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

**INDICATIONS FOR USE**

If applicable, use standard double wrap method.

No maintenance activities are necessary.

If damage or wear is apparent, visually check for damage and/or wear.

**CLEANING:**

*Reusable surgical devices require full sterilization. Disinfection is only acceptable as an optional step, next to full sterilization.*

*Instruments should be cleaned as soon as possible after use to minimize the drying of contaminants to the surface.*

*Body fluids should not be allowed to dry on the device prior to cleaning. Remove excess body fluids.*

*New or used, contaminated devices must be cleaned.*

**PREPARATION AT THE POINT OF USE:**

*Ensure the device is free from lint and dust.*

**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.*

**CLEANING, DISINFECTION, STERILIZATION**

**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 a 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.

**DISINFECTANT CONCENTRATION MIN SOAK TIME MAX SOAK TIME**

<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% NaOCl)</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.

**STERILIZATION:**

1. Follow the cleaning instructions.

2. Steam sterilization is the preferred method of sterilization. Steam sterlization 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.

**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.