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## Volk Optical Gonioscopy Lenses (Gonio)

### ENGLISH (EN): INSTRUCTIONS FOR USE

#### INTENDED USE

Volk Optical's Gonioscopy 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 | Contact Style                      | Fluid    | Anti-Reflective Laser Coating | Laser Compatible |
|---|---------------|-------------------|---------------------------------|------------------------------------|----------|-------------------------------|------------------|
| G-1 Trabeculum (VG1)  | 1.50          | 1                 | 0.67                            | Standard Flange                    | Required | BBAR                          | Yes              |
| G-1 Trabeculum NF (VG1NF)                                   | 1.50          | 1                 | 0.67                            | No Flange                          | Optional | BBAR                          | Not Recommended  |
| G-2 Trabeculum (VG2)  | 1.50          | 2                 | 0.67                            | Standard Flange                    | Required | BBAR                          | Yes              |
| G-2 Trabeculum NF (VG2NF)                                   | 1.50          | 2                 | 0.67                            | No Flange                          | Optional | BBAR                          | Not Recommended  |
| G-3 Goniofundus (VG3)                                       | 1.06          | 3                 | 0.94                            | Standard Flange                    | Required | BBAR                          | Yes              |
| G-3 Goniofundus Mini NF (VG3MININF)                         | 1.00          | 3                 | 1.00                            | No Flange                          | Optional | BBAR                          | Not Recommended  |
| G-3 Goniofundus NF (VG3NF)                                  | 1.03          | 3                 | 0.97                            | No Flange                          | Required | BBAR                          | Not Recommended  |
| G-4 Goniolaser (VG4)  | 1.00          | 4                 | 1.00                            | Standard Flange                    | Required | BBAR                          | Yes              |
| G-4 Gonio NF Large Ring (VG4LNF)                            |               |                   |                                 |                                    |          |                               |                  |
| G-4 Gonio NF Small Ring (VG4SNF)                            | 1.00          | 4                 | 1.00                            | No Flange                          | Optional | Uncoated                      | Not Recommended  |
| G-4 Gonio NF Handle (VG4HAN2) (with ring or handle)         |               |                   |                                 |                                    |          |                               |                  |
| G-4 High Mag Goniolaser (VG4HM)                             | 1.50          | 4                 | 0.67                            | Standard Flange                    | Required | BBAR                          | Yes              |
| G-4 High Mag Gonio NF Large Ring (VG4HMLNF)                 |               |                   |                                 |                                    |          |                               |                  |
| G-4 High Mag Gonio NF Small Ring (VG4HMSNF)                 | 1.50          | 4                 | 0.67                            | No Flange                          | Optional | Uncoated                      | Not Recommended  |
| G-4 High Mag Gonio Handle (VG4HMHAN2) (with ring or handle) |               |                   |                                 |                                    |          |                               |                  |
| G-6 Gonio NF (VG6LNF)                                       | 1.00          | 6                 | 1.00                            | No Flange                          | Optional | Uncoated                      | Not Recommended  |
| G-6 Gonio NF Handle (VG6HAN2) (with ring or handle)         |               |                   |                                 |                                    |          |                               |                  |
| Classic 3-Mirror Goniofundus (V3MIR)                        | 1.03          | 3                 | 0.97                            | No Flange                          | Required | BBAR                          | Yes              |
| Uncoated Classic 3-Mirror Goniofundus (VU3MIR)              | 1.03          | 3                 | 0.97                            | No Flange                          | Required | Uncoated                      | Not Recommended  |
| Classic 3-Mirror Goniofundus ANF+ (V3MIRANF+)               | 1.06          | 3                 | 0.94                            | ANF+ - Advanced No Fluid (Flanged) | Optional | BBAR                          | Yes, with Fluid  |
| Uncoated Classic 3-Mirror Goniofundus ANF+ (VU3MIRANF+)     | 1.06          | 3                 | 0.94                            | ANF+ - Advanced No Fluid (Flanged) | Optional | Uncoated                      | Not Recommended  |
| 4-Mirror Mini ANF+ (V4MANF+)                                | 1.00          | 4                 | 1.00                            | ANF+ - Advanced No Fluid (Flanged) | Optional | BBAR                          | Yes, with Fluid  |
| SLT (VSLT)  | 1.00          | 1                 | 1.00                            | No Flange                          | Required | Uncoated                      | Yes              |
| Rapid SLT (VMSLT)   | 1.00          | 4                 | 1.00                            | Standard Flange                    | Required | BBAR                          | Yes              |

