

*MERLIN™ Surgical System*  
*ROLS® ∞ Reverter*  
Operator's Manual



Volk Optical Inc.  
7893 Enterprise Drive  
Mentor, OH 44060

## Introduction

Volk Optical Inc., the leader in aspheric optics is pleased to deliver the MERLIN Surgical System- Volk Optical's next generation non-contact retinal viewing system providing precision maneuvering and control capabilities for non-contact surgical lenses.

# MERLIN



The MERLIN RA (Rotational Assembly) Surgical System is compatible with all leading surgical microscopes, and provides an elegant maneuverability solution for your surgical lens.

It is designed to ensure your lens is positioned precisely where you require, with easy manipulation, obtaining the best views for your surgical procedures.



Volk's next generation Reinverting Operating Lens System® (ROLS® ∞), rights an inverted image created by indirect lenses.

The ROLS ∞ is an optional addition to your MERLIN Surgical System.



Volk has designed the system to be used with non-contact lens options to suit your personal preferences. Our non-contact lenses are available in a variety of technical specifications: from the widest non-contact field of view available to mid-field magnification, as well as a design for deep access in difficult anatomies. Volk lenses deliver the crispest, high resolution image available with a non-contact lens. See our catalog for all the lens options available to you.

## Table of Contents

|   |    |
|---|----|
| Function and Intended Application   | 4  |
| Warnings, Markings & Symbols  | 5  |
| Safety Instructions   | 6  |
| Technical Specifications  | 7  |
| MERLIN RA   | 7  |
| ROLS ∞  | 7  |
| MERLIN Components and Equipment List  | 8  |
| Unpacking Your New System   | 9  |
| Customize the MERLIN to Your Microscope   | 11 |
| Operating – MERLIN RA   | 12 |
| Acquiring the Retinal Image – MERLIN RA   | 13 |
| Dismantling – MERLIN RA   | 14 |
| Installing the ROLS ∞ (Optional Equipment)  | 15 |
| Operating the ROLS ∞ (Optional Equipment)   | 17 |
| Dismantling – ROLS ∞  | 18 |
| Cleaning and Sterilization  | 19 |
| MANUAL CLEANING INSTRUCTIONS FOR ROTATIONAL ASSEMBLY, LENS POSITIONING UNIT, LENSES, REMOVABLE HANDLE<br>and STERILIZATION TRAY (as applicable) | 19 |
| Inspection / Function Check   | 20 |
| Packaging   | 20 |
| STERILIZATION INSTRUCTIONS FOR ROTATIONAL ASSEMBLY, LENS POSITIONING UNIT, LENSES, REMOVABLE HANDLE<br>and STERILIZATION TRAY (as applicable)   | 20 |
| CLEANING THE ROLS ∞ ASSEMBLY (Optional Equipment)   | 20 |
| Troubleshooting   | 21 |
| Storage & Transport   | 22 |
| Service and Repair  | 23 |
| Inspection / Preventative Maintenance   | 23 |
| MERLIN Components   | 24 |
| Product Warranty  | 25 |
| Regulatory Information  | 26 |
| Appendix A – Microscopes and Adapters   | 27 |

## Function and Intended Application

The Volk MERLIN Surgical System and ROLS ∞ are accessories used to enhance the utility of stereomicroscopes during ophthalmic surgeries.

The Volk MERLIN Surgical System is a modular system that allows the surgeon to dynamically adjust the position and orientation of non-contact indirect (inverting) ophthalmic surgical lenses in relation to a patient's eye. The properly aligned MERLIN can be directed to provide firm mechanical support keeping the lens in the optimum orientation – freeing the surgeon or nurse-assistant from supporting the ophthalmic lens during surgery.

The MERLIN Surgical System hard mounts directly below the objective of the surgical microscope. The system consists of two major sub-assemblies, the Rotational Assembly (RA) and the Fine Focus Lens Positioning Unit (referred to as LPU in this manual).

The RA (defined above) is mounted and positioned for precise lens alignment to the surgical microscope optical axis. It allows 360° rotation of the attached LPU and lens about the optical axis. The LPU consists of a connection assembly that attaches it to the RA, a pair of vertical shafts, turn knobs for fine focus control, and lens holder. The LPU can be pivoted completely out of the surgical field when the non-contact lens is not in use.

It is the action of the full-scale adjustment of the LPU that makes the MERLIN unique. An ophthalmic lens is mounted to one end of the LPU. The ophthalmic lens can be dynamically positioned above the patient's eye. The surgeon is able to adjust the microscope and associated ophthalmic lens just as would be done during a slit lamp examination. The ophthalmic lens is then firmly coupled to the surgical microscope. The LPU mates to the mount using a quick-connect assembly. It allows the LPU to be easily connected to and removed from the RA. Both the RA and the LPU are compatible with steam sterilization using an autoclave. Its interface has been engineered so that it can be easily processed for autoclaving after each and every surgery.

