

Instructions for Use

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1 Description

SOLR is a non-contact vitreoretinal viewing system that works in conjunction with a surgical microscope. It allows the surgeon to dynamically adjust the position and orientation of non-contact indirect ophthalmic surgical lenses in relation to a patient's eye.

The SOLR system consists of the following items:

- Volk SOLR Rotation Base
- Volk SOLR Lens arm
- Volk SOLR Condensing lens
- Volk SOLR Surgical Lenses

The system is used with Volk SOLR Surgical Lenses. The system is mounted to the microscope using Volk Optical mounting kits sold separately.

Surgical Lens Specifications				
Lens	Field of View	Image Magnification	Working Distance	Lens Diameter
Wide Angle	102° / 120°	0.43x	3 mm	19 mm
Small Diameter	95° / 112°	0.42x	3 mm	13 mm
Mid Field	80° / 95°	0.74x	4 mm	19 mm









2 Intended Use

The Volk SOLR is intended for use in diagnosis and therapy of intraocular abnormalities while attached to a surgical microscope.

3 Indications for Use

To be used by a licensed physician for visualization of intraocular abnormalities in the general population, while attached to a surgical microscope.

4 Warnings, Markings, and Symbols

Symbol	Description
	ATTENTION: Refer to this manual. The user is advised of important operating and maintenance instructions.
	Read accompanying user documentation, indicates that important operating instructions are included in this manual. Failure to follow these instructions could place the patient or operator at risk.
	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.
	The symbol is accompanied by the name and address of the manufacturer.
	Indicates the date when the medical device was manufactured.
	Authorized representative in the European Community accompanied by the name and the contact information of the authorized representative.
	Indicates that the item is a medical device.
	The device has been tested and conforms to the provisions noted within the EU Medical Devices Regulation 2017/745.

Components of this system which are sterilizable are shipped in a non-sterile condition. Clean and sterilize before using in any surgical procedure.

Service or repair is to be performed by qualified, authorized personnel. Return to Volk for servicing. Do not attempt to repair this Assembly.

Disassembly of this unit beyond the instructions in this manual will void the warranty.

5 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.

The SOLR 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.

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 SOLR surgical system must be in proper working order; do not use if there is any damage or if the system is in need of repair.

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.

Do not operate the SOLR surgical system outside of the stated environmental operating conditions.

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Do not dispose of the product as unsorted municipal waste. When disposing of this product, please follow the procedure which conforms to the laws and regulations applicable to your area.

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

The SOLR surgical system must be used only with the original accessories and parts supplied or specified by Volk Optical otherwise the warranty is void.

ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO THE DEVICE SHOULD BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED

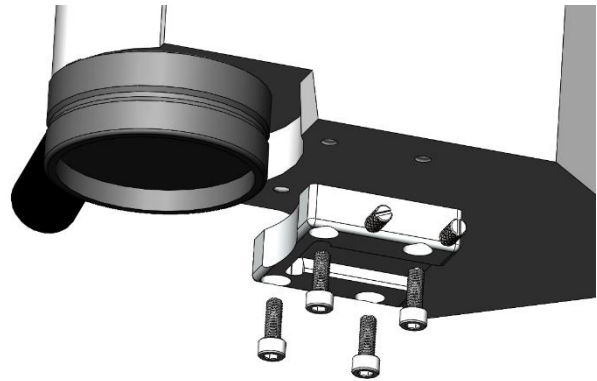
5.1 Environmental Conditions

Operating Conditions	Storage and Transport Conditions
Temperature: 10°C to 40°C	Temperature: -40°C to 65°C
Relative Humidity: 30% to 75% (non-condensing)	Relative Humidity: 10% to 90%
Atmospheric Pressure: 70kPa to 101kPa	Atmospheric Pressure: 70kPa to 101kPa

6 Mounting Kit Installation

Find the accessory attachment points on the bottom of your microscope. Align the supplied mounting plate with the attachment points. The open end of the mounting plate will face away from the microscope's objective lens. Using a hex screwdriver and the supplied screws, tighten the mounting screws to hold the mounting plate flush to the bottom surface of the microscope.

