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PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 1

DEVICE(S): All Ocular Argon/Diode, YAG and Diagnostic Lenses* and OLIV-EQNA, Landers NA Equatorial Vitr. Lens, OLIV-WFNA, Landers NA Wide Field Vitr. Lens, OLTK-7.2 or 8.2, Landers WF Temp. Keratoprosthesis, OTSG, Thorpe Surgical Gonioscope, OUV-132-2, Peyman-Wessels-Landers 132D, Upright Vitr. Lens, OWIV-HMNA, Woldoff NA High Mag Vitr. Lens, OKSG, Khaw Surgical Gonioprism, OMUSG, Mori Upright Surgical Gonio

*Note: See Cleaning Method 3 for O4MAC, O4MAC-15, O4MAC-17, O4MAC-1X, O4MAC-1X-15, O4MAC-1X-17, O4MAC-1X-H, O4MAC-1X-LR, O4MAC-1X-LR-15, O4MAC-1X-LR-17, Maxfield® AC Four Mirror Gonio, O4MAC-LR, O4MAC, OG3MAC-10, OG3MAC-15, OG3MAC-17, Autoclavable Three Mirror.

WARNINGS	<ul style="list-style-type: none"> • 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. • Never Steam Autoclave or Boil listed lenses. • Never soak in Acetone or Other Solvents.
Limitations on reprocessing	Repeated processing has minimal effect on these devices. 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	<p>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.</p> <p>Rinse: Thoroughly rinse lens and flush lumens in cool or tepid high purity water, then dry carefully with a <i>non-linting</i> tissue or hospital grade compressed air.</p> <p>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.</p> <p>Caution: <i>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.</i></p>
Disinfection:	<p>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 manufacturers recommended concentrations and contact durations. Ensure that disinfectant solution makes complete contact with all device surfaces and lumens.</p> <p>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.</p>

	<p>Caution: <i>To avoid damage to the lens, do not exceed recommended exposure time.</i></p> <p>Caution: <i>If used on an ulcerated cornea, lens must be STERILIZED before next procedure.</i></p>
Disinfection: <i>(continued)</i>	
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 (<i>wrapped</i>) 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:	<p>EO Minimum Time: 1 hour Temperature: 130°F (54°C) Aerations Time: 12 Hours</p> <p>STEAM AUTOCLAVE</p> <p>NO</p> <p>STERRAD No (<i>See notes 1, 2, 3 & 4 below</i>)</p> <p>Steris SYSTEM 1E⁴ Follow Steris Instructions Not compatible with OMRA-HM, OMRA-HM-2</p> <p>Steris V-Pro Models^{1,3} No</p> <p>3MTM OptreozTM 125-Z Low Temperature Sterilization System – Cycle 1¹ Follow 3MTM OptreozTM 125-Z Low Temperature Sterilization System instructions.</p> <p>Notes: 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. 3. Devices with PMMA (clear plastic) will have limited life after 10 cycles. 4. Devices containing Grey paint will have limited life after 25 cycles.</p> <p>For information on compatibility with alternative product care methods, contact Customer Service.</p>
Storage:	Ensure devices are cleaned, disinfected and dry before storage. Store in a clean and dry room temperature environment.

Additional Information:	<p>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.</p> <p>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; Bleach is corrosive to metals, to avoid corrosion do not exceed recommended exposure times), Medical disinfectant wipes (Asepti-Wipe II, Cavicide, DisCide Ultra, Envirocide, Tristel Wipes System and Opti-Cide-3) and Medical disinfectant solutions such as Cidex and Cidex OPA. Also compatible with H₂O₂-3%, except the following lenses: OG3M-10, Three Mirror 10mm Diagnostic, OPDSG, OPDSG-2, OPDSG-3, Posner Gonioprisms; OS4M, OS4M-2, Sussman Gonioscopes; OK4DG, Khaw Direct View Gonio, OMUSG Mori Upright Surgical Gonio. Compatible with Steris Resert except: OG4MG-X, and OG3MHD-X</p>
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.