The ROLS ∞ Assembly, an optional component of the MERLIN Surgical System, is a device that is used to re-invert the inverted retinal image that is formed when one uses indirect-type ophthalmic lenses during eye surgery. The image inversion is achieved by placing a suitably formed optical prism within the collimated beam pathway of a stereo surgical microscope. More specifically, the ROLS ∞ Assembly is placed between the microscope objective and the surgeon's eyepieces. When the inverting prism is out of the beam pathway, the lens under the stereomicroscope provides inverted imagery. When the prism is switched into the beam pathway, the lens image is re-inverted. This complete level of re-inversion allows the retinal image to be upright and correctly oriented for surgical procedures. The ROLS ∞ Assembly allows the surgeon to switch between normal and inverted image mode whenever necessary by just moving the detachable handles.

Thank you for purchasing the Volk MERLIN Surgical System. Please read and follow the instructions found in this manual before using your new system to ensure safe and dependable service.

Please register your product on line at [www.volk.com](http://www.volk.com) or complete and mail the enclosed registration card. Registering your purchase will safeguard your investment by:

- ensuring you receive updates with product information, maintenance tips or industry news
- ensuring Volk Optical can contact you or your distributor if servicing is needed on your product
- enabling Volk Optical to improve product design based on your input and needs

## Warnings, Markings & Symbols

| Symbol  | Description  |
|---|--|
|  | <p>ATTENTION: Refer to the manual. The user is advised of important operating and maintenance instructions.</p>  |
|   | <p>Follow the cleaning and sterilization instructions detailed within this manual</p>  |
|   | <p>Service or repair is to be performed by qualified, authorized personnel. Return to Volk for servicing. Do not attempt to repair this Assembly.</p>                                      |
|   | <p>Disassembly of this unit beyond the instructions in this manual will void the warranty.</p>   |
|  | <p>Do not operate or leave this Assembly in any environment that may exceed +10° C to 40°C; relative humidity of 30% to 75%; and an atmospheric pressure range of 700 hPa to 1060 hPa.</p> |
|  | <p>The CE mark on this device indicates that it has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive.</p>                                    |

## Safety Instructions

Before installing or using this equipment familiarize yourself with the operating instructions and all safety features.

If you cannot understand these instructions, including warnings and cautions, contact Volk personnel before installation or use.

Follow all the instructions for setup, usage, sterilization and disassembly. If you have any questions, please contact a Volk representative.

Check all parts for damage and test before use. The MERLIN Surgical System must be in proper working order; do not use if there is any damage or if the Assembly is in need of repair.

The MERLIN Surgical System must be used only with the original accessories and parts supplied or specified by Volk Optical otherwise the warranty is void.

The MERLIN Surgical System may only be used for its intended use in the surgical specialties by educated and qualified personnel. The surgeon shall be responsible for the proper selection for each application, for obtaining the appropriate training, knowledge and experience.

Volk Optical cannot be responsible for any liability for damages caused by inappropriate application and use or by inappropriate cleaning and sterilization and care of the system.

Never connect this instrument with any other product that is not specifically designed to be used with the MERLIN system.

Do not operate the MERLIN Surgical System outside of the stated environmental operating conditions.

## Technical Specifications

### Merlin RA

| Equipment classification   | Class 1   |
|--|---|
| Degree of Protection against the Presence of Flammable Anesthetic Mixtures | Ordinary equipment, not for use in a flammable atmosphere                         |
| Interfaces:  | Hard mounts to common surgical microscopes.<br>Volk MERLIN Lens Positioning Unit. |
| Mount Size:  | 142mm x 70mm x 28mm<br>(5.6" x 2.8" x 1.1")                                       |
| Weight:  | 183 g   |
| Storage/Transport Conditions:  | Temperature: +10° C to +40°C  |
| Operating Conditions:  | Temperature: +10° C to +40°C  |
| Mode of Operation  | Continuous Operation  |
| Materials:   | All metal components are surgical grade materials.<br>This product is latex free. |

### ROLS ∞

| Equipment classification   | Class 1   |
|--|---|
| Degree of Protection against the Presence of Flammable Anesthetic Mixtures | Ordinary equipment, not for use in a flammable atmosphere                         |
| Interfaces:  | Hard mounts to common surgical microscopes.                                       |
| Mount Size:  | 91mm x 107mm x 58mm<br>(3.6" x 4.2" x 2.3")                                       |
| Weight:  | 326 g   |
| Storage/Transport Conditions:  | Temperature: +10° C to +40°C  |
| Operating Conditions:  | Temperature: +10° C to +40°C  |
| Mode of Operation  | Continuous Operation  |
| Materials:   | All metal components are surgical grade materials.<br>This product is latex free. |

## MERLIN Components and Equipment List



Rotational Assembly (RA) – Hard mounts below Microscope objective. Provides attachment assembly for Lens Positioning Unit with 360° rotation about optical axis.

