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PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 3

DEVICE(S): ALL Ocular Surgical Lenses and Rings* and OI-20A, OI-28A, O4MAC, O4MAC-LR, O4MAC-H, OG3MAC-10.

***Note:** See Cleaning Method 1 for OLIV-EQNA, Landers NA Equatorial Vitrectomy Lens, OLIV-WFNA, Landers NA Wide Field Vitrectomy Lens, OLTK-7.2 or 8.2, Landers WF Temporary Keratoprosthesis, OTSG, Thorpe Surgical Gonioscope, OUV-132-2, Peyman-Wessels-Landers 132D Upright Vitr. Lens, OWIV-HMNA, Woldoff NA High Mag Vitrectomy Lens, OKSG, Khaw Surgical Gonioprism, OMUSG Mori Upright Surgical Gonio*

WARNINGS	• Read all instructions before use. • Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants 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. • Inspect these devices carefully for damage, cracks or malfunctions before each use. • Do not use damaged devices. • Use only approved disinfectant solutions (e.g., FDA, DGHM, CE Mark…). • Each device requires cleaning and disinfection before its first use and any subsequent use. • Ensure cleaning and disinfection solutions fully contact all device surfaces and lumens. • Store devices in a cleaned, disinfected and dry state. • Sterilize all devices before surgery. • Allow devices to air cool to room temperature before use. Rapid cooling may damage devices.
Limitations on reprocessing	Repeated processing has minimal effect on these devices[1, 2]. Rapid cooling may damage devices.

INSTRUCTIONS	
Point of Use:	Rinse: Immediately upon removal from patient's eye, thoroughly rinse in cool or tepid water to avoid soil drying on surfaces or lumens.
Preparation for decontamination:	Reprocess all devices as soon as reasonably practical following use. Disassemble devices only where intended.
Cleaning: Automated	Not recommended.
Cleaning: Manual	Wash: 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. Gently clean with a circular motion until all soil has been removed. Flush all lumens with detergent solution to remove soil. Rinse: Thoroughly rinse lens and flush lumens in cool or tepid high purity water, then dry carefully with a *non-linting* tissue or hospital grade compressed air. Inspect: Visually inspect all surfaces, crevices, joints, holes and lumens for complete removal of soil and fluid. If any soil or fluid is visible, then repeat cleaning. **Caution:** *If fluid/gas exchange has occurred, wipe lens with alcohol to remove any trace of oil present. If lens is not promptly and properly cleaned, permanent damage may result.*
Disinfection:	Disinfectant solutions (e.g., Approved by FDA, DGHM, CE Mark…) may be used in accordance with label instructions of the disinfectant manufacturer. Pay strict attention to disinfectant manufactures recommended concentrations and contact durations. Ensure that disinfectant solution makes complete contact with all device surfaces and lumens. After manual high level disinfection, soak and rinse lens in large volume of cool or tepid sterile water for 1 minute and thoroughly flush lumens. Repeat this procedure 2 times with fresh rinse water to ensure removal of disinfection solution. **Caution:** *To avoid damage to the lens, do not exceed recommended exposure time.* **Caution:** *If used on an ulcerated cornea, lens must be STERILIZED before next procedure.*
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 these devices carefully for damage, cracks or malfunctions before each use. Do not use damaged devices.
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:	**EO** Minimum Time: 1 hour Temperature: 130°F (54°C) Aerations Time: 12 Hours **STEAM AUTOCLAVE** Prep: Rinse devices with sterile water. Place product in sterilization case. *Gravity Cycle (wrapped)* Temperature: 270°F (132°C) min. or Temperature: 250°F (121°C) min. Time: 15 minutes min. Time: 30 minutes min. Dry Time: 15 minutes min. Dry Time: 15 minutes min. *Pre-Vacuum Cycle (wrapped)* Temperature: 270°F (132°C) min. or Temperature: 273°F (134°C) min. Time: 4 minutes min. Time: 3 minutes min. Dry Time: 20 minutes min. Dry Time: 20 minutes min. *FOR IMMEDIATE USE ONLY -FLASH AUTOCLAVE* *Gravity Cycle (unwrapped)* Temperature: 270°F (132°C) min. Time: 10 minutes min. *Pre-Vacuum Cycle (unwrapped)* Temperature: 270°F (132°C) min. or Temperature: 273°F (134°C) min. Time: 4 minutes min. Time: 3 minutes min. **Caution:** Use water with hardness less than 1 ppm $CaCO_3$ (i.e., Deionized or High-Purity water) in steam autoclave. If water with high hardness is used, mineral deposits from hard water (steam) will leave a cloudy film on the lens. The deposit can only be removed by regrinding and re-polishing the lens and repair costs approximate that of a new lens. **Note:** Allow Vitrectomy Lenses to air cool. Rapid cooling as in cool water rinse may fracture the lens. **STERRAD 100NX: Standard Cycle[1, 2]** Process product in STERRAD approved tray or container and wrap when applicable. Follow STERRAD instructions. Not compatible with: OCTK-6.5, OLTA, OLTA-2, Silicone tubing and Luer adapters supplied with products (i.e., lumens are less than 0.7mm ID). **STERRAD NX: Standard Cycle[1, 2] | STERRAD 100S, 200: Short Cycle[1, 2] | STERRAD 50 [1, 2]** Process product in STERRAD approved tray or container and wrap when applicable. Follow STERRAD instructions. Not compatible with: OLV-1-IN, OLV-1-IR, OBVI, OFVI, OPFVI, OMVI, OPGVI, OPV1-3, OPGVI, OPVI-3, OCTK-6.5, OLTA, OLTA-2, Silicone tubing and Luer adapters supplied with products (i.e., lumens are less than 1.00 mm ID) **Steris SYSTEM 1E** Follow Steris instructions. **3M™ Optreoz™ 125-Z Low Temperature Sterilization System – Cycle 1[1]** Follow 3M™ Optreoz™ 125-Z Low Temperature Sterilization System instructions. Not compatible with: OCTK-6.5, OHFVE, OHMVE, OHBVE, OHWVE, OBVI, OFVI, OPFVI, OMVI, OPGVI, OPVI-3, OLTA, OLTA-2 Silicone tubing and Luer adapters supplied with products (lumens smaller than 1.0mm diameter are not compatible) **3M™ Optreoz™ 125-Z Low Temperature Sterilization System – Cycle 2[1]** Follow 3M™ Optreoz™ 125-Z Low Temperature Sterilization System instructions. Not compatible with: OCTK-6.5 **Note: 1.** Colored aluminum will fade to a natural aluminum color within 25 cycles. **2.** Polyacetal components (black or white plastic) may have limited life after repeated sterilization with this method. For information on compatibility with alternative product care methods, contact Customer Service.
Storage:	Ensure devices are cleaned, disinfected and dry before storage. Store in a clean and dry room temperature environment.

Additional Information:	Other forms of cleaning and sterilization equipment are available. 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. **Note:** These lenses are known to be compatible with Glutaraldehyde *(2% or 3.4%),* BLEACH *(10% solution mixed at: 1 part bleach to 9 parts cool or tepid water, recommended exposure time = 10 minutes)*, Medical disinfectant wipes (e.g. Asepti-Wipe II, Cavicide, DisCide Ultra, Envirocide, and Opti-Cide-3) and Medical disinfectant solutions such as Cidex and Cidex OPA.
Manufacturer contact:	See brochure for telephone number and address of local representative.

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.