INDICATIONS FOR 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. The Volk Infusion® Handle is to be used in conjunction with Volk Vitrectomy Contact lenses.

INDICATIONS FOR USE
1. To be used by a licensed physician in a method consistent with other accessories for contact vitreoretinal surgery.
2. The Volk Vitreolens® Handle is to be used in conjunction with Volk Vitrectomy Contact lenses.
3. To install the lens, push the Gripping Fingers into the recess of the lens’ ring.
4. To remove the lens, securely hold the lens with one hand and pull off the handle.
5. The spring quality of the stainless steel allows the Lens Holder to be adjusted.
   a. To increase the grip tension, carefully squeeze the Gripping Fingers together.
   b. To decrease the grip tension, carefully push the Gripping Finger apart.
   c. To adjust the handle angle, bend the Holder Extension to the desired angle.
6. 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:
1. A THOROUGH, MECHANICAL CLEANING WITH ULTRASONIC CYCLE 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, 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:
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 manner 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 listed 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:
1. Clean with a mild, near-neutral pH detergent and a clean soft cotton cloth or swab. Do not use detergents containing Emollients (moisturizers).
2. Rinse the cleaning solution from the device by flushing with room temperature tap water for a minimum of 1 minute.
3. Place the instrument in an ultrasonic bath containing a mild, near-neutral pH detergent for a minimum of 5 minute cycle.
4. After ultrasonic cycle, rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.
5. Dry instruments immediately after each cleaning and rinsing cycle.

DISINFECTING:
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 solutions from the table below:

<table>
<thead>
<tr>
<th>DISINFECTANT</th>
<th>CONCENTRATION</th>
<th>MIN SOAK TIME</th>
<th>MAX SOAK TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>2% aqueous solution</td>
<td>25 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium hypochlorite (5000 ppm NaOCl)</td>
<td>2 parts water: 1 part household bleach (5.25% NaOCl)</td>
<td>10 minutes</td>
<td>25 minutes</td>
</tr>
<tr>
<td>Clorex®</td>
<td>See Manufacturer’s Instructions</td>
<td>12 minutes</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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-immerses. Repeat rinse procedure two additional times using fresh water.
6. Dry with a soft, lint-free cotton cloth.

STERILIZATION:
1. Follow the cleaning instructions.
2. 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 -
3. Ethylene oxide sterile 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 PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL VOLK LENSES, UNLESS SPECIFICALLY DESIGNED FOR AUTOCLAVE USE.

INFUSION HANDLES
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
1. To be used by a licensed physician in a method consistent with other ocular irrigation accessories for contact vitreoretinal surgery.
2. The Volk Infusion Handle is to be used in conjunction with Volk Vitrectomy Contact lenses.
3. 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.
4. Attach the irrigating solution’s tube to the distal end of the Volk Infusion Handle’s tube.
5. 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:
1. A THOROUGH, MECHANICAL CLEANING WITH ULTRASONIC CYCLE 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, 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:
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 lens surface. When possible place the lenses in water or cover them with a damp cloth.

CLEANING:
1. Clean the outer surfaces with a mild, near-neutral pH detergent and a clean soft cotton cloth or swab. Flush the device’s tubing using the detergent solution for approximately 1 minute or until the solution is free of visible debris. Do not use detergents containing Emollients (moisturizers).
2. Rinse the cleaning solution from the device and its tubing by flushing with room temperature tap water for a minimum of 1 minute.
3. Place the instrument in an ultrasonic bath containing a mild, near-neutral pH detergent for a minimum of 5 minute cycle.
4. After ultrasonic cycle, rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.
5. Dry instruments immediately after each cleaning and rinsing cycle.

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:

<table>
<thead>
<tr>
<th>DISINFECTANT</th>
<th>CONCENTRATION</th>
<th>MIN SOAK TIME</th>
<th>MAX SOAK TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>2% aqueous solution</td>
<td>25 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium hypochlorite (5000 ppm NaCIO)</td>
<td>9 parts water:1 part household bleach (5.25% NaCIO)</td>
<td>10 minutes</td>
<td>25 minutes</td>
</tr>
<tr>
<td>Cidex OPA</td>
<td>See Manufacturer’s Instructions</td>
<td>12 minutes</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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-immerses. Repeat rinse procedure two additional times using fresh water.
6. Dry with a soft, lint-free cotton cloth.

STERILIZATION:
1. Follow the cleaning instructions.
2. 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.
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 (126 - 140°F) and not to exceed 66°C (150°F).

CAUTION:
TO AVOID LENS PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL VOLEK LENSES, UNLESS SPECIFICALLY DESIGNED FOR AUTOCLAVE USE.

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.

INDICATIONS FOR USE
1. To be used by trained healthcare professionals in a method consistent with other sterilization vessels.
2. 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).
3. Remove the Volk Sterilization Tray’s lid, and with the tray’s mat inside the base, carefully secure the product on the mat.
4. It is recommended to place a Volk lens on its side or with the contacting surface down.
5. Replace the lid securely on the base before sterilization procedures.

CAUTION:
TO AVOID PRODUCT DAMAGE, CAREFULLY PLACE VOLEK 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.

Cleansing:
1. 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).
2. Rinse by flushing with room temperature tap water for a minimum of 1 minute.

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:

<table>
<thead>
<tr>
<th>DISINFECTANT</th>
<th>CONCENTRATION</th>
<th>MIN SOAK TIME</th>
<th>MAX SOAK TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>2% aqueous solution</td>
<td>25 minutes</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium hypochlorite (5000 ppm NaCIO)</td>
<td>9 parts water:1 part household bleach (5.25% NaCIO)</td>
<td>10 minutes</td>
<td>25 minutes</td>
</tr>
</tbody>
</table>
4. 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).
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-immers. Repeat rinse procedure two additional times using fresh water.
6. Dry with a soft, lint-free cotton cloth.

PRODUCT STERILIZATION IN VOLK STERILIZATION TRAY:

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