Lens Positioning Unit (LPU) – Holds the lens over the patient with full-scale adjustment. LPUs are sized specifically for microscope objective lens focal lengths of 175mm or 200mm.

Non-contact Lens – The optical viewing element for viewing the eye anatomy.

ROLS ∞ Assembly – Optical prism device that allows the user to switch between indirect and normally inverted image modes.

## Unpacking Your New System

All materials and containers should be kept in a safe place for future storage and transportation. All components and parts should be handled with care.

*Verify all components for shipping damage*

Remove and check that the following components are present and free from any damage:

### MERLIN Lenses and sterilization case

- Lens mini sterilization case should be opened, shipping material removed and all lenses checked for shipping damage.
- Lens elements (quantity and type will vary based on your order) – Check to make sure the lenses are not cracked, loose or dislodged from their housings.



### MERLIN Rotational Assembly

- Remove from case and check for damage.



### MERLIN Lens Positioning Unit

- Remove from case and check for damage.

**Note – Use only the focus adjustment knobs to adjust the height of the lens. Do not push or pull directly on the assembly rod.**

MERLIN Lens Positioning Unit

### MERLIN Microscope Adapter Plates

- All plates have a code, which relates to your microscope. See appendix A to identify the correct code and mounting instructions.



See Appendix A

### Reinverting Operating Lens System ∞ (ROLS ∞) (Optional Equipment)

- Remove from case and check for damage.
- Remove foam shipping lock from slot on side of unit.



**Note - The system should be assembled and tested for correct functionality prior to first use.**

## Installing - MERLIN

- Turn off the electrical power to the microscope and attached microscope accessories.
- Identify the correct adapter for your microscope (see appendix A).
- Attach the selected adapter plate to the microscope with the enclosed socket head cap screws using an Allen key or hex-wrench (not included). The screws will fit into the existing mount holes on the microscope, through the bottom of the adapter plate.
- Mount the MERLIN RA to your microscope by aligning the unit into the plate groove in the adapter plate.
- Adjust and fix the small dovetail plate against the MERLIN RA mounting dovetail plate.
  - The small dovetail plate serves as a hard-stop for consistent front-to-back alignment of the device relative to the scope objective lens.
- Hand-tighten the screws on the side of the adapter plate.
- To attach the LPU:
  - Press and hold the quick disconnect button on the LPU.
  - Mate the LPU locating pins to the matching holes in the rotational ring of the RA.
  - Release the quick disconnect button on the LPU.
  - Gently pull on the LPU to confirm that it is properly and securely mounted in the rotational ring of the RA.
- To attach a lens
  - Hold the LPU at the lens mounting assembly.
  - Hold the lens with your other hand and push in until the lens is securely in place. You will hear a click when the lens is fully seated.
  - After inserting the lens, if needed rotate the lens to its centered position in the LPU. You will feel the locating detent click when the lens is properly centered.

See Appendix A



## Customize the MERLIN to Your Microscope

- Look at a model eye through the microscope and the LPU.
- A suggested starting point is with the lens about 3 – 5 mm from the eye and the Lens Positioning shaft at mid-point of its adjustment range.
- The LPU shaft is designed to adjust up or down using the adjustment knobs.
- The LPUs are specifically designed for specific objective lens focus lengths (175mm or 200mm).
- The shaft will move about 30mm to properly focus the non-contact lens on the retinal image.
- Rotate the fine focus adjustment knob until an image is seen.

**Note – Use only the focus adjustment knobs to adjust the height of the lens. Do not push or pull directly on the assembly rod.**



## Operating - MERLIN

**Note - the LPU and lenses must be cleaned and sterilized before they are used in any surgical procedure. See cleaning and sterilization instructions.**

- Attach the MERLIN mount to your microscope per the installation instructions on page 10.
- Rotate the LPU to its retracted position out from under the microscope objective lens.
- The LPU's design allows for 360° rotation about the optical axis:
  - with the LPU deployed (LPU is "lens down" in vertical position with lens under objective).
  - with the LPU retracted (LPU is "lens up" in horizontal position).
- The LPU pivot block includes a detent that fixes the LPU in the "up" position when retracted.
  - The LPU pivot block can rotate 90° "up" from either side of its vertical deployed position to its horizontal retracted position.
- To place the lens in the field of view, the shaft should be adjusted to the position determined during the installation. If not, re-adjust the shaft until an image is obtained.



