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Volk®1 Single-Use Contact Laser and Diagnostic Lenses (Direct Contact)

- 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 Single-Use Contact Laser and Diagnostic Lenses (Direct Contact) are indicated for use as diagnostic lenses for eye examinations and use in the therapy of intraocular abnormalities.

SPECIFICATIONS

Product	Magnification	Laser Spot Magnification Factor	Available Contact Designs	Anti-Reflective Laser Coating
Volk Capsulotomy	1.57	0.63	Standard Fluid	BBAR
Volk Iridotomy	1.70	0.58	Standard Fluid	BBAR

WARNINGS

1. Do not immerse the device in a decontaminating product before use.
2. Inspect the contacting surface(s) to make sure they are 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 Single-Use Contact Laser and Diagnostic Lenses (Direct Contact) 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 lens.
3. The sterile packaging and lens should be inspected prior to use.
4. Volk Single-Use Contact Laser and Diagnostic Lenses (Direct Contact) 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.

“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. 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. 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 you are using.



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 number



Reference number



Manufacturer



Authorized representative in the European Community