

THIS GUIDE APPLIES TO THE FOLLOWING DEVICES ONLY

* Denotes devices must be sterilized.

MERLIN® SURGICAL SYSTEM	
*MERLIN® Rotational Assembly (RA)	11179
*MERLIN® Lens Positioning Unit (LPU)	11171, 11172, 11173, 11174
*MERLIN® Surgical Lenses	11182, 11183, 11184
MERLIN® Condensing Lens Assembly (CLA)	11375, 11376, 11377, 11378, 11181, 11270
MERLIN® Condensing Lens	11275, 11277
*Removeable Sterilizable Handle	11178
ROLS® ∞	
*Removeable Sterilizable Handle	11178
ROLS® ∞ Reinverter	11313, 11315, 11363, 11364
ROLS®	
*ROLS® Magnetic Handle	VROLSMAGHAN
ROLS® Reinverter	VROLS-Z, VROLS-Z+, VROLS-L, VROLS-L+, VROLS-LX, VROLS-LX+

⚠ 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.

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

STORAGE

Ensure devices have been cleaned, sterilized and dried before storage. Store devices in a clean, dry, room-temperature environment in their appropriate, supplied case.

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.

CLEANING

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

CLEANING STEPS

MERLIN® Condensing Lens Assembly (CLA) MERLIN® Condensing Lens

Clean the external surface of the CLA housing with a soft, lint-free cloth moistened with any of the following:

- Isopropyl alcohol (70%)
- Sodium hypochlorite (0.5%)
- hydrogen peroxide (3%)

The condenser lens should be cleaned using Volk's Precision Optical Lens Cleaner.

NOTES

- + The MERLIN Condensing Lens Assembly (CLA) should not be submerged at any time.

ROLS® ∞ Reinverter and ROLS® Reinverter

Clean the external surface of the ROLS housing with a soft, lint-free cloth moistened with any of the following:

- Isopropyl alcohol (70%)
- Sodium hypochlorite (0.5%)
- hydrogen peroxide (3%)

The condenser lens should be cleaned using Volk's Precision Optical Lens Cleaner.

NOTES

- + The ROLS® ∞ Reinverter and ROLS® Reinverter should not be submerged at any time.
- + Do no attempt to clean the ROLS® ∞ and ROLS® glass prism.

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) – 1 ounce per gallon using warm (-30-43°C), sterile, deionized water.

2. Soak

Disassemble all devices and soak each device in solution for 20 minutes. Make sure to actuate all moving parts while submerged.

3. Brush

After soaking, brush devices 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 glass portion of lens 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, sterile, de-ionized water bath (not under running water) until all visible cleaner has been removed. Make sure to actuate all moving parts while submerged.

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. Make sure to actuate all moving parts while submerged.

NOTE: Inadequate rinsing could result in trace amounts of cleaning solutions being left on the device. A syringe could be used to deliver cleaning solution or rinse water to hard-to-reach areas.

7. Dry

Dry the devices 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 STEPS

PRODUCT TYPE	MERLIN® ROTATIONAL ASSEMBLY (RA)	MERLIN® LENS POSITIONING UNIT (LPU)	MERLIN® SURGICAL LENSES	REMOVEABLE STERILIZABLE HANDLE	ROLS® MAGNETIC HANDLE
Steam	+	+	+	+	+

Steam Sterilization: Pre-vacuum cycle for 5 minutes at a minimum temperature of 132°C.

⚠ The MERLIN® Condensing Lens Assembly (CLA), MERLIN® Condensing Lens, ROLS® ∞ Reinverter, and ROLS® Reinverter are not designed to be sterilized. Sterilization of these devices will cause product damage.

NOTES

- + The use of a Volk Sterilization Case (VSCA or VSCB) or Tray is recommended to avoid product loss or damage.
- + If applicable, use standard, medical-grade steam sterilization wrap following the double wrap method.
- + Ensure all devices are disassembled prior to reprocessing.