#### INDICATIONS FOR USE

- To be used by a trained, licensed physician in a method consistent with other gonioscopic contact lenses.
- Device may be used in conjunction with a biomicroscope to achieve the desired image.
- For lenses specified as Laser Compatible, a coupling fluid is required for laser treatment procedures. Refer to the Specifications table to determine which Gonio lenses are Laser Compatible.
- Required Fluid Gonio lenses require methylcellulose or other similar interface solution be applied to the concave contact surface.
- No Flange (NF) and Advanced No Fluid (ANF+) contact lenses can be used with a natural tears solution or methylcellulose applied to the concave contact surface if required.
- When calculating the laser spot size at the retina or in the anterior segment, 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.
- Inspect the contacting surface(s) before each use and after reprocessing to make sure they are free from any damage (e.g. chips, scratches, etc).
- Inspect the mirroring surface(s) before each use to make sure the surfaces are free from any damage (e.g. laser burns etc.).



#### WARNINGS:

- DO NOT USE THE DEVICE IF THE CONTACTING SURFACE SHOWS ANY SIGN OF DAMAGE.
- DO NOT USE THE DEVICE IF THE MIRRORING SURFACE(S) SHOW(S) ANY SIGN OF DAMAGE, BEFORE OR DURING LASER USAGE.
- DO NOT ATTEMPT TO USE THE LENS IF, FOR ANY REASON, THE IMAGE IS UNCLEAR OR UNFOCUSED.
- DO NOT ATTEMPT TO USE THE LENS UNLESS AN ADEQUATE TYPE AND AMOUNT OF COUPLING FLUID IS PRESENT BETWEEN THE CORNEA AND THE CONTACTING LENS SURFACE.
- GONIO LENSES APART FROM VSLT AND RAPID SLT (VMSLT) LENSES ARE NOT SUITABLE FOR SLT (SELECTIVE LASER TRABECULOPLASTY) PROCEDURE
- 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
- CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PRESSURE ON THE CORNEA AS IT MAY AFFECT AQUEOUS DYNAMICS OR CAUSE INJURY.

#### REPROCESSING



#### WARNINGS:

- A THOROUGH, MANUAL CLEANING PROCESS IS RECOMMENDED.
- CORROSIVE CLEANING AGENTS (I.E. ACIDS, ALKALINES, ETC) ARE NOT RECOMMENDED. DETERGENT CLEANING AGENTS WITH NEUTRAL PH ARE RECOMMENDED.

#### PREPARATION AT THE POINT OF USE:

- New or used, contaminated lenses must be cleaned.
- Body fluids should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids.
- Universal precautions for handling contaminated materials should be observed.
- Instruments should be cleaned as soon as possible after use to minimize the drying of any fluids on their surfaces.
- Devices should always be handled in an appropriate method to ensure that contamination is not introduced to a recently cleaned, disinfected, and/or sterilized device.

#### REPROCESSING LIMITATIONS:

Repeated cleaning, disinfection, and sterilization have minimal effect on Volk Gonio Lenses when processed according to instructions. End of the product's life cycle is normally determined by wear and damage due to use.



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#### PREPARATION BEFORE CLEANING:

The following cleaning, disinfection, and sterilization instructions are aided by not allowing contamination to dry on the lens surface. When possible, place the lenses in water or cover them with a damp cloth.

