EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

OCULAR INSTRUMENTS
2255 116TH Ave NE, Bellevue, Washington 98004-3039 USA
T: 425-455-5200 or 800-888-6616 F: 425-462-6669
E: contact@ocularinc.com I: www.ocularinc.com

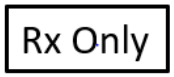
PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 5

DEVICE(S): OUSG-1.3X-H, & MaxAC Lenses.

WARNINGS	• Read all instructions before use. • Follow instructions and warnings as issued by manufacturers of any decontaminants, and cleaning agents used. • Wherever possible avoid the use of abrasive materials for cleaning and drying. • Incorrect handling and care or misuse can lead to premature wear of these devices. • Use only cleaning solutions, and sterilizers listed on this method. Polysulfone components are susceptible to damage if exposed to various chemicals and stress. • Inspect these devices carefully for damage, cracks or malfunctions before each use. • Do not use damaged devices. • Each device requires cleaning and sterilization before its first use and any subsequent use. • Ensure cleaning solutions fully contact all device surfaces. • Sterilize all devices before surgery. • Allow devices to air cool to room temperature before handling and use. • 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.
Limitations on reprocessing	Repeated processing has minimal effect on the performance on these devices [1]. Product's service life is determined by wear and tear or damage due to use such as, scratches caused by mechanical cleaning (e.g.by hard brushes), or calciferous residues (e.g. hard water used in the sterilizer) that impair the optical quality. Thus the end of a product's service life varies and is therefore determined by the user. Rapid cooling may damage devices. Slight changes to the appearance, such as color of adhesive, are normal with repeated sterilization and use.

INSTRUCTIONS	
Point of Use:	Rinse: Immediately upon removal from patient's eye, thoroughly rinse (at least 100 milliliters) in cool or tepid water for 1 minute to avoid soil drying on surfaces.
Preparation for decontamination:	• Reprocess all devices as soon as reasonably practical following use. • Reprocessing instructions are aided by not allowing contaminants to dry on surface. To avoid drying of contaminants submerged the lens completely in water. • Disassemble devices only where intended. See specific product sheets for disassembly/reassembly instructions.
Cleaning: Automated	Not recommended.
Cleaning: Manual	1. Place a few drops of low foaming mild soap (i.e., neutral pH (7.0) detergent formulated for medical instruments) on a moistened cotton ball. 2. Gently clean with a circular motion until all soil has been removed. 3. Thoroughly rinse lens in cool or tepid high purity water (at least 100 milliliters) for 1 minute. 4. Carefully dry with a *non-linting* tissue or hospital grade compressed air. 5. Visually inspect all surfaces, crevices, joints, and holes for complete removal of soil and fluid. If any soil or fluid is visible, then repeat cleaning.
Disinfection: Automated	Not recommended.
Disinfection:	Not recommended. Sterilization is the preferred method prior to use.
Drying:	Dry devices carefully with lint free tissues or hospital grade compressed air and place in a dry storage case.
Maintenance, Inspection and Testing:	• Inspect for visible contaminants or debris before each use. Repeat cleaning procedure if contaminants or debris are visible. • Inspect these devices carefully for damage, cracks or malfunctions before each use. Do not use damaged devices. • See specific Product Sheets for disassembly/reassembly instructions. • No maintenance required.
Packaging:	Standard biological peel packs *(wrapped)* may be used. The pack should be large enough to contain the device without stressing the seals. Biological peel packs ensure sterility after the sterilization process.

Sterilization:	**STEAM AUTOCLAVE** ***(See note 1)*** Prep: Rinse devices with sterile water. Place product in sterilization case. *Pre-Vacuum Cycle (wrapped/unwrapped)* Temperature: 270°F (132°C) minimum or Temperature: 273°F (134°C) minimum Time: 4 minutes minimum Time: 3 minutes minimum Dry Time: 20 minutes minimum Dry Time: 20 minutes min. *Gravity Cycle (wrapped)* Temperature: 270°F (132°C) minimum or Temperature: 250°F (121°C) minimum Time: 15 minutes minimum Time: 30 minutes minimum Dry Time: 15 minutes minimum Dry Time: 15 minutes minimum *FOR IMMEDIATE USE ONLY -FLASH AUTOCLAVE* *Gravity Cycle (unwrapped)* Temperature: 270°F (132°C) minimum Time: 10 minutes minimum **Additional Note:** Use of distilled water in steam sterilizer is recommended. If not distilled, mineral deposits from hard water (steam) could leave a cloudy film on the lens. The deposits can only be removed by regrinding and re-polishing the lens and repair costs approximate that of a new lens. Allow Lenses to air cool. Rapid cooling as in cool water rinse may fracture the lens. **Note: 1.** Devices containing coated mirrored surfaces may exhibit minor accumulative changes with repeated cycling. **2.** MaxAC Indirect lenses should be placed on edge to reduce water spots on the surface of the lens. MaxAC autoclavable lens stand, OI-LSA, may be used to facilitate lens positioning. For information on compatibility with alternative product care methods, contact Customer Service.
Storage:	Ensure devices are cleaned, sterile, and dry before storage. Store in a clean and dry room temperature environment that provides protection from loss of sterility.

Explanation of Symbols:		Medical Device
		Prescription only - device restricted to use by or on the order of a physician
		Part Number

Additional Information:	These lenses are known to be compatible with Glutaraldehyde *(2% or 3.4%)*, and may be used in accordance with label instructions of the disinfectant manufacturer. Pay strict attention to disinfectant manufacturers recommended concentrations and contact durations. Ensure that disinfectant solution makes complete contact with all device surfaces. Please consult instructions of the processing equipment or the manufacturer for compatibility claims. All cleaning and sterilization processes require validation at the point of use.
Manufacturer contact:	See brochure for telephone number and address of local representative. Cleaning methods are also available on website at www.ocularinc.com under product care.

The instructions contained herein have been validated as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, material and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

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