

Volk Optical Inc.

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Rev: A

Effective: April 16, 2012



EU REPRESENTATIVE
The Volk authorized representative based in the European Union (EU) is:

Keeler Limited Clewer Hill Road Windsor Berkshire SL4 4AA U.K. Tel: +44(0) 1753 857177

INTRODUCTION

Your new Volk Surgical Gonio ACS[®] Lens is designed for ease of use with a convenient, comfortable handle. The Surgical Gonio lens and handle are sterilizable using steam sterilization.

CONTACT DESIGN

The contact design requires a viscous, sterile tear-like fluid (methylcellulose or similar interface solution) applied to the concave contact surface (patient side).

ILLUMINATION

It is suggested that a light source appropriate for use with filtering microsurgery procedures be used to provide illumination of the angle.

REPROCESSING

Warnings:

- A thorough, manual cleaning process is recommended.
- 2. Corrosive cleaning agents (e.g. acids, alkalines, etc.) are not recommended. Detergent cleaning agents with neutral pH are recommended.

Reprocessing Limitations: Repeated cleaning, disinfection and sterilization have minimal effect on the Surgical Gonio ACS lens when processed according to instructions. End of life is normally determined by wear and damage due to use.

Preparation at the Point of Use:

- New or used, contaminated lenses must be cleaned.
- Body fluids and/or tissue should not be allowed to dry on the unit prior to cleaning. Remove excess body fluids and tissue.
- 3. Universal precautions for handling contaminated materials should be observed.
- Instruments should be cleaned as soon as possible after use to minimize the drying.

Preparation before cleaning: The following cleaning and sterilization instructions are aided by not allowing

contamination to dry on the lenses. When possible place the lenses in water or cover them with a damp cloth.

Cleaning:

1. Using a mild, nearly neutral pH detergent at room temperature, clean the entire surfaces of the lens with a clean, soft cotton cloth, paying special

- attention to crevices and other hard to reach areas.
- Rinse thoroughly by immersing the lens in room-temperature, distilled water for at least one minute and agitating the lens under water. Bring the lens up, out of the water and resubmerge under the water. Repeat two additional times or until there is no evidence of cleaner or soil.
- 3. Dry with a clean, soft cotton cloth.
- Automated washer/disinfection systems are not recommended. These lenses should be cleaned following the manual cleaning procedure above.

Disinfection: Reusable surgical devices require full sterilization.

Drying: Dry the lens with a clean, soft cloth.

Inspection, Maintenance, and Testing:

- 1. Carefully check to ensure that all visible debris has been removed. If any contamination is visible, repeat the cleaning procedure.
- 2. Visually check for damage and/or wear.
- If damage or wear is apparent that may interfere with the performance of the lens, contact Volk Optical or your distributor for return.

Sterilization:

 Steam sterilization is the preferred method of sterilization. Steam sterilize using a prevacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). Volk recommends using distilled water for steam sterilization. The use of distilled water greatly increases the lifetime

No maintenance activities are necessary.

Packaging:



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- The hospital is responsible for in-house procedures for inspection and packaging of the lenses in a method that will allow adequate drying steam sterilization.
- 2. If applicable, use standard medical grade steam sterilization wrap following the double wrap method.
 - of your Volk Surgical Gonio lens. Where the use of distilled water is not practical, the use of a reverse osmosis (RO) filter is recommended just prior to the autoclave water intake.

Storage: Sterile instruments should be stored in an area that provides protection from loss of sterility.

WARRANTY SERVICE

If the product fails to function due to defects in either materials or workmanship, Volk will, at its option, either repair or replace the product without charge, subject to the Warranty Limitations.

WARRANTY COVERAGE

Volk Optical warrants its Volk Surgical Gonio Lenses against defects in materials or workmanship for a period of 1 year from receipt by end user.

WARRANTY LIMITATIONS

Warranty service may not be provided without proof the product was purchased from Volk Optical Inc. or an Authorized Volk Distributor. This Warranty becomes null and void if the customer fails to return the product in packaging that is consistent with the original protective packaging and it results in shipping damage.

This Warranty becomes null and void if the customer fails to follow the recommended cleaning, disinfection and sterilization instructions and/or cautions contained in the product instruction manual. This Warranty does not cover service required because of disassembly, unauthorized modifications or service, misuse or abuse.

LIMIT OF LIABILITY

Volk shall not be responsible for loss of income or profit resulting from downtime costs or loss of equipment use.

If you have questions regarding Volk's Warranty, please contact Volk Optical.

SPECIFICATIONS

Lens	Magnification
Surgical Gonio Lens	1.2x

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