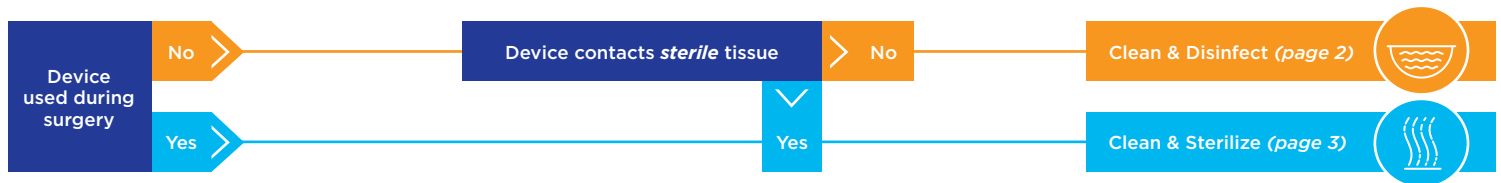


THIS GUIDE APPLIES TO THE FOLLOWING DEVICES ONLY

SURGICAL LENS ACCESSORIES	
Vitreo Lens Handle (Fits MQ, CRL, DV)	VVITHAN-LG
MiniQuad XL Vit Handle (Fits MQXL, SMAC, HRX)	VVITHAN-MQXL
Infusion Handle (Fits non-SSV Vitrectomy Lenses)	VINFHAN
Suture Ring	VSRS2
Sterilization Case - Small	VSCA
Sterilization Case - Large	VSCB

The information contained within this document applies only to Volk's Surgical Lens Accessories (see above).
Information regarding the care of other devices can be found on Volk's website: www.volk.com

CHOOSING BETWEEN DISINFECTION AND STERILIZATION



STORAGE

Ensure devices have been cleaned, disinfected/sterilized, and dried before storage.
Store devices in a clean, dry, room-temperature environment.

IMPORTANT INFORMATION

Limitations on Reprocessing

When the instructions are followed properly, the cleaning, disinfection, and sterilization techniques have a minimal effect on the functionality of Volk devices.

Never use a device that shows any sign(s) of damage.

Preparation for Decontamination

Ensure the device surface does not contain dried fluids or tissues.
If fluids or tissues are present, they **must** be removed by the cleaning steps below prior to further reprocessing.

Point-of-Use Processing

Devices should be cleaned as per the instructions of this document immediately after use to minimize the drying of any fluids or tissues on the device surface.

If immediate reprocessing is not possible, the device(s) should be covered with a moist cloth or soaked in distilled or deionized water until cleaning.

Failure to follow the point-of-use processing steps could adversely affect further decontamination steps.

DISCLAIMERS

- ✦ All Volk products that contact a patient must be thoroughly cleaned, and then disinfected OR sterilized.
- ✦ Only follow the reprocessing procedures listed in Volk's Instructions for Use, and as stipulated by your hospital/facility.
- ✦ Always ensure proper regulatory compliance from your competent authority and facility when choosing a reprocessing technique (FDA, DGHM, etc.).
- ✦ The instructions provided within have been validated by Volk Optical as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

DISINFECTION

Reusable surgical devices require sterilization. Therefore, disinfection is NOT recommended for surgical accessories. All devices that contact the patient's eye **must** be disinfected using a High-Level Disinfectant.



CLEANING STEPS

1. Clean

Clean with a mild, pH neutral detergent and a moist, clean, cotton cloth or swab until all visible soil is removed. Flush all hard to reach areas with a detergent solution.

Do not use detergents that contain any type of emollients.

NOTE: Visually inspect all devices after cleaning to ensure all cleaner and foreign matter is removed. Repeat the above, appropriate cleaning procedure using freshly prepared solutions if needed.

2. Rinse

Thoroughly rinse the device until all traces of cleaner have been removed. Use room temperature, sterile, distilled or deionized water.

Rinsing should be performed by:

- + Gently shaking the device under water.
- + Bringing the device above the water level.
- + Re-immersing the device under water.
- + This should be completed at least 3 times with fresh rinse water to ensure proper removal of the cleaning solution.

NOTE: Inadequate rinsing could result in trace amounts of cleaning solutions being left on the device. Extended exposure to mineral deposits found in tap water can cause device damage.

3. Dry

Dry the device with an ultra-soft, low-lint, cotton cloth such as a cloth diaper.

NOTE: Always dry the device after cleaning. Failure to do so could adversely affect further reprocessing steps.

