



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 Riestler 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®1 Single Use Binocular Indirect Ophthalmoscope (BIO) 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 Binocular Indirect Ophthalmoscope (BIO) Lenses are indicated for visualization and laser therapy of the human retina (fundus) using a binocular indirect ophthalmoscope.

SPECIFICATIONS

Product	Product Code	Magnification	Field of View	Laser Spot Magnification Factor	Working Distance	Anti-Reflective Laser Coating
Volk®1 Single Use 20D	V20LCD	3.13	45° / 58°	0.32	47 mm	Yes
Volk®1 Single Use 28D	V28LCD	2.27	54° / 70°	0.44	30 mm	Yes



WARNINGS

1. Do not immerse the device in a decontaminating product before use.
2. Inspect the optical 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

1. Do not attempt to use the Volk®1 Single Use Binocular Indirect Ophthalmoscope (BIO) Lens prior to completely reading and understanding these instructions for use.
2. To be used by a licensed physician in a method consistent with other indirect image ophthalmic non-contact diagnostic and laser surgery lenses.
3. The sterile packaging and lens should be inspected prior to use.
4. The Volk®1 Single Use Binocular Indirect Ophthalmoscope (BIO) Lens is 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.

"USE BY" DATE

Use the device prior to the "Use By" 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. Handle the device only by the grip ring to avoid contacting the optical surfaces of the lens.
3. Volk's BBAR Anti-Reflective Laser Coating is optimized for diagnostic imaging, as well as visible and near-infrared wavelength laser procedures (e.g., argon and diode).
4. 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.

STERILE

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-by date

LOT

Lot number

REF

Reference number



Manufacturer

EC REP

Authorized representative in the European Community

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