Note: The number and placement of these mounting screws will vary by microscope model.



7 System Assembly & Disassembly

NOTE: The system must be cleaned and sterilized before being used in any surgical procedure. See cleaning and sterilization instructions.

Follow the steps below to assemble and install the system. Perform the steps in reverse to disassemble and uninstall the system.

- (1) Install the Condensing Lens into the Lens Arm. Align the tabs on the side of the lens with the notches on the top of the lens arm. Place the condensing lens into the support ring and turn clockwise until you feel the lens snap into place.



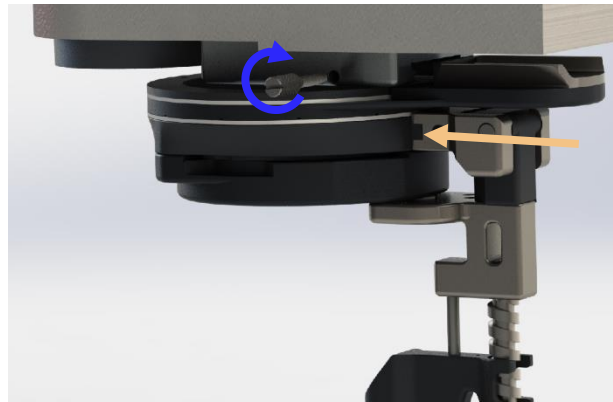
- (2) Attach the Lens Arm to the Rotation Base. Align the post and tab features on the side of the Rotation Base with the associated features on the top of the Lens Arm. Press the two subassemblies together until you feel them snap into place. Give a small outward tug to verify they are fully attached.



- (3) Install the surgical lens. Align the flat tab on the end of the surgical lens with the thin slot at the base of the Lens Arm. Press the lens into the slot until it clicks into place. Give a small outward tug to verify they are fully attached.

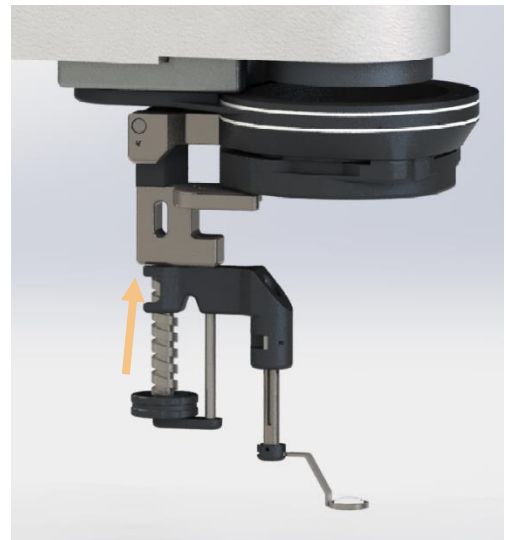


- (4) Attach the device into the mounting plate. Take care not to touch the non-sterile mounting kit or microscope. Slide the dovetail feature on the top of the Lens Positioning Assembly into the mating feature on the mounting plate. Press it in until it touches the position stop. Now tighten the thumbscrew by turning clockwise to lock the Lens Positioning Assembly in place. Give the assembly a small tug to verify proper attachment.

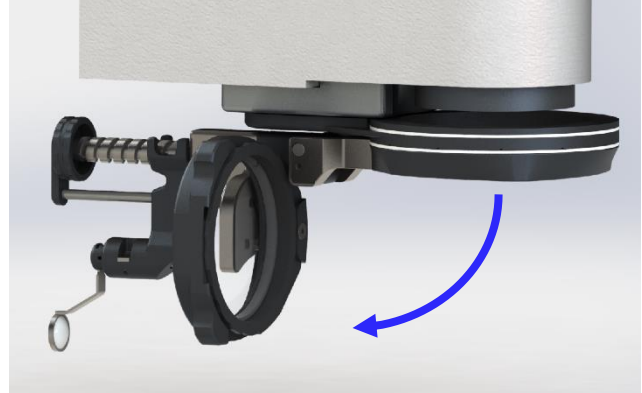


8 Obtaining a Focused Image

- (1) Install device as outlined above. Ensure the focus adjustment on the device is at its top-most position.