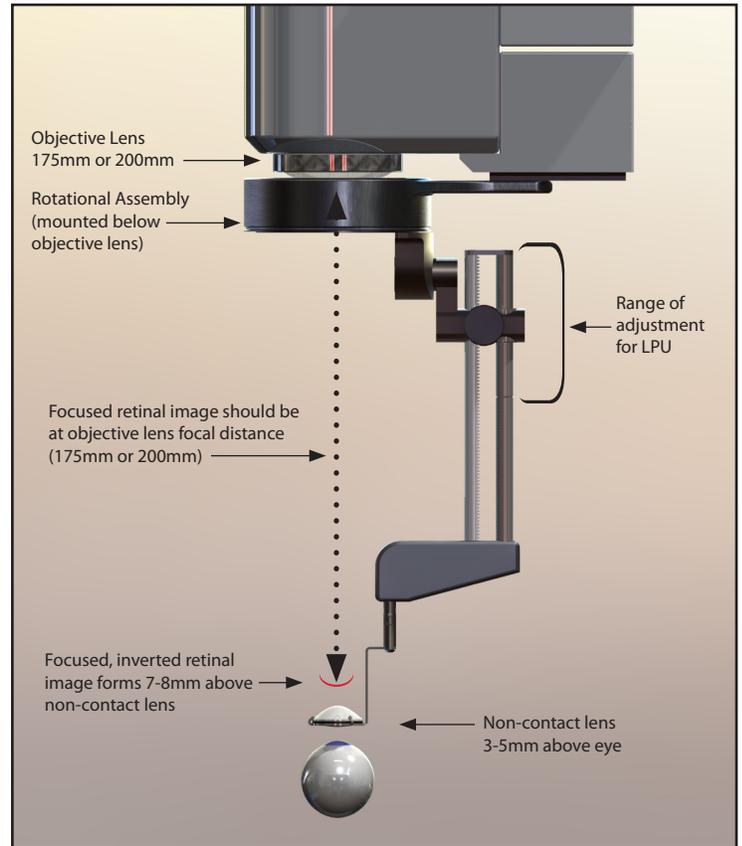
**Note - All MERLIN lenses have a hinge that allows the device to move up in the vertical plane to reduce the risk of injury to the patient:**

- If the lens is lowered onto the patient's eye
- If the patient moves up suddenly during a procedure



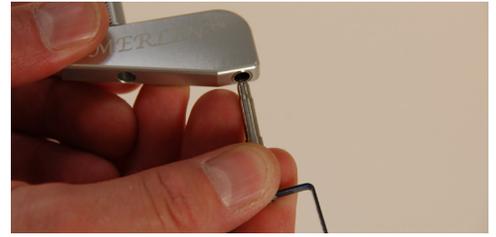
## Acquiring the Retinal Image - MERLIN RA

- 1) Attach the MERLIN RA, LPU and a non-contact lens and align the system using a model eye or target.
  - a) Recommendation: the Wide Angle lens is a good starting lens.
  - b) Move the LPU and lens to the horizontal "up" position after aligning the system.
- 2) Center the microscope in its automated movement range.
  - a) Most automated scopes have a centering function activated by a single button.
- 3) Achieve a focused corneal image with the microscope.
  - a) Again, for this step the LPU and non-contact lens should be in the horizontal "up" position
  - b) For a focused corneal image, the scope objective lens should be about 175mm or 200mm above the cornea, depending on its focal length design.
- 4) Use the scope focus control pedal to move the scope head up about 5cm.
- 5) Deploy the LPU to its vertical "down" position with the lens over the eye.
- 6) Position the LPU at the mid-point of its adjustment range.
- 7) Use the LPU focusing knob to achieve a focused retinal image.
  - a) Do NOT use the scope pedals for this focusing step. You may wish to advise the physician to remove feet from the pedals to prevent the habitual scope focusing response.
  - b) You should see some retinal structures, though the field of view will be very small.
- 8) Now use the scope focusing pedal to move the scope head down so that the non-contact lens approaches the eye.
  - a) As the scope lowers toward the eye the image field of view will increase.
- 9) Using the scope focusing pedals does NOT change image focus when the non-contact lens is deployed: the scope focusing motion essentially becomes a "field of view" adjustment.
  - a) Optimal location of the non-contact lens is about 3-5mm above the eye. This should provide the widest image field of view with a comfortable working distance of the lens above the eye.



## Dismantling the MERLIN RA

- Remove lens by grasping the hand-hold on the LPU shaft and by the lens above the hinge and pull apart until the lens is released.
- To detach the LPU:
  - Press and hold the quick disconnect button on the LPU.
  - Pull the LPU from the mating holes in the rotating ring.
  - Release the quick disconnect button on the LPU.
- Cleaning & Sterilization: Follow the cleaning and sterilization instructions in this manual.
- If desired, reverse the installation instructions to dismantle and remove the remaining components.
- The Rotational Assembly has been validated for cleaning and sterilization per the instructions provided in this manual.
  - Remove the Rotational Assembly from the adapter plate prior to the starting the cleaning and sterilization steps in this manual.
  - It is at the discretion of the user whether to clean and sterilize the Rotational Assembly per the instructions in this manual or wipe it down using a cloth with cleaning or disinfectant agent.