#### CLEANING, DISINFECTION, STERILIZATION

##### CLEANING:

Select the desired method of cleaning:

|                  |   |
|------------------|---|
| <b>Method A:</b> | Clean with a mild detergent and a clean, soft cotton cloth or swab. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing. Do not use detergents containing Emollients (moisturizers).   |
| <b>Method B:</b> | Clean the glass element with Volk Precision Optical Lens Cleaner (POLC) or a Volk LensPen®. Clean lens surface in a clockwise direction to help prevent loosening of the retaining ring within the housing.<br><b>CAUTION:</b> Do not use Volk's POLC, or the Volk LensPen® on surfaces that contact the eye.   |
| <b>Method C:</b> | <ol style="list-style-type: none"> <li>1. Prepare fresh enzymatic cleaner (e.g. Enzol) solution – 2 ounces per gallon using warm (~30 - 43°C) tap water.</li> <li>2. Soak each device in solution for 20 minutes.</li> <li>3. After soaking, brush knurled surface on device ring with a soft-bristle brush and wipe lens portion with a soft cloth until all traces of cleaner and soil are removed. Clean lens surface in a clockwise direction. Pay special attention to all crevices and other hard-to-reach areas. NOTE: Do not brush lens portion to avoid scratching; use soft cloth.</li> <li>4. Thoroughly rinse devices in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.</li> <li>5. Transfer the device(s) to a freshly prepared enzymatic solution (per step 1 above) and sonicate for 20 minutes.</li> <li>6. After sonication, thoroughly rinse device(s) in a room temperature tap water bath (not under running water) until all visible cleaner has been removed.</li> <li>7. Inspect each device for remaining debris. If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.</li> </ol> |



##### CAUTION:

TO AVOID LENS SURFACE DAMAGE NEVER CLEAN THE CLASSIC 3 MIRROR LENSES, MINI 4 MIRROR LENS, OR SLT LENS CONTACT ELEMENT WITH ALCOHOL, PEROXIDE, OR ACETONE. G-SERIES LENSES MAY BE CLEANED WITH THESE CHEMICALS.

##### DISINFECTION:

1. Follow the **Method A** or **Method C** cleaning instructions from above.
2. Select one of the solution types from the table below:

| DISINFECTANT               | CONCENTRATION                   | MIN SOAK TIME | MAX SOAK TIME |
|----------------------------|---------------------------------|---------------|---------------|
| Glutaraldehyde             | 2% aqueous solution             | 25 minutes    | N/A           |
| CIDEX® OPA Solution        | See Manufacturer's Instructions | 12 minutes    | N/A           |
| Revital-Ox™ Resert® XL HLD | ≥ 1.5% aqueous solution         | 8 minutes     | 16 minutes    |

3. Immerse device completely, and then immerse the device completely in the selected disinfectant solution for the minimum soak time listed above (minimum of 20°C). Ensure to fill all lumens, hard-to-reach areas, and eliminate air pockets.
4. Rinse thoroughly in a room temperature water bath (minimum of 20°C). Rinse by immersing device completely for a minimum of one minute. Manually flush all lumens or other hard-to-reach areas with water. Agitate device under water, bring above water level, then re-immers. Repeat rinse procedure two additional times using fresh water.
5. Dry with a soft, lint-free cotton cloth.

##### STERILIZATION:

1. Follow the **Method C** cleaning instructions.
2. Sterilize using the Steris V-Pro® 60 Low Temp Sterilization System, V-Pro® s2 Low Temp Sterilization System, V-Pro® maX Low Temp Sterilization System, or V-Pro® maX 2 Low Temp Sterilization System. Sterilize using the Non-lumen cycle or Fast cycle.
3. Alternatively, the Classic 3-Mirror, 4-Mirror Mini, and SLT lenses may be sterilized using the ethylene oxide (ETO) sterilization process. Sterilize using a 2-hour cycle with a temperature of 130°F and a concentration of 600 mg/L, but not exceeding 150°F.
4. Do not sterilize lenses within standard lens cases, as they are not meant for use in sterilization systems.



##### CAUTION:

1. G-SERIES GONIO LENSES ARE **NOT** RECOMMENDED FOR ETO STERILIZATION DUE TO MIRROR DEGRADATION.
2. TO AVOID PRODUCT DAMAGE, NEVER AUTOCLAVE OR BOIL VOLK GONIO LENSES.
3. TO AVOID PRODUCT DAMAGE, NEVER SUBJECT VOLK GONIO LENSES TO STERRAD STERILIZATION.

#### 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.



Consult the Instructions for Use for important cautionary information



Lot number



Reference number



Manufacturer



Authorized representative in the European Community



Date of manufacture



Medical Device