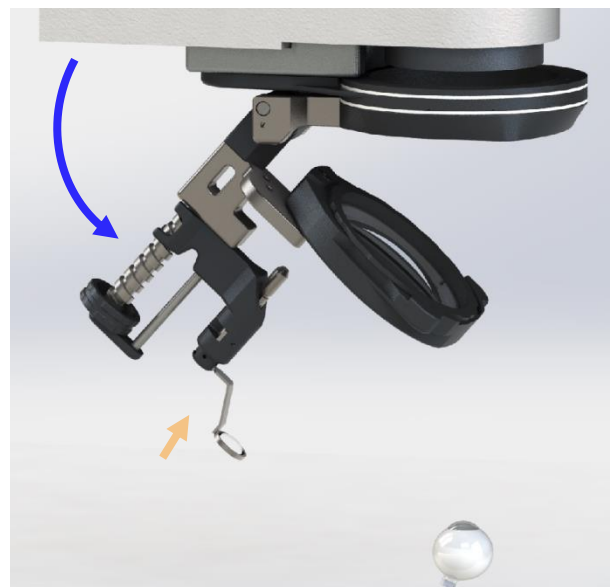


- (2) Swing the device out of the optical pathway and into the parked position.

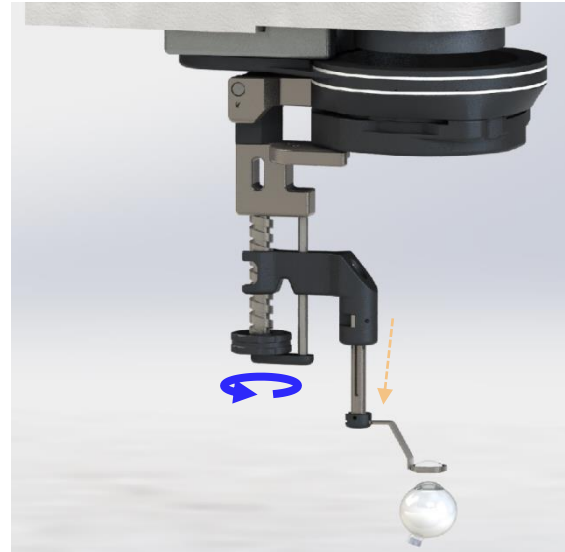


- (3) Turn on microscope illumination. Using the microscope, adjust focus and zoom to obtain desired view of the surgical field.

- (4) Turn off the microscope illumination. While holding the collapsible safety rod depressed, swing the device into its working position. Release the shaft, allowing the surgical lens to drop into place.



- (5) Use intraocular illumination. By rotating the focus adjustment knob the retina image will come into focus. Be aware of the placement of the surgical lens relative to the patient. Be sure not to adjust the lens into contact with the patient.



9 Cleaning and Sterilization Instructions

- (1) Disassemble instrument prior to cleaning and sterilization (see step 3 of Manual Cleaning Instructions)
- (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 have minimal effect on the system when processed according to instructions. End of life is normally determined by wear and damage due to use.

