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Volk®1 Single Use Surgical Gonio Lens and Accessories

- 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

INTENDED USE

The Volk®1 Single Use Surgical Gonio Lens and Accessories are ophthalmic instruments used for general and surgical gonioscopy. The devices are sterile, single use, disposable lens systems.

SPECIFICATIONS

Product	Product Code	Magnification	Tool Access
Single Use GonioPro Surgical Single-Port Stabilizer	VSGSAD	N/A	1 x 120°
Single Use GonioPro Surgical Multi-Port Stabilizer	VSGSBD	N/A	1 x 60°, 2 x 35°
Single Use GonioPro Surgical Lens + Single-Port Stabilizer	VSGLSAD	1.1x	1 x 120°
Single Use GonioPro Surgical Lens + Multi-Port Stabilizer	VSGLSBD	1.1x	1 x 60°, 2 x 35°
Single Use GonioPro Surgical Lens + Handle	VSGLHD	1.1x	360°

INDICATIONS FOR USE

1. The device is a single-handed instrument that is intended to enhance the surgeon's ability to simultaneously articulate the device and to obtain anterior chamber angle visualization during surgical and non-surgical procedures.
2. The device may be indirectly interfaced with surgical microscopes to enhance the user's ability to position and obtain anterior chamber angle visualization.
3. The lens component of the device is placed directly on the cornea.
4. Outcomes can be affected by the user's level of experience. It is highly recommended that the user is adequately trained in this procedure prior to actually using the Surgical Gonio lens.
5. A lubricant such as Ophthalmic Viscoelastic Device (OVD) agents or Ophthalmic Balanced Salt Solution (BSS) must be applied onto the cornea.



WARNINGS

1. CAREFULLY EXAMINE THE DEVICE FOR DAMAGE PRIOR TO EACH USE. DO NOT USE THE DEVICE IF ANY SURFACE(S) SHOW(S) ANY EVIDENCE OF DAMAGE, OR PATIENT INJURY COULD RESULT.
2. Do not immerse the device in a decontaminating product before use.
3. 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.
4. 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.
5. 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 Surgical Gonio 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 Surgical Gonio lenses.
3. The sterile packaging and lens should be inspected prior to use.
4. The Volk®1 Single Use Surgical Gonio 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.

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. All lens designs require methylcellulose or other similar viscous interface solution to be applied to the concave contact surface (i.e., between the cornea and the device).
3. The Volk®1 Single Use Surgical Gonio Lens is a surgical lens device that is placed on the cornea and helps improve accuracy and clarity of images during surgical gonioscopy.

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.



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



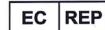
Lot number



Reference number



Manufacturer



Authorized representative in the European Community



Medical Device