devices must be cleaned.
- Body fluids should not be allowed to dry on the device prior to cleaning. Remove excess body fluids.
- Universal precautions for handling contaminated materials should be observed.
- Instruments should be cleaned as soon as possible after use to minimize the drying of contaminants to the surface.
- 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 handle surface. When possible place the lens handles in water or cover them with a damp cloth.

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 C:	<ol style="list-style-type: none"> Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water. Soak each device in solution for 20 minutes. After soaking, brush surface of device with a soft-bristle brush until all traces of cleaner and soil are removed. Pay special attention to all crevices and other hard-to-reach areas. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes. After sonication, thoroughly rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.

DISINFECTION:

- Reusable surgical devices require full sterilization. Disinfection is only acceptable as an optional step, next to full sterilization.
- Follow the cleaning instructions for Method A or Method C.
- 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

- Immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C).
- 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-immerses. Repeat rinse procedure two additional times using fresh water.
- Dry with a soft, lint-free cotton cloth.

STERILIZATION:

- Follow the cleaning instructions for Method C.
- Steam sterilization is the preferred method of sterilization. Steam sterilize using a pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). 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.

- or -
- 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.



CAUTION:

TO AVOID LENS HANDLE DAMAGE, NEVER AUTOCLAVE OR BOIL VOLK LENS HANDLES, UNLESS SPECIFICALLY DESIGNED FOR AUTOCLAVE USE.



CAUTION:

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.

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 product as unsorted municipal waste. When disposing of this product, please follow the procedure which conforms with the laws and regulations applicable to your area.



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INFUSION HANDLE

INTENDED USE

The Volk Infusion Handle is an ocular surgery irrigation device intended to be suspended over the ocular area during ophthalmic surgery to deliver continuous, controlled irrigation to the surgical field.

INDICATIONS FOR USE

- To be used by a licensed physician in a method consistent with other ocular irrigation accessories for contact vitreo-retinal surgery.
- The Volk Infusion Handle is to be used in conjunction with Volk Vitrectomy Contact lenses.
- At the point of use, insert the Volk Vitrectomy Contact Lens into the Volk Infusion Handle's lens retaining ring. The lens should fit securely in the retaining ring.
- Attach the irrigating solution's tube to the distal end of the Volk Infusion Handle's tube.
- At the point of use, follow the instructions provided in the appropriate instruction manual of your Volk Vitrectomy Contact Lenses.

REPROCESSING

NOTE:

Refer to the appropriate instruction manual for the cleaning, disinfection, and sterilization procedures for your Volk Vitrectomy Contact Lenses.



WARNING:

- A THOROUGH, MECHANICAL CLEANING WITH ULTRASONIC CYCLE PROCESS IS RECOMMENDED.
- 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 Vitrectomy Lens Accessories 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:

- New or used, contaminated devices must be cleaned.
- Body fluids should not be allowed to dry on the device prior to cleaning. Remove excess body fluids.
- Universal precautions for handling contaminated materials should be observed.
- Instruments should be cleaned as soon as possible after use to minimize the drying of contaminants to the surface.
- 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 handle surface. When possible, place the lens handles in water or cover them with a damp cloth.

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 C:	<ol style="list-style-type: none"> Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water. Soak each device in solution for 20 minutes. After soaking, brush surface of device with a soft-bristle brush until all traces of cleaner and soil are removed. Pay special attention to all crevices and other hard-to-reach areas. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes. After sonication, thoroughly rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.

DISINFECTION:

- Reusable surgical devices require full sterilization. Disinfection is only acceptable as an optional step, next to full sterilization.
- Follow the cleaning instructions for Method A or Method C.
- 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

- Immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C).
- 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-immerses. Repeat rinse procedure two additional times using fresh water.
- Dry with a soft, lint-free cotton cloth.

STERILIZATION:

- Follow the cleaning instructions for Method C.
- Steam sterilization is the preferred method of sterilization. Steam sterilize using a pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). 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.
- or -
- 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 (126° - 140°F) and not to exceed 66°C (150°F).



CAUTION:

TO AVOID LENS HANDLE DAMAGE, NEVER AUTOCLAVE OR BOIL VOLK LENS HANDLES, UNLESS SPECIFICALLY DESIGNED FOR AUTOCLAVE USE.



CAUTION:

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.

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 product as unsorted municipal waste. When disposing of this product, please follow the procedure which conforms with the laws and regulations applicable to your area.

VOLK STERILIZATION TRAY

INTENDED USE

The Volk Sterilization Tray is a surgical instrument tray intended to facilitate storage of select Volk Lenses, Adapters, and Filters during Ethylene Oxide (ETO) sterilization processes, as well as select Volk Lenses, Vitrectomy Accessories, and Surgical System components during ETO or steam sterilization processes.



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INDICATIONS FOR USE

- To be used by trained healthcare professionals in a method consistent with other sterilization vessels.
- Verify that the Volk product to be sterilized, and the Volk Sterilization Tray, is properly cleaned (read the appropriate Volk product instruction manual for the recommended cleaning procedures)
- Remove the Volk Sterilization Tray's lid, and with the tray's mat inside the base, carefully secure the product on the mat.
- It is recommended to place a Volk lens on its side or with the contacting surface down.
- Replace the lid securely on the base before sterilization procedures.



CAUTION:

TO AVOID PRODUCT DAMAGE, CAREFULLY PLACE VOLK LENSES IN THE STERILIZATION TRAY TO PREVENT CHIPPING OR SCRATCHING.

REPROCESSING

NOTE:

Refer to the appropriate instruction manual for the cleaning, disinfection, and sterilization procedures for your Volk Lenses & Surgical System products.

CLEANING:

- Wash the Sterilization Tray's base, mat, and lid with a mild, near-neutral pH detergent and a clean, soft brush or cotton cloth. Do not use detergents containing Emollients (moisturizers).
- Rinse by flushing with room temperature tap water for a minimum of 1 minute.

DISINFECTION:

- Reusable surgical devices require full sterilization. Disinfection is only acceptable as an optional step, next to full sterilization.
- Follow the cleaning instructions.
- 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

- Position the Sterilization Tray (base, mat, and lid) on its side, then immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C).
- 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-immers. Repeat rinse procedure two additional times using fresh water.
- Dry with a soft, lint-free cotton cloth.

PRODUCT STERILIZATION IN VOLK STERILIZATION TRAY:

- Follow the cleaning instructions for the Volk Sterilization Tray and the respective Volk product.
- Place the product in the Volk Sterilization Tray and then place into a surgical craft paper or mylar pouch.
- Select one of the sterilization types based on the respective Volk product's recommended sterilization procedures.



CAUTION:

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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 product 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



Reference number



Manufacturer



Authorized representative in the European Community



Lot number



Date of manufacture



Medical Device