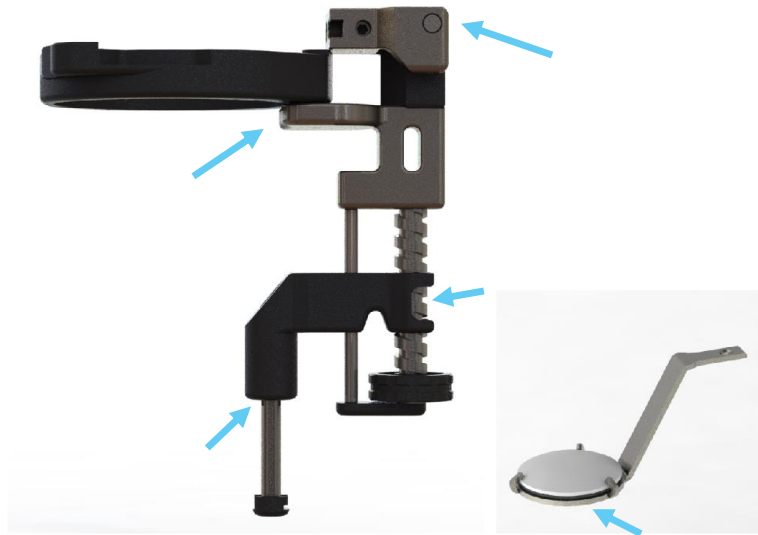
Preparation at the Point of Use

- (1) New, used, or contaminated units must be cleaned.
- (2) Body fluids and/or tissue should not be allowed to dry on the unit 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 the drying of any body fluids and tissue. When possible, place the instruments in water or cover with a damp cloth.

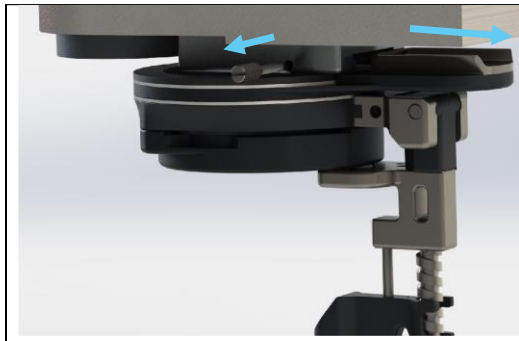
Preparation of cleaning agent: Prepare a neutral pH enzymatic detergent (ENZOL®) according to manufacturer's recommendations: (enzymatic detergent - 1 ounce per gallon) using warm (30-43°C), sterile, de-ionized water.

MANUAL CLEANING INSTRUCTIONS FOR ROTATIONAL BASE, LENS ARM, CONDENSING LENS, SURGICAL LENS, AND MOUNTING SCREW

- (1) Use a lint free tissue dampened with an antibacterial, aldehyde-free solution to remove macroscopic visible deposits from each instrument. 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,
 - b) The collapsible safety rod
 - c) The focus adjustment gear
 - d) The hinge mechanism of the Lens Arm.
 - e) The condensing lens pivot



- (2) Prepare fresh Enzol solution (enzymatic cleaner - 1 ounce per gallon) using warm (30-43°C), sterile, de-ionized water.
- (3) Disassemble device (Lens Arm should be removed from the Rotational Base, Condensing Lens and Surgical Lens both removed from the Lens Arm).



Unscrew the Mounting Screw. Now the system can be slid out the back of the microscope mounting plate.



Detach the Lens Arm from the Rotational Base by pulling the units apart.



Remove the Condensing Lens by a short counter-clockwise turn, and pulling it upward.



Remove the Surgical Lens by pulling it out the front of the Lens Arm.

- (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 components 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,
 - b) The collapsible safety rod
 - c) The focus adjustment gear
 - d) The hinge mechanism of the Lens Arm
 - e) The condensing lens pivot

NOTE: Do not brush glass lens to avoid damage but do brush the lens stem and lens mounting ring.

- (6) After brushing thoroughly rinse* components 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 unit. Repeat rinsing cycle 5 times, changing water between cycles.

- (7) Transfer the components to a freshly prepared Enzol solution (enzymatic cleaner - 1 ounce per gallon, using warm (30-43°C), sterile, de-ionized water.) and sonicate for 20 minutes.
- (8) After sonication, thoroughly rinse* components 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 unit. Repeat rinsing cycle 5 times, changing water between cycles.
- (9) Inspect each component 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:

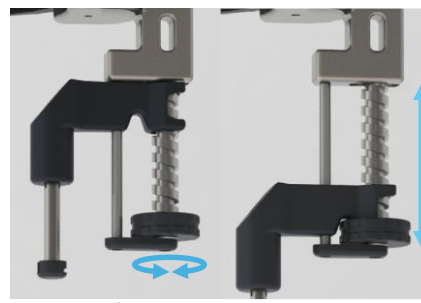
- Agitating the component under water;
- Bringing the component above the water level;
- Re-immersing component under water.

