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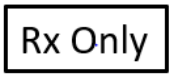
PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 6

DEVICE(S): All Ocular Surgical Lenses with Lumens and Lumen accessories

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. • 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 and lumens. • 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, 2, 3]. 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 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. • 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. Flush all lumens with detergent solution to remove soil. 3. Thoroughly rinse lens and flush lumens 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, 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: 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 3)*** Prep: Rinse devices with sterile water. Place product in sterilization case. *Pre-Vacuum Cycle (wrapped/unwrapped)* Temperature: 270°F (132°C) minimum Time: 4 minutes minimum Dry Time: 20 minutes minimum **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 Vitrectomy Lenses to air cool. Rapid cooling as in cool water rinse may fracture the lens. **STERRAD 100NX: Standard Cycle** ***(See Note 1 & 2 for all Sterrad)*** 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). **Steris V-Pro Max: Lumen cycle | Steris V-Pro 60: Lumen cycle** ***(See note 1)*** Follow Steris instructions. All models not compatible with: OHBVE, OHFVE, OHMVE, OHWVE, OCTK-6.5 **STERIZONE® VP4 Sterilizer Low Temperature Sterilization System – <u>Cycle 2 Only</u>** ***(See note 1)*** Follow **STERIZONE® VP4 Sterilizer** Low Temperature Sterilization System instructions. Not compatible with: OCTK-6.5 **These devices are not compatible with the following:** **-STERRAD NX: Standard Cycle | STERRAD 100S, 200: