

DISCLAIMER

1. *Reprocessing of Volk Optical product that contacts a patient should follow a two-step process in all situations. The device should be (1) thoroughly cleaned then (2) either disinfected OR sterilized.*
2. *Volk Optical product designated as “non-contact” is recommended to be cleaned thoroughly at a frequency determined by the discretion of the practitioner. Non-contact product does not require disinfection or sterilization; however, periodic disinfection is recommended.*
3. *Volk Optical offers common industry-established product reprocessing guidelines, but has not validated every possible reprocessing technique, or every set of possible reprocessing parameters. Always follow the reprocessing procedures listed in Volk’s Instructions for Use, of your hospital, or your facility, and contact Volk regarding product compatibility with alternative reprocessing methods, or emerging technologies, where applicable.*

CLEANING

1. Cleaning should be performed regularly to remove bodily fluids, dust, and soils from the surface of the product.
2. Select the appropriate method of cleaning from the CLEANING METHODS TABLE listed below.
3. If a product is to be sterilized prior to its re-use, Volk recommends that it first be cleaned using cleaning Method C.

CLEANING METHODS TABLE

Method A:	Clean with a mild, pH neutral detergent and a clean soft cotton cloth or swab. Do not use detergent with any type of Emollients.
Method B:	<p>Clean the glass element with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®. Clean lens surface in a clockwise direction to help prevent loosening of the insert in the ring.</p> <p>CAUTION: Do not use the Volk LensPen® or Volk’s POLC on surfaces that contact the eye.</p>
Method C:	<ol style="list-style-type: none">1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30-43°C) tap water.2. Soak each device in solution for 20 minutes.3. After soaking, brush knurled surface of housing with a soft-bristle brush and wipe lens portion with a soft cloth until all traces of cleaner and soil are removed. Pay special attention to all crevices and other hard-to-reach areas. Note: Do not brush lens portion to avoid scratching; use soft cloth.4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.5. Transfer the devices to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.6. After sonication, thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.7. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.

PRECAUTIONS:

- Whenever possible dry Volk lenses with an ultra-soft, low-lint, cotton cloth such as a cloth diaper.
- Cleaning Method C is the preferred method for cleaning Volk’s 2-piece autoclavable (ACS) vitrectomy lenses (e.g. Mini Quad ACS, Central Retinal ACS, etc.). However, the sonication step of Cleaning Method C may cause lens damage, which limits the useful life of these lenses. Use of an alternate validated cleaning method that does not include automated sonication is highly recommended by Volk Optical whenever practicable for these lenses.

DISINFECTION

1. Clean lens & surgical products first by following Cleaning Method A (See CLEANING METHODS TABLE)
2. Disinfect by selecting one of the solution types from the Table below:

Product Type ✓ = OK to Use	*Cidex OPA	*Glutaraldehyde	**Bleach Solutions (Sodium Hypochlorite)	*Revital-Ox™ Resert XL® HLD	Perasafe	Bode Mikorbac Tissues	Alkacide / Alkazyme	CaviWipes
BIO Lenses (Black & All Colors)	✓	✓	✓		✓	✓		✓
BIO Lenses (ACS)	✓	✓	✓		✓	✓		✓
Classic Series Lenses (Black & All Colors)	✓	✓	✓		✓	✓		✓
Super & Digital Series Lenses (Black & All Colors)	✓	✓	✓		✓	✓		✓
Mirrored Lenses (3-Mirror Lenses, Mini 4-Mirror Lens, & SLT)	✓	✓	✓	✓		✓	✓	✓
G-Series Gonio Lenses	✓	✓	✓	✓		✓		✓
Contact Lenses	✓	✓	✓			✓		✓
Research Lenses	✓	✓				✓		✓
Vitrectomy Lenses (Standard)	✓	✓	✓			✓		✓
Vitrectomy Lenses (ACS)	✓	✓	✓			✓		✓
Vitrectomy Handles, Infusion Handles, & Suture Rings	✓	✓	✓			✓		✓
Sterilization Case	✓	✓	✓			✓		✓
Lens Accessories	✓	✓	✓			✓		✓

* When using immersion solutions such as: CIDEX OPA, GLUTARALDEHYDE, & REVITAL-OX™ RESERT® XL HLD refer to Manufacturer's Instructions.