## Installing the ROLS ∞ (Optional Equipment)

The ROLS ∞ Assembly is easy to install on your operating microscope and is available in two flange styles\*. If you ordered a Zeiss Flange Style unit, it will only fit on Zeiss microscopes or microscopes manufactured by Topcon, Moeller and Inami that accept Zeiss compatible accessories. If your ROLS ∞ Assembly is a Leica Flange Style, it will only fit Leica or Wild microscopes. If you are uncertain of compatibility, please contact Volk Optical Inc.

Installing The ROLS ∞ Assembly On A Single Scope Unit (with only a surgeon's set of oculars):

- Turn off the electrical power to the microscope and attached microscope accessories.
- Lock the microscope in an easily accessible position.
- Remove any accessories attached to the Beam Splitter, including the Observer's Tube.
- Loosen the lock screw to remove the Upper Microscope Assembly.
  - For a Leica microscope, completely remove the lock screw and use the replacement lock screw supplied with the ROLS ∞.
  - For a Zeiss microscope, loosen screw enough to remove the Upper Microscope Assembly.
- Remove the entire upper microscope assembly (Binoculars, Beam Splitter, Laser Safety Filter Attachment) from the base portion of the microscope.
  - **NOTE:** If applicable, do not remove the Assistant's Scope. For proper operation, the ROLS ∞ Assembly must be positioned below the Surgeon's Scope but above the Assistant's Scope.
  - **NOTE:** For proper clearance, the laser filter or the beam splitter must be positioned between the ROLS ∞ Assembly and the Surgeon's binoculars.
- Hold the ROLS ∞ Assembly in a horizontal position with the Volk lettering readable from the surgeon's position (typically at the patient head end of the OR gurney).
- Slide the lower Male Flange Lock on the ROLS ∞ Assembly into the upper female Flange Lock of the base portion of the microscope.
- Attach the sterilizable handle to the handle post on the right side of the ROLS ∞.
  - The handle should be cleaned and sterilized prior to use following the instructions in this manual.



- Verify that the two flanges are seated flush together. If necessary, slightly rotate the ROLS ∞ Assembly left and right until the exact fit is achieved.



- Tighten the thumbscrew on the microscope base. The ROLS ∞ Assembly is now locked to the base portion of the microscope.



- Slide the lower Male Flange Lock on the Upper Microscope Assembly into the upper Female Flange Lock on the ROLS ∞ Assembly while observing the assembly is in the correct orientation.
- Verify that the two flanges are seated flush together. If necessary, slightly rotate the Upper Microscope Assembly left and right until the exact fit is achieved.



- Tighten the lock screw. The Upper Microscope Assembly is now locked to the base portion of the microscope.
- Reinstall accessories to the beam splitter, unlock the operating microscope and turn on the electrical power to the microscope and accessories.



## Operating the ROLS ∞ (Optional Equipment)

- Use the attached sterilizable handle to slide the inverting prism into and out of the microscope's field of view.

- The inverting prism is OUT of the field of view when the handle is positioned at the FRONT of the ROLS ∞.



- The inverting prism is IN the field of view when the handle is positioned at the BACK of the ROLS ∞.



- Verify that all flanges are seated flush together. If necessary, slightly rotate the appropriate assembly left and right until the exact fit is achieved.
- Tighten all thumbscrews, reinstall accessories to the beam splitter, unlock the operating microscope and turn on the electrical power to the microscope and accessories.
- To invert the image, turn the handles on the side of the ROLS ∞

## Dismantling - ROLS ∞

To remove the ROLS ∞ Assembly from the microscope:

1. Turn off the electrical power to the microscope and the attached microscope accessories.
  - Lock the microscope in an easily accessible position.
  - Remove any accessories attached to the Beam Splitter, including the Observer's Tube.
  - Remove all microscope assemblies up to and including the Surgeon's Scope.
  - Remove the ROLS ∞ Assembly and place into the storage case.
  - Reassemble the scope(s) and the remaining microscope assemblies.
  - Verify that all flanges are seated flush together. If necessary, slightly rotate the appropriate assembly left and right until the exact fit is achieved.
  - Tighten all thumbscrews, reinstall accessories to the beam splitter, unlock the operating microscope and turn on the electrical power to the microscope and accessories.

## Cleaning and Sterilization

### Notes:

1. Disassemble instrument prior to cleaning and sterilization
2. Corrosive cleaning agents (e.g. chloride, saline, etc.) are not recommended. Enzymatic and cleaning agents with neutral pH are recommended.

