

THIS GUIDE APPLIES TO THE FOLLOWING DEVICES ONLY

INDIRECT TRADITIONAL VIT AND SSV	
SuperMacula	VSMACVIT
Central Retinal	VCRLVIT
Central Retinal SSV	VCRLVITSSV
MiniQuad	VMQVIT
MiniQuad SSV	VMQVITSSV
DynaView 156	VDVVIT
MiniQuad XL	VMQXLVIT
MiniQuad XL SSV	VMQXLVITSSV
HRX Vit	VHRXVIT
HRX Vit SSV	VHRXVITSSV

INDIRECT ACS VIT AND SSV*	
Central Retinal ACS Vit*	VCRLVITACS*
Central Retinal ACS SSV Vit*	VCRLVITSSVACS*
MiniQuad ACS Vit*	VMQVITACS*
MiniQuad ACS SSV Vit*	VMQVITSSVACS*
HRX ACS Vit*	VHRXVITACS*
HRX ACS SSV Vit*	VHRXVITSSVACS*

HIGH RESOLUTION (HR) DIRECT	
HR Direct 1X	VHRD1XACS
HR Direct 1X (NSR)	VHRD1XNSRACS
HR Direct High Mag	VHRDHMACS
HR Direct High Mag (NSR)	VHRDHMNSRACS
HR Direct Bi-Concave	VHRDBCACS
HR Direct 20 Prism	VHRD20PACS

DIRECT SELF-STABILIZING	
Flat SSV ACS	VFLATSSVACS
High Mag SSV ACS	VFHMSSVACS
15 ° Prism SSV ACS	VPRISMSSVACS
30 ° Prism SSV ACS	V30PRISMSSVACS
45 ° Prism SSV ACS	V45PRISMSSVACS
Mid Field SSV ACS	VMFSSVACS
Air Fluid Exchange SSV ACS	VAFXSSVACS

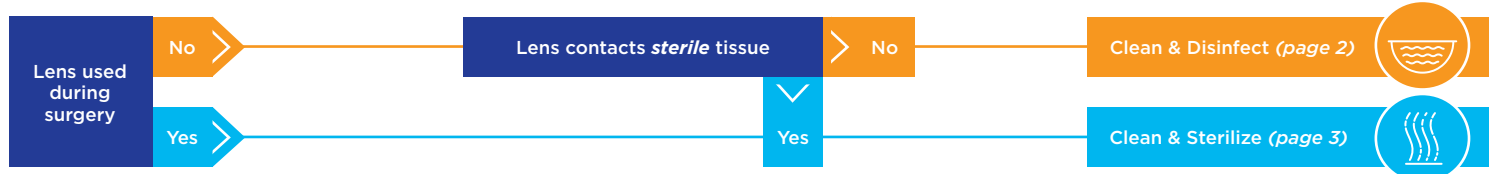
DO NOT USE a microfiber cloth, as over time these tend to collect dirt and dust which can damage the anti reflective coating on the lens.

*Must be disassembled prior to cleaning, disinfection, and sterilization

The information contained within this document applies only to Volk's Surgical Vitrectomy Lenses (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 vitrectomy lenses. All lenses that contact the patient's eye **must** be disinfected using a High-Level Disinfectant.

To avoid surface damage to contact lenses, **NEVER** clean the contact elements with alcohol, peroxide or acetone.



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. Use a clockwise motion to avoid loosening the retaining ring. 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 lens 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 lens damage.

3. Dry

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

Wiping the lens with a microfiber cloth will cause lens damage. Be sure to use only a soft, lint-free cotton cloth.

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

DISINFECTANT CHOICES AND STEPS

BRAND	VITRECTOMY SURGICAL LENSES - TRADITIONAL	VITRECTOMY SURGICAL LENSES - ACS
Bode Mikorbac Tissues	+	+
CaviWipes	+	+

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

HIGH-LEVEL DISINFECTANT CHOICES AND STEPS

PRODUCT TYPE	VITRECTOMY SURGICAL LENSES - TRADITIONAL	VITRECTOMY SURGICAL LENSES - ACS
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 lens on its side, and then immerse the entire lens in the selected solution for the listed soak time.

Rinse and Dry

Remove the lens 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.

Rings may discolor when exposed to Sodium Hypochlorite or Glutaraldehyde. To avoid further degradation please follow only the disinfection procedures indicated for these products in this document. This color change is purely cosmetic and will not affect the function of the lens.

STERILIZATION

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

⚠ To avoid surface damage to contact lenses, **NEVER** clean the contact elements with alcohol, peroxide or acetone.



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 knurled surface of housing with a soft-bristle brush and wipe lens portion with a soft, cotton cloth until all traces of cleaner and soil are removed. Pay special attention to all crevices and other hard-to-reach areas.

⚠ Do not brush lens portion to avoid scratching; use a soft, cotton cloth.

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 lens damage.

7. Dry

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

⚠ Wiping the lens with a microfiber cloth will cause lens damage. Be sure to use only a soft, lint-free cotton cloth.

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

STERILIZATION CHOICES AND STEPS

PRODUCT TYPE	VITRECTOMY SURGICAL LENSES - TRADITIONAL	VITRECTOMY SURGICAL LENSES - ACS
ETO	+	+
Steam		+
V-Pro®		+
Sterizone VP4		+

Ethylene Oxide: Follow hospital procedures with aeration up to, but not exceeding 130°F / 55°C for contact lenses.

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.

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.
- + The ring color may fade to a natural aluminum color after multiple repeated reprocessing cycles. This change is purely cosmetic and will not affect the function of the lens
- + The Volk black leatherette or clamshell lens cases should not be sterilized.