- Position the lens on its side, and then immerse the entire lens in the selected solution for the listed soak time.
- Remove the lens from the solution, thoroughly rinse with room temperature water, and dry with a soft lint free cotton cloth.

** When using BLEACH SOLUTIONS (NaClO, Sodium Hypochlorite; household bleach), prepare the following solution:

Solution Type	Example Dilution	Minimum Soak Time	Maximum Soak Time
0.525% (5000ppm) 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)	10 Minutes	26 Minutes

PRECAUTIONS:

- To avoid surface damage to contact lenses, never clean the contact elements with alcohol, peroxide or acetone.
- Do not use the Volk LensPen® or Volk's POLC on surfaces that contact the eye.
- Colored rings may discolor when exposed to higher concentrations of Sodium Hypochlorite or Glutaraldehyde, or for longer periods of time. To avoid discoloration please follow only the disinfection procedures indicated for these products.
- Extended exposure to recommended concentrations, and/or exposure to higher concentrations of Sodium Hypochlorite will result in accelerated degradation of most Volk product. Avoid extended exposure to bleach solutions.
- Contact Volk regarding product compatibility with other disinfection methods.

DISINFECTION CONT.

<u>Pictor & Pictor Plus Digital Imaging Device</u>	
Camera Handset Retina Module Anterior Module FA Module Otoscope Module Cradle	<ul style="list-style-type: none">Disinfect housing with soft cloth moistened with alcohol (e.g. 70% ethyl alcohol). NOTE: Avoid touching system connectors in the handset and cradle.
Dermatoscope Module & Glass	<ul style="list-style-type: none">Disinfect glass with soft cloth moistened with alcohol (70% ethyl alcohol), orRemove glass and soak it in glutaraldehyde-based solution, or hydrogen peroxide & peracetic acid solution.
Silicone Eyecup	CAUTION: The Silicone Eyecup should be disinfected before each use on a new patient. <ul style="list-style-type: none">Disinfect Silicone Eyecup with a soft cloth moistened with alcohol (70% ethyl alcohol), orSoak silicone support in glutaraldehyde-based solution.

PRECAUTIONS:

- Shut down device before cleaning.
- Remove the Cradle from MAINS power before cleaning.
- Pictor is not intended to be sterilized.

• STERILIZATION

- Cleaning should always be performed prior to sterilization. Volk recommends that most products first be processed using cleaning Method C^{††}. See CLEANING METHODS TABLE and observe stated PRECAUTIONS.
- Sterilize by selecting one of the methods from the Table below:

Product Type	✓ = OK to Use	ETO	Steam	†Sterrad®	Amsco® V-Pro®	TSO ₃
Classic BIO Lenses (Black)		✓		✓		✓
Classic BIO Lenses (Colors) & BIO Digital Series Lenses (Colors)		✓		✓		
Classic BIO Lenses (ACS)		✓	✓	✓		✓
Classic Slit Lamp Lenses (Black)		✓		✓		✓
Classic Slit Lamp Lenses (Colors)		✓		✓		
Super Series & Digital Series Slit Lamp Lenses (Black)		✓		✓		✓
Super Series & Digital Series Slit Lamp Lenses (Colors)		✓		✓		
Mirrored Lenses (3-Mirror Lenses, Mini 4-Mirror Lens, & SLT)		✓			✓	
G-Series Gonio Lenses					✓	
Surgical Gonio (ACS)		✓	✓			
Volk Transcend TVG			✓			
Contact Lenses		✓				✓
Research Lenses		✓				
Vitrectomy Contact Lenses		✓				✓
Vitrectomy Lenses (ACS) ^{††}		✓	✓		✓	✓
Vitrectomy Handles & Suture Rings		✓	✓	✓		✓
Infusion Handles		✓	✓			✓
ROLS® Handles & ROLS®∞ Handles			✓			
OptiFlex® Lens Positioning Unit (LPU) & OptiFlex® Surgical Lenses			✓			
MERLIN® Rotational Assembly (RA), MERLIN® Lens Positioning Unit (LPU), MERLIN® Surgical Lenses, & Sterilization Tray			✓			
Lens Accessories		✓				✓
Sterilization Cases		✓	✓		✓	✓

NOTE: The use of a Volk Sterilization Case or Tray is recommended to avoid product loss or damage.