**Reprocessing Limitations:** Repeated cleaning and sterilization has minimal effect on the arm assembly of the system when processed according to instructions. End of life is normally determined by wear and damage due to use.

### Preparation at the Point of Use

1. New, used or contaminated units must be cleaned.
2. **Body fluids and/or tissue should not be allowed to dry on the device prior to cleaning.** Remove excess body fluids and tissue.
3. Universal precautions for handling contaminated materials should be observed.
4. Instruments should be cleaned as soon as possible after use to minimize drying of any body fluids and tissue.

**Preparation of cleaning agent:** Prepare a neutral pH enzyme and cleaning agent according to manufacturer's recommendations.

### **MANUAL CLEANING INSTRUCTIONS FOR ROTATIONAL ASSEMBLY, LENS POSITIONING UNIT, LENSES, REMOVABLE HANDLE and STERILIZATION TRAY (as applicable)**

- 1) Use a lint free tissue dampened with an antibacterial, aldehyde-free solution to remove macroscopic visible deposits from each device. Pay special attention to any uneven surfaces, lumens, crevices, joints, corners and other hard-to-reach areas, e.g.:
  - a) Surfaces around the periphery of the lens, and the lens hinge;
  - b) The interior of the removable handle;
  - c) Screw heads, grooves and mating sockets in the Rotational Assembly;
  - d) The geared rack and shaft of the Lens Positioning Unit (LPU), the LPU engagement mechanism, and screw heads and recesses in the LPU.
- 2) Prepare fresh enzymatic cleaner solution (1 ounce per gallon) using warm (30-43°C) sterile de-ionized water.
- 3) Disassemble devices (Rotational Assembly should be separated from LPU, LPU should be separated from lens assembly, sterilization tray lid should be removed from tray).
- 4) Soak components in Enzol solution for 20 minutes. Actuate all movable parts while submersed in the cleaner. Use a syringe to "deliver" Enzol solution to hard-to-reach areas prior to soaking.
- 5) After soaking, aggressively brush devices with a soft-bristle brush until all traces of cleaner and soil are removed. Pay special attention to any uneven surfaces, lumens, crevices, joints, corners and other hard-to-reach areas, e.g.:
  - a) Surfaces around the periphery of the lens, and the lens hinge;
  - b) The interior of the removable handle;

- c) Screw heads, grooves and mating sockets in the Rotational Assembly;
- d) The geared rack and shaft of the Lens Positioning Unit (LPU), the LPU engagement mechanism, and screw heads and recesses in the LPU.

NOTE: Do not brush glass lens to avoid damage but do brush the lens shaft, lens mounting ring and lens retention tines.

- 6) After brushing thoroughly rinse\* devices in a room temperature sterile de-ionized water bath (not under running water) until all visible cleaner has been removed. Actuate all movable parts while submersed in the rinse bath. Use a syringe to “deliver” rinse water to the hard-to-reach areas of each device. Repeat rinsing cycle 5 times, changing water between cycles.
- 7) Transfer the devices to a freshly prepared Enzol solution (per step 1 above) and sonicate for 20 minutes.
- 8) After sonication, thoroughly rinse\* devices in a room temperature sterile de-ionized water bath (not under running water) until all visible cleaner has been removed. Use a syringe to “deliver” rinse water to the hard-to-reach areas of each device. Repeat rinsing cycle 5 times, changing water between cycles.
- 9) Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions until debris is removed.

\*The rinsing will be conducted under the water level to prevent aerosolization. Rinsing will be performed by:

- Agitating the device under water;
- Bringing the device above the water level;
- Re-immersing device under water.

### **Inspection / Function Check**

- 1) Carefully check to ensure that all visible blood and soil has been removed.
- 2) Visually check for damage and/or wear.
- 3) Check the assembly and action of the moving joints to ensure operation throughout the range of motion. If damage or wear is apparent, contact Volk Optical or your distributor for return.

### **Packaging**

- 1) Make sure the shaft and lens are disassembled.
- 2) Place in the sterilization case provided. If applicable, use standard medical grade steam sterilization wrap following the double wrap method.

### ***STERILIZATION INSTRUCTIONS FOR ROTATIONAL ASSEMBLY, LENS POSITIONING UNIT, LENSES, REMOVABLE HANDLE and STERILIZATION TRAY (as applicable)***

Steam sterilize using a pre-vacuum cycle for 5 minutes at a minimum temperature of 132°C.

### ***CLEANING THE ROLS ∞ ASSEMBLY (Optional Equipment)***

#### **HOUSING**

1. The external surface of the ROLS ∞ housing may be cleaned with a slightly moist cloth.
2. To avoid damage to the ROLS ∞ Assembly, do not submerge the housing in any solution or attempt to clean the ROLS ∞ prism.

