FIELD SAFETY NOTICE – IMPORTANT DEVICE INFORMATION

Date: February 7, 2020

Affected Devices: Volk Gonioscopy Lenses (Product Codes - V3MIR, V3MIRANF+, VU3MIR, VU3MIRANF+, VG1, VG1NF, VG2, VG2NF, VG3, VG3NF, VG3MININF, VG4, VG4LNF, VG4SNF, VG4HAN2, VG4HM, VG4HMLNF, VG4HMSNF, VG4HMHAN2, VG6LNF, VG6HAN2, V4MANF+, VSLT, VMSLT)

Dear Customer:

This document is intended to provide important information for continued proper and safe usage of Volk's gonioscopy lenses. Please review the following information with all users who need to be aware of the contents of this communication. Please also retain this copy with the device IFU (Instructions for Use).

Volk Optical is implementing additional instructions for its gonioscopy lenses to reduce any hazards associated with use of lenses that exhibit any damage to the mirrored surfaces of the lenses. The affected product codes are listed in the beginning of this document and the affected devices can be identified by the product descriptions (as listed in the IFU) engraved on the body of the device. No other Volk product is involved in this Field Safety Notice.

Volk has recently received a report in which the mirroring surface of a 3-mirror lens being used for Argon Laser Trabeculoplasty (ALT) exhibited damage consistent with laser burns. If laser procedures are attempted using a lens that has damage to its mirror surfaces, the mirror surface may not fully deflect the laser beam and instead may absorb the laser energy causing further damage in the form of laser burns. As a damaged mirror surface may not allow effective laser deflection into the patient's eye, the laser energy applied to the trabecular meshwork may be too low to achieve the desired clinical effect. This would therefore render the device unusable, leading to treatment delay. Although damage to mirror surfaces may be readily apparent and visible to the naked eye, the existing lFU (Instructions for Use) for these lenses does not include specific instructions to inspect the lens for any damage on the mirrored surface(s) before use. It furthermore does not instruct to stop usage upon indication of any such damage. Therefore, Volk is issuing an updated IFU that includes these specific instructions for users to inspect the mirrored surface(s) of the lens before each use, and to caution the user against using a lens with damaged mirrored surface(s). The updated IFU is included with this letter.

Upon receipt of this notification, please follow the instructions below. This notice has been reported to the appropriate Regulatory Agency (BfArM).

FIELD SAFETY NOTICE – IMPORTANT DEVICE INFORMATION

INSTRUCTIONS TO THE CUSTOMER/USER:

1. Please carefully read this notice and the attached updated IFU (Instructions for Use). Please also review this information with ALL users that participate in the device usage.
2. Please complete the attached Acknowledgement form even if you do not have any affected product.
3. When completed, please return the Acknowledgement to Volk Optical Inc.
4. Please pass on this notice to any healthcare professionals from your organization that need to be aware and to any organizations where the above listed devices have been utilized (if appropriate).

Appendix:

A – Updated Instructions for Use (IM-037 Rev. G)

Volk sincerely regrets any inconvenience that this notice may cause you. Your satisfaction with Volk's products and with our response to this issue is very important to us. Please contact your local Volk representative or Volk's Customer Care Service at +1 440-942-6161 with questions or concerns about this notice or any affected device.

Yours Sincerely,

Snigdha Katragadda
Director, Quality & Compliance

Volk Optical Inc.

7893 Enterprise Drive

Mentor, OH 44060 USA

Volk Optical Inc
7893 Enterprise Drive
Mentor, OH 44060 USA
Tel: 440-942-6161
Fax: 440-942-2257
Email: volk@volk.com

EC REP **EU Representative:**
Rudolf Riester GmbH
Bruckstraße 31
72417 Jungingen, Germany
Email: info@riester.de
Phone: +49 74 77 / 92 70-0
Fax: +49 74 77 / 92 70-70

Volk Optical Gonioscopy Lenses (Gonio)

ENGLISH: INSTRUCTIONS FOR USE

INTENDED USE

Volk Optical's Gonioscopy Lenses are indicated for use as diagnostic contact lenses for eye examinations (including the anterior chamber, trabecular meshwork, central retina, and peripheral retina) and use in the therapy of intraocular abnormalities.

