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PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 1

DEVICE(S): All Ocular Laser and Diagnostic Lenses

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. • 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. • 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 these devices[1, 2, 3, 4]. 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) 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.

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 submerge 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: **Disinfection:**	1. Perform manual cleaning per instructions 2. Choose one of the following: (See Additional Information below for other compatible solutions) 3. Submerge the device and ensure that disinfectant solution makes complete contact with all device surfaces. 4. After manual high-level disinfection, soak and rinse lens in large volume (at least 100 milliliters) of cool or tepid sterile water for 1 minute. Repeat this procedure 2 times with fresh rinse water to ensure removal of disinfection solution.

Disinfectant	Concentration	Contact time
Cidex, Activated Glutaraldehyde Solution	See manufacturer's instructions	See manufacturer's instructions
Steris Revital-Ox Resert *(Not compatible with OMRA-WFEX, OG4MG All types, OG3MHD All types, OLIV-WFNA, OLIV-EQNA, OWIV-HMNA, & OIV-132)*	See manufacturer's instructions	See manufacturer's instructions

	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 for visible contaminants or debris. 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:	**EO** (ethylene oxide) Minimum Time: 1 hour Temperature: 130°F (54°C) Aerations Time: 12 Hours Concentration: 600mg/L Humidity: 100% **Steris SYSTEM 1E** ***(See Note 4)*** Follow Steris Instructions Not compatible with OMRA-HM, OMRA-HM-2 **These devices are not compatible with the following:** **- Steam Autoclave** **- STERRAD** ***(See notes 1 ,2, 3 & 4 below*****)** **- Steris V-Pro Models** ***(See note 1 & 3)*** **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. 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.

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

Additional Information:	**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 OPA. Also compatible with H_2O_2-3%, 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. 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. 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.
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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