

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 € 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: 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

- Do not immerse the device in a decontaminating product before use
- 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.



PRECAUTIONS

- 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
- 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 6 infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

"USE BY" DATE

Use the device prior to the "Use By" date on the package label.

SUGGESTED DIRECTIONS FOR USE

- 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.

STERILEEO

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



Use-hy date



Lot number



Reference number



REP



Manufacturer



Authorized representative in the European Community

Toll Free: 800-345-8655 (USA) Telephone: 440-942-6161 Fax: 440-942-2257 Email: volk@volk.com