SPECIFICATIONS

Product	Magnification	Number of Mirrors	Laser Spot Magnification Factor	Available Contact Designs	Anti-Reflective Laser Coating
G-1 Trabeculum (VG1)	1.50	1	0.67	Standard Fluid	BBAR
G-1 Trabeculum NF (VG1NF)	1.50	1	0.67	NF - No Flange (no fluid)	BBAR
G-2 Trabeculum (VG2)	1.50	2	0.67	Standard Fluid	BBAR
G-2 Trabeculum NF (VG2NF)	1.50	2	0.67	NF - No Flange (no fluid)	BBAR
G-3 Goniofundus (VG3)	1.06	3	0.94	Standard Fluid	BBAR
G-3 Goniofundus Mini NF (VG3MININF)	1.00	3	1.00	NF - No Flange (no fluid)	BBAR
G-3 Goniofundus NF (VG3NF)	1.03	3	0.97	NF - No Flange (no fluid)	BBAR
G-4 Goniolaser (VG4)	1.00	4	1.00	Standard Fluid	BBAR
G-4 Gonio NF Large Ring (VG4LNF) G-4 Gonio NF Small Ring (VG4SNF) G-4 Gonio NF Handle (VG4HAN2) (with ring or handle)	1.00	4	1.00	NF - No Flange (no fluid)	Uncoated
G-4 High Mag Goniolaser (VG4HM)	1.50	4	0.67	Standard Fluid	BBAR
G-4 High Mag Gonio NF Large Ring (VG4HMLNF) G-4 High Mag Gonio NF Small Ring (VG4HMSNF) G-4 High Mag Gonio Handle (VG4HMHAN2) (with ring or handle)	1.50	4	0.67	NF - No Flange (no fluid)	Uncoated
G-6 Gonio NF (VG6LNF) G-6 Gonio NF Handle (VG6HAN2) (with ring or handle)	1.00	6	1.00	NF - No Flange (no fluid)	Uncoated
Classic 3-Mirror Goniofundus ANF+ (V3MIRANF+, VU3MIRANF+)	1.06	3	0.94	ANF+ - Advanced No Fluid (no flange)	Coated (BBAR) or Uncoated
Classic 3-Mirror Goniofundus (V3MIR, VU3MIR)	1.03	3	0.97	Standard Fluid (no flange)	Coated (BBAR) or Uncoated
4-Mirror Mini ANF+ (V4MANF+)	1.00	4	1.00	ANF+ - Advanced No Fluid (flanged)	BBAR
SLT (VSLT)	1.00	1	1.00	Standard Fluid (no flange)	Uncoated
Rapid SLT (VMSLT)	1.00	4	1.00	Standard Fluid	BBAR

INDICATIONS FOR USE

1. To be used by a trained, licensed physician in a method consistent with other gonioscopic contact lenses.
2. Device may be used in conjunction with a biomicroscope to achieve the desired image.
3. For laser treatment procedures, a Standard Fluid lens and coupling fluid are required. Refer to the Specifications table to determine which Gonio lenses are available in this format.
4. Standard Fluid contact Gonio lenses require methylcellulose or other similar interface solution be applied to the concave contact surface.
5. No Flange (NF) and Advanced No Fluid (ANF+) contact lenses can be used with a natural tears solution or methylcellulose applied to the concave contact surface if required.
6. When calculating the laser spot size at the retina or in the anterior segment, the laser spot setting should be multiplied by the appropriate *Laser Magnification Factor*. Refer to the Specifications table to find the appropriate *Laser Magnification Factor* for the lens you are using.
7. Inspect the contacting surface(s) before each use and after reprocessing to make sure they are free from any damage (e.g. chips, scratches, etc).
8. Inspect the mirroring surface(s) before each use to make sure the surfaces are free from any damage (e.g. laser burns etc.)

⚠ ***WARNINGS:***

1. DO NOT USE THE LENS WHEN THE CONTACTING SURFACE(S) SHOW(S) ANY SIGNS OF DAMAGE.
2. DO NOT USE THE LENS IF THE MIRRORING SURFACE(S) SHOW(S) ANY SIGNS OF DAMAGE BEFORE OR DURING LASER USAGE.
3. DO NOT ATTEMPT TO USE THE LENS IF, FOR ANY REASON, THE IMAGE IS UNCLEAR OR UNFOCUSED.
4. DO NOT ATTEMPT TO USE THE LENS UNLESS AN ADEQUATE TYPE AND AMOUNT OF COUPLING FLUID IS PRESENT BETWEEN THE CORNEA AND THE CONTACTING LENS SURFACE.
5. CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PRESSURE ON THE CORNEA AS IT MAY AFFECT AQUEOUS DYNAMICS OR CAUSE INJURY.

REPROCESSING

⚠ ***WARNINGS:***

1. A THOROUGH, MANUAL CLEANING PROCESS IS RECOMMENDED.
2. CORROSIVE CLEANING AGENTS (I.E. ACIDS, ALKALINES, ETC) ARE NOT RECOMMENDED. DETERGENT CLEANING AGENTS WITH NEUTRAL PH ARE RECOMMENDED.