Ethylene Oxide: Follow hospital procedures with aeration up to, but not exceeding 150°F / 66°C for non-contact lenses or 130°F / 55°C for contact lenses.

Steam Sterilization: **US** - Pre-vacuum, wrapped, 132°C minimum, 4 minutes (lenses), dry time 20 min
 Note - MERLIN® components require 5 minutes cycle time

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

Amsco® V-Pro®: Applicable sterilization systems: V-Pro® 1 Low Temp, V-Pro® 1 Plus Low Temp, V-Pro® maX Low Temp. 28 minute non-lumen cycle, 12 minute sterilant exposure, 2.1g sterilant injection per pulse (~59% H₂O₂), 0.4 -1.0 Torr pre-injection pressure, and a 50°C chamber temperature.

†Sterrad®: Use in the 100S Short Cycle or use in 100NX Express (available outside the US only).
 Caution: Rings may discolor after multiple reprocessing cycles.

PRECAUTIONS:

- To avoid lens surface damage, never clean a lens' contact element with alcohol, peroxide, or acetone.
- Do not use the Volk Lens Pen® or Volk's POLC on surfaces that contact the eye.
- Disassemble 2-piece vitrectomy lenses (e.g. Mini Quad ACS, Central Retinal ACS, etc.) prior to cleaning and sterilization.
- ^{††} Cleaning Method C is the preferred method for cleaning Volk's 2-piece autoclavable (ACS) vitrectomy lenses (e.g. Mini Quad ACS, Central Retinal ACS, etc.). However, the sonication step of Cleaning Method C may cause lens damage, which limits the useful life of these lenses. Use of an alternate validated cleaning method that does not include automated sonication is highly recommended by Volk Optical whenever practicable for these lenses.
- Contact Volk regarding product compatibility with other sterilization methods.

PRODUCT REFERENCE GUIDE FOR VOLK LENSES & FAMILIES

BIO Lenses	
Macula Plus 5.5	VMP5.5
14D Large Clear	V14LC
15D Large Clear	V15LC
20D Large Clear*	V20LC
Pan Retinal 2.2 Clear*	VPRC
25D Large Clear	V25LC
28D Large Clear*	V28LC
30D Large Clear	V30LC
30D Small Clear	V30SC
40D Large Clear	V40LC
BIO Lenses (Autoclavable)	
20D Clear ACS PermaView	V20LCACSPV
28D Clear ACS PermaView	V28LCACSPV
BIO Lenses (Digital Series)	
Digital Clear Mag	VDGTLCM
Digital Clear Field*	VDGTLCF
Slit Lamp Lenses (Classic Series)	
60D Clear	V60C
78D Clear*	V78C
90D Clear*	V90C
Slit Lamp Lenses (Super and Digital Series)	
Super 66*	VS66
SuperField NC*	VSFNC
Super VitreoFundus	VSVF
SuperPupil XL	VSPXL
Digital High Mag*	VDGTLHM
Digital 1.0X Imaging	VDGTL1
Digital Wide Field*	VDGTLWF
*NOTE: Colors inclue Blue, Gold, Green, Purple, Red, Silver and Pin	
Mirrored Lenses	
Three-Mirror Laser Lens - NF	V3MIR
Three-Mirror Laser Lens ANF+	V3MIRANF+
Three-Mirror (Uncoated) - NF	VU3MIR
Three-Mirror (Uncoated) ANF+	VU3MIRANF+
One Mirror SLT Gonio Lens	VSLT
Mini Four Mirror Gonio Lens ANF+	V4MANF+
G-Series / Gonio Lenses	
One-Mirror Glass Trabeculum Lens Flange	VG1
One-Mirror Glass Trabeculum Lens No Flange No Fluid	VG1NF
Two-Mirror Glass Trabeculum Lens Flange	VG2
Two-Mirror Trabeculum Lens No Flange No Fluid	VG2NF
Three-Mirror Glass Gonio Fundus Lens Flange	VG3
Three-Mirror Glass Gonio Fundus Lens No Flange	VG3NF
Three-Mirror Glass Gonio Fundus Lens Mini No Flange	VG3MININF
Four-Mirror Glass Gonio Lens Flange Fluid	VG4
Four-Mirror Glass Gonio Lens (Large Ring) No Flange	VG4LNF
Four-Mirror Glass Gonio (Small Ring) No Flange	VG4SNF
Four-Mirror Glass 2 in 1 Handle Gonio No Flange	VG4HAN2
Four-Mirror Glass High Mag Gonio Flange	VG4HM
Four-Mirror Glass High Mag Gonio (Large Ring) No Flange	VG4HMLNF
Four-Mirror Glass High Mag Gonio (Small Ring) No Flange	VG4HMSNF
Four-Mirror Glass High Mag 2 in 1 Handle Gonio No Flange	VG4HMHAN2
Six-Mirror Glass Hand Held Gonio (Large Ring) No Flange	VG6LNF
Six-Mirror Glass 2 in 1 handle Gonio No Flange	VG6HAN2
Surgical Gonio	
Volk Surgical Gonio Lens	VSGACS
Volk Transcend TVG	VTSTVG
Lens Accessories	
Steady Mount 60/78/90/SFNC	VSM60/78/90/SFNC
SM Clip Set	VSMCLIPSET
60D Clip	VCLIP60
78D Clip	VCLIP78
90D Clip	VCLIP90
SFNC Clip	VCLIPSFNC
Sterilization Cases	
Sterilization Case Small	VSCA
Sterilization Case Large	VSCB