## Troubleshooting

### I do not see the desired image of the retina.

- Reset your LPU and scope adjustments:
  - Start with the LPU in the middle position of its adjustment range.
  - Deploy the LPU and non-contact lens under the objective lens so that the non-contact lens is about 1-2 cm above the eye.
  - Adjust the LPU fine focus knob to focus the retinal image.
    - The focused retinal image actually forms about 7-8mm above the top surface of the lens. It is this point on which the scope objective lens focuses:
      - It should be 175mm (~ 7") below the objective lens for a 175mm lens.
      - It should be 200mm (~ 8") below the objective lens for a 200mm lens.
  - With a focused image, leave the LPU adjustment set. At this point in the focusing process, the retinal image will have a small field of view.
    - To widen the field of view of the retinal image, use the microscope focusing pedal to move the non-contact lens down to about 3-5mm above the eye (again, no further adjustment to the LPU).
- Other suggestions:
  - Make sure that the MERLIN lens is properly aligned to the optical axis of the microscope under the objective lens.
  - Make sure that the Objective Lens on the microscope is either 175mm or 200mm. Confirm that your LPU is designated with the same focal length number (175 or 200).
    - The MERLIN system Lens Positioning Units are designed use with specific objective lens focal lengths and are not interchangeable.
      - LPUs designed for 175mm objective lenses will not work with 200mm objective lenses, nor will 200mm LPUs work with 175mm objective lenses.

## Storage and Transport

- Retrieve all original shipping containers and packing materials. The shipping containers are customized to the components and should be used to prevent any damage that may occur during shipping.
- Ensure the lenses are placed in the smaller sterilization case and shipping foam placed within to prevent any movement.
- Ensure the RA and LPU are placed in the correct foam cut outs in the storage case.
- Ensure that the ROLS ∞ is placed in its correct foam cut in its storage case.
- Place packing foam on top of all components and close the case.
- If shipping, it is recommended placing all cases within cardboard boxes to minimize any shipping damage.
- If keeping in storage, ensure the components are stored in the following conditions and stored in the cases provided:
  - Temperature: +10° C to +40°C

## Service & Repair

All components are to be inspected periodically for proper functionality. If any component or part is considered to be malfunctioning or defective, contact Volk Optical customer service (see contact details in this manual).

Repairs and corrective maintenance must only be carried out by Volk Optical Inc. Any work carried out by unauthorized persons will nullify any warranty.

### **Inspection / Preventative Maintenance**

The following steps should be done before each usage

Check the mating plate of the LPU for damage.

## Components available for order from Volk

| Device                | Platform  | 175 mm or 200 mm<br>Objective Lens | Scope Make     | PN            |
|-----------------------|---|------------------------------------|----------------|---------------|
| Rotational Assembly   |   |                                    |                | 11179         |
|                       |   |                                    |                |               |
| Lens Positioning Unit | Rotational Assembly                               | 175                                |                | 11171         |
|                       | Rotational Assembly                               | 200                                |                | 11172         |
|                       |   |                                    |                |               |
| Lenses:               |   |                                    |                |               |
| Wide Angle            |   |                                    |                | 11183         |
| Small Dia. Wide Angle |   |                                    |                | 11184         |
| Mid-Field             |   |                                    |                | 11182         |
|                       |   |                                    |                |               |
| ROLS ∞                |   |                                    | Zeiss          | 11306         |
|                       |   |                                    | Leica          | 11310         |
|                       |   |                                    | Leica M520     | 11374         |
|                       |   |                                    |                |               |
| Adapter Plate         | Rotational Assembly or<br>Condenser Lens Assembly |                                    | See Appendix A | Call to order |
| Storage Case          | MERLIN  |                                    |                | 11431         |
| Storage Case          | ROLS ∞  |                                    |                | 11432         |

## Product Warranty

The Seller warrants to the Purchaser that the goods furnished hereunder will, for the appropriate periods of product warranties, as defined on our user instructions shipped with each product, conform to Sellers' agreed to specifications. The obligation of the Seller, and the Purchaser's sole and exclusive remedy hereunder, shall be limited, at the Seller's option, to replacement of defective goods or refund of the purchase price thereof. Purchaser shall not return goods unless authorized in writing by Seller. Seller shall have the right to inspect the goods at Purchaser's installation. Purchaser's failure to give prompt written notice (30 days) upon discovery of any alleged defect shall constitute a waiver by Purchaser of all claims with respect thereto. Notwithstanding the foregoing warranties and remedies, seller shall have no obligation hereunder if the goods become defective as a result of improper storage, contamination, adulteration, improper use or misapplication after delivery thereof to Purchaser. If the product fails to function due to defects in either materials or workmanship, Volk will, at its option, either repair or replace the product without charge, subject to the Warranty Limitations.

Volk Optical warrants its MERLIN Surgical System against defects in material or workmanship for a period of 1 year from receipt by end-user.