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. Motions/joints to be sure to inspect:
 - a) Articulation of the primary hinge on the Lens Arm
 - b) Smooth action of the focus adjustment wheel
 - c) Free movement of the collapsible safety rod



a) Unit should swing open and closed without resistance



b) Turn focus wheel to ensure adjuster has smooth action across full range of motion



c) Check the free movement of the safety rod by sliding it up and down. When action is free the control marks will be visible

If damage or wear is apparent, contact Volk Optical or your distributor.

If a component does not pass the functional test, discontinue use.

Packaging for Sterilization

(1) Make sure the Rotational Base, Lens Arm, Condensing Lens, Surgical Lens, and Mounting Screw are disassembled.

(2) Place lenses in standard medical grade steam sterilization pouch for sterilization in the autoclave.

Avoid damage to the lens surfaces. Always place the optical components on a soft surface when not mounted to the system.

To minimize water stains on the optics, the Condensing Lens and Surgical Lenses should be kept in a vertical position (or alternately, concave-down position) during sterilization.

STERILIZATION INSTRUCTIONS FOR ROTATIONAL BASE, LENS ARM, CONDENSING LENS, SURGICAL LENS, and MOUNTING SCREW

Steam sterilize using a pre-vacuum cycle for 3 minutes at a minimum temperature of 132°C with 20 minutes dry time.

10 Warranty Terms

Volk provides a limited warranty against manufacturing defects for the SOLR for a period of one (1) year from the date of delivery of the SOLR to the customer. The obligation of Volk and the customer's sole exclusive remedy hereunder, shall be limited, at Volk's option, to replacement or repair of the defective SOLR unit. The customer must not return goods unless authorized in writing by Volk. Volk shall have the right to inspect the goods at the customer's installation. The customer's failure to give prompt written notice (30 days) upon discovery of any alleged defect shall constitute acceptance of the SOLR as delivered, and a waiver by customer of all claims with respect thereto.

Notwithstanding the foregoing warranties and remedies, Volk shall have no obligation hereunder if the SOLR becomes defective as a result of the customer's disassembly or modification of the goods, unauthorized service or repair, misuse or abuse of the SOLR hardware or software, or combination with unauthorized software, hardware, or systems, or improper storage, accidents, contamination, adulteration, improper configuration, improper use or misapplication after delivery thereof to the customer, or customer's failure to use the SOLR consistent with the Instructions for Use and any other documentation provided, including but not limited to failure to follow the recommended cleaning instructions and/or warnings contained in the Instructions for Use or customer's breach of any Volk Terms and Conditions of Sale or SOLR Terms and Conditions which can be found on www.volk.com.

The customer shall be responsible for returning products for warranty service to Volk Optical, 7893 Enterprise Drive, Mentor, Ohio 44060 - USA. In the event the SOLR is not eligible for warranty service, the customer is solely responsible for all costs of shipping and handling.

Warranty repairs will include all labor, adjustments, and replacement parts. Replacement parts may be re-manufactured or contain remanufactured materials. The warranty service will not be provided without proof the product was purchased directly from Volk Optical, an authorized Volk distributor, or a Volk-authorized e-commerce platform. In the event of a product recall during the warranty period, the SOLR will be replaced at no cost to the customer. Any repair for issues not covered by the above warranty may be conducted at the sole discretion of Volk at a cost to be determined by Volk.

VOLK MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, REGARDING THE HARDWARE OR SOFTWARE, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE, AND ALL SUCH WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED.

11 Support and Servicing

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

For servicing and repairs, contact the Authorized Volk Optical Distributor from whom you purchased the device or contact us at rma.support@volk.com or the numbers listed at the end of this section.

If you have any questions about how to set up, use or troubleshoot your device, or to request Instructions for Use in paper form at no additional cost, please contact our Customer Care Team at volk@volk.com or the numbers listed at the end of this section.

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