IM-093 Rev. E Issue Date: 2025-06-13

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

CE 2797

Volk®1 Single Use Gonio Lenses

- **STERILE. STERILIZED WITH ETHYLENE OXIDE GAS.**
- **FOR SINGLE USE ONLY.**
- **DO NOT USE IF THE PACKAGE IS OPEN OR DAMAGED.**
- **FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

ENGLISH (EN): INSTRUCTIONS FOR USE

INDICATIONS FOR USE

The Volk®1 Single Use Gonio 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	Anti-Reflective Laser Coating
Volk®1 Single Use 4-Mirror Gonio (V4MIRD)	1.00	4	1.00	Uncoated
Volk®1 Single Use 3-Mirror Gonio (V3MIRD)	1.00	3	1.00	Uncoated
Volk®1 Single Use SLT (VSLTD)	1.00	1	1.00	Uncoated

⚠ WARNINGS

1. Do not immerse the device in a decontaminating product before use.
2. Inspect the device(s) to make sure it is free from any damage (e.g. chips, scratches, etc.). Do not use or repair if the device is damaged.
3. Inspect the contacting surface(s) to make sure it is free from any damage (e.g. chips, scratches, etc.). Do not use or repair if the device is damaged.
4. Inspect the mirroring surface(s) prior to use, to make sure it is free from any damage (e.g. chips, scratches, etc.). Do not use or repair if the device is damaged.
5. Please Note that the VSLTD lens is the only Volk disposable lens that has been approved to perform Selective Laser Trabeculoplasty (SLT) procedures.
6. 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.

⚠ PRECAUTIONS

1. Do not attempt to use the Volk®1 Single Use Gonio Lenses prior to completely reading and understanding these instructions for use.
2. To be used by a licensed physician in a method consistent with other direct image ophthalmic contact laser and diagnostic lenses.
3. The sterile packaging and lens should be inspected prior to use.
4. The Volk®1 Single Use Gonio Lenses are intended for single patient use only.
5. Do not resterilize and reuse.
6. This device is packaged and sterilized for single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

EXPIRATION DATE

Use the device prior to the Expiration Date on the package label.

SUGGESTED DIRECTIONS FOR USE

1. Remove the lens from its package and place it in a sterile work area.
2. Standard Fluid contact lenses require methylcellulose or other similar viscous interface solution be applied to the concave contact surface (i.e., between the cornea and the device).
3. When calculating the spot size at the treatment site, 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 that is being used.
4. When performing laser procedures, only direct the laser to areas of the mirroring surface that are free from damage. Do not apply if the intended target cannot be visualized through the lens.

STORAGE

Devices should be stored at room temperature. Sterile instruments should be stored in an area that provides protection from loss of sterility.

DEVICE DISPOSAL

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

VOLK®

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CE 2797

STERILE EO
Sterilized using ethylene oxide

Do not re-use

Consult the Instructions for Use for important cautionary information

Do not use if package is damaged or open

Expiration Date

LOT
Lot number

REF
Reference number

Manufacturer

EC REP
Authorized representative in the European Community

MD
Medical Device