DISINFECTANT CHOICES AND STEPS

BRAND	SURGICAL LENS ACCESSORIES	STERILIZATION CASES
Bode Mikorbac Tissues	+	+
CaviWipes	+	+

Follow the manufacturer's instructions for the above disinfectant products.

HIGH-LEVEL DISINFECTANT CHOICES AND STEPS

PRODUCT TYPE	SURGICAL LENS ACCESSORIES	STERILIZATION CASES
Bleach Solutions (Sodium Hypochlorite)	+	+
Cidex OPA	+	+
Glutaraldehyde	+	+
Tristel Duo OPH	+	+

Prepare Immersion Solution

Bleach Solutions (Sodium Hypochlorite)

- + For Bleach, prepare the following solution (NaClO, Sodium Hypochlorite, Household Bleach):

SOLUTION TYPE	EXAMPLE DILUTION	SOAK TIME
0.525% (5250ppm) Sodium Hypochlorite Solution (NaClO) (household bleach)	1 Part 5.25% NaClO: 9 Parts Water Ambient/ Room Temp: 62° - 72°F (16.67° - 22.22°C)	25 Minutes

Cidex OPA & Glutaraldehyde

- + Prepare the solution following the manufacturer's instructions.

Immersion

Position the device on its side, and then immerse the entire device in the selected solution for the listed soak time.

Rinse and Dry

Remove the device from the solution and follow steps 2 and 3 from the cleaning steps above.

IMPORTANT INFORMATION

Ensure the device is completely submerged in the disinfectant solution for the entirety of the recommended or desired soak time. Do NOT allow the device to become unsubmerged from the disinfectant solution.

Exposure to disinfectant solutions beyond the recommended soak time, and/or exposure to higher concentrations of disinfectant solution, will result in accelerated degradation of most Volk product.

STERILIZATION

If the device is used during surgery or contacts an ulcerated cornea, sterilization is required.



CLEANING STEPS

1. Prepare Solution

Prepare a low-foaming, neutral pH, enzymatic cleaner solution (e.g. Enzol) – 2 ounces per gallon using warm (~37-43°C), potable water.

2. Soak

Soak each device in solution for 20 minutes.

3. Brush

After soaking, brush surface 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.

NOTE: Visually inspect all devices after cleaning to ensure all cleaner and foreign matter is removed. Repeat the above, appropriate cleaning procedure using freshly prepared solutions if needed.

4. Rinse

Thoroughly rinse devices in a room temperature, potable water bath (not under running water) until all visible cleaner has been removed.

Rinsing should be performed by:

- + Gently shaking the device under water.
- + Bringing the device above the water level.
- + Re-immersing the device under water.
- + This should be completed at least 3 times with fresh rinse water to ensure proper removal of the cleaning solution.

5. Sonicate

Transfer the devices to a freshly prepared enzymatic solution from step 1 and sonicate for 20 minutes.

6. Rinse

After sonication, thoroughly rinse devices in a room temperature, sterile, distilled or deionized water bath (not under running water) until all visible cleaner has been removed.

NOTE: Inadequate rinsing could result in trace amounts of cleaning solutions being left on the device. Extended exposure to mineral deposits found in tap water can cause device damage.

7. Dry

Dry the device with an ultra-soft, low-lint, cotton cloth such as a cloth diaper.

NOTE: Always dry the device after cleaning. Failure to do so could adversely affect further reprocessing steps.

STERILIZATION CHOICES AND STEPS

PRODUCT TYPE	SURGICAL LENS ACCESSORIES: VITREO LENS HANDLES AND SUTURE RINGS	SURGICAL LENS ACCESSORIES: INFUSION HANDLES	STERILIZATION CASES
ETO	+	+	+
Steam	+	+	+
Sterrad®	+		
V-Pro®			+
Sterizone VP4			+

Ethylene Oxide: Follow hospital procedures with aeration up to, but not exceeding 150°F / 55°C.

Steam Sterilization: **US** – Pre-vacuum, wrapped, 132°C minimum, 4 minutes (lenses), dry time 20 min.

EU / UK – Pre-vacuum, wrapped, 134°C minimum, 3 minutes (lenses), dry time 20 min.

Sterrad®: Use in the 100NX Express or use in 100S Short Cycle (available outside the US only).

V-Pro®: Applicable sterilization systems: V-Pro maX, V-Pro maX 2, V-Pro 60, V-Pro s2. Use the Non-Lumen or Fast cycle.

NOTES

- + The use of a Volk Sterilization Case (VSCA or VSCB) or Tray is recommended to avoid product loss or damage.