PREPARATION AT THE POINT OF USE:

1. New or used, contaminated lenses must be cleaned.
2. Body fluids should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids.
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 fluids on their surfaces.
5. Devices should always be handled in an appropriate method to ensure contamination is not introduced to a recently cleaned, disinfected, and/or sterilized device.

REPROCESSING LIMITATIONS:

Repeated cleaning, disinfection, and sterilization have minimal effect on Volk Gonio Lenses when processed according to instructions. End of the product's life cycle is normally determined by wear and damage due to use.

PREPARATION BEFORE CLEANING:

The following cleaning, disinfection, and sterilization instructions are aided by not allowing contamination to dry on the lens surface. When possible place the lenses in water or cover them with a damp cloth.

Volk Optical Inc
7893 Enterprise Drive
Mentor, OH 44060 USA
Tel: 440-942-6161
Fax: 440-942-2257
Email: volk@volk.com

EC REP
EU Representative:
Rudolf Riester GmbH
Bruckstraße 31
72417 Jungingen, Germany
Email: info@riester.de
Phone: +49 74 77 / 92 70-0
Fax: +49 74 77 / 92 70-70

CLEANING, DISINFECTION, STERILIZATION

CLEANING:

Select the desired method of cleaning:

Method A:	Clean with a mild detergent and a clean soft cotton cloth or swab. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. Do not use detergents containing Emollients (moisturizers).
Method B:	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 retaining ring within the housing. ***CAUTION:*** Do not use Volk's POLC, or the Volk LensPen® on surfaces that contact the eye.
Method C:	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 on device ring with a soft-bristle brush and wipe lens portion with a soft cloth until all traces of cleaner and soil are removed. Clean lens surface in a clockwise direction. 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 device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes. 6. After sonication, thoroughly rinse device(s) 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.

⚠ ***CAUTION:***

TO AVOID LENS SURFACE DAMAGE NEVER CLEAN THE CLASSIC 3 MIRROR LENSES, MINI 4 MIRROR LENS, OR SLT LENS CONTACT ELEMENT WITH ALCOHOL, PEROXIDE, OR ACETONE. G-SERIES LENSES MAY BE CLEANED WITH THESE CHEMICALS.

DISINFECTION:

1. Follow the ***Method A*** or ***Method C*** cleaning instructions from above.
2. Select one of the solution types from the table below:

DISINFECTANT	*CONCENTRATION*	*MIN SOAK TIME*	*MAX SOAK TIME*
Glutaraldehyde	2% aqueous solution	25 minutes	N/A
CIDEX® OPA Solution	See Manufacturer's Instructions	12 minutes	N/A
Revital-Ox™ Resert® XL HLD	≥ 1.5% aqueous solution	8 minutes	16 minutes

3. Immerse device completely, and then immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C). Ensure to fill all lumens, hard-to-reach areas, and eliminate air pockets.
4. Rinse thoroughly in a room temperature water bath (minimum of 20°C). Rinse by immersing device completely for a minimum of one minute. Manually flush all lumens or other hard-to-reach areas with water. Agitate device under water, bring above water level, then re-immerse. Repeat rinse procedure two additional times using fresh water.
5. Dry with a soft, lint-free cotton cloth.

STERILIZATION:

1. Follow the ***Method C*** cleaning instructions.
2. Sterilize using the Amsco® V-Pro® 1 Low Temp Sterilization System, V-Pro® 1 Plus Low Temp Sterilization System, or V-Pro® maX Low Temp Sterilization System. Sterilize for a minimum of 28 minutes using a non-lumen cycle, with a 12 minute sterilant exposure and 2.1g sterilant injection per pulse (~59% H_2O_2) at 0.4 -1.0 Torr pre-injection pressure, and at 50°C chamber temperature.
3. Alternatively, the Classic 3-Mirror, 4-Mirror Mini, and SLT lenses may be sterilized using the ethylene oxide (ETO) sterilization process. Sterilize using a 2-hour cycle with a temperature of 130°F and a concentration of 600 mg/L, but not exceeding **150°F**.
4. Do not sterilize lenses within standard (black leatherette) lens cases as they are not meant for use in sterilization systems.

⚠ ***CAUTION:***

1. G-SERIES GONIO LENSES ARE **NOT** RECOMMENDED FOR ETO STERILIZATION DUE TO MIRROR DEGREDATION.
2. TO AVOID PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL VOLK GONIO LENSES.
3. TO AVOID PRODUCT DAMAGE, NEVER SUBJECT VOLK GONIO LENSES TO STERRAD STERILZIATION.

STORAGE:
Sterile instruments should be stored in an area that provides protection from loss of sterility.