Contact Lenses	
SuperMacula 2.2	VSMAC2.2
HR Centralis	VHRC
Area Centralis	VAC
Area Centralis ANF+	VACANF+
Area Centralis NF	VACNF
TransEquator	VTE
TransEquator ANF+	VTEANF+
TransEquator NF	VTENF
QuadrAspheric	VQFL
QuadrAspheric ANF+	VQFLANF+
QuadrAspheric NF	VQFLNF
SuperQuad 160	VSQUAD160
SuperQuad 160 NF	VSQUAD160NF
High Resolution Wide Field	VHRWF
PDT Lens	VPDT
EquatorPlus ANF+	VEPANF+
EquatorPlus NF	VEPNF
QuadPediatric	VQPED
Centralis Direct	VCD
Centralis Direct ANF+	VCDANF+
Iridectomy	VIRID
Blumenthal Iridotomy	VBIRID
MagPlus Iridectomy	VMPIRID
Capsulotomy	VCAPS
Fundus	VFUNDUS
Fundus 20MM	VFUNDUS20
Blumenthal Suturelysis	VBSL
Research Lenses	
2mm Fundus Lens	V2MFUNDUS
2 mm Gonio Lens	V2MGONIO
Vitrectomy Lenses (Standard)	
HRX Vit	VHRXVIT
HRX Vit SSV	VHRXVITSSV
MiniQuad	VMQVIT
MiniQuad SSV	VMQVITSSV
MiniQuad XL	VMQXLVIT
MiniQuad XL SSV	VMQXLVITSSV
Central Retinal	VCRLVIT
Central Retinal SSV	VCRLVITSSV
SuperMacula	VSMACVIT
DynaView 156	VDVVIT
Vitrectomy Lenses (Autoclavable)	
HRX ACS Vit	VHRXVITACS
HRX ACS SSV Vit	VHRXVITSSVACS
MiniQuad ACS Vit	VMQVITACS
MiniQuad ACS SSV Vit	VMQVITSSVACS
Central Retinal ACS Vit	VCRLVITACS
Central Retinal ACS SSV Vit	VCRLVITSSVACS
High Resolution Direct 1X	VHRD1XACS
High Resolution Direct 1X (NSR)	VHRD1XNSRACS
High Resolution Direct High Mag	VHRDHMACS
High Resolution Direct High Mag (NSR)	VHRDHMNSRACS
High Resolution Direct Bi-Concave	VHRDBCACS
High Resolution Direct 20 Prism	VHRD20PACS
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
Vitrectomy Handles, Infusion Handles, & Suture Rings	
Vitreo Lens Handle (Fits MQ and CRL Vit)	VVITHAN-LG
MiniQuad XL Vit Handle (Fits MQXL and SMAC Vit)	VVITHAN-MQXL
Infusion Handle (Fits non-SSV Vit and ClariVit Lenses)	VINFHAN
Suture Ring	VSR52