Volk Optical warrants its Volk Vitrectomy Lenses against defects in materials or workmanship for a period of 1 year from receipt by end-user.

Volk Optical warrants its Volk Autoclave Sterilizable (ACS) Vitrectomy Lenses against defects in materials or workmanship for the lesser of 6 months from receipt by end-user or 100 sterilization cycles.

Volk Optical warrants its ROLS Reinverter against defects in materials or workmanship for a period of 1 year from receipt by end-user.

Customers shall be responsible for returning products for warranty service to Volk Optical, 7893 Enterprise Drive, Mentor, Ohio 44060 - USA.

Warranty repairs will include all labor, adjustments and replacement parts. Replacement parts may be re-manufactured or contain remanufactured materials.

Warranty service may not be provided without proof the product was purchased from Volk Optical Inc. or an Authorized Volk Distributor.

This Warranty becomes null and void if the customer fails to return the product in packaging that is consistent with the original protective packaging and it results in shipping damage.

This Warranty becomes null and void if the customer fails to follow the recommended cleaning, disinfection and sterilization instructions and/or cautions contained in the product instruction manual.

This Warranty does not cover service required because of disassembly, unauthorized modifications or service, misuse or abuse.

SELLER MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, OF THE PRODUCT SUPPLIED HEREUNDER, INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL SUCH WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED. SELLER SHALL HAVE NO LIABILITY FOR LOSS OF PROFITS, OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES UNDER ANY CIRCUMSTANCES OR LEGAL THEORY, WHETHER BASED ON NEGLIGENCE, BREACH OF WARRANTY, STRICT LIABILITY, TORT, CONTRACT, OR OTHERWISE. SELLER SHALL IN NO EVENT BE LIABLE IN RESPECT OF THIS ORDER AND/OR PRODUCT DELIVERED ON ACCOUNT OF THIS ORDER FOR ANY AMOUNT GREATER THAN THAT PAID TO SELLER ON ACCOUNT OF THIS ORDER. THE PURCHASER ACKNOWLEDGES THAT IT IS PURCHASING THE GOODS SOLELY ON THE BASIS OF THE COMMITMENTS OF THE SELLER EXPRESSLY SET FORTH HEREIN.

## Ordering Information

Orders may be placed with the Authorized Volk Distributor in your region. Authorized Distributor contact information is available directly from Volk.

Volk Optical Inc.  
7893 Enterprise Drive  
Mentor, Ohio 44060  
USA

Toll free within the United States: 1-800-345-8655  
Phone: 440 942 6161  
Fax: 440 942 2257  
Email: [volk@volk.com](mailto:volk@volk.com)  
Website: [www.volk.com](http://www.volk.com)

## Regulatory Information



### EU REPRESENTATIVE

The Volk authorized representative based in the European Union (EU) is:

Rudolf Riester GmbH  
Bruckstraße 31  
72417 Jungingen, Germany  
Email: [info@riester.de](mailto:info@riester.de)  
Phone: +49 74 77 / 92 70-0  
Fax: +49 74 77 / 92 70-70

Note: This product complies with current required standards for electromagnetic interferences and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device in close proximity to other equipment.

Members of the European Union should contact their authorized Volk Distributor for disposal of this unit.

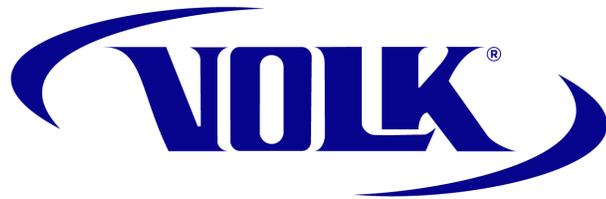


Certificate  
FM 71461

## Appendix A - Microscopes and Adapters

Note: Please check your microscope model for the correct style needed before ordering. Contact your authorized distributor to order other styles than shown below.

| Volk Optical<br>Kit Part Number<br>(plate and screws) | Assembly Instructions for your<br>Microscope Style | Adapter Plate Style   |
|---|--|---|
| 11408   | Zeiss  |    |
| 11409   | Leica / Wild                                       |    |
| 11410   | Moller-Wedel<br>(also ships with #6-32 screws)     |   |
| 11412   | Takagi   |  |
| 11413   | Topcon   |  |
| 11411   | Leica 690  |  |
| 11425   | Spacer Kit   |  |



**Volk Optical Inc.**

7893 Enterprise Drive  
Mentor, Ohio 44060  
USA

Phone: 440 942 6161

Toll free within the United States: 1-800-345-8655

Fax: 440 942 2257

Email: [volk@volk.com](mailto:volk@volk.com)

Website: [www.volk.com](http://www.volk.com)

MERLIN Surgical is patent pending  
Copyright © 2009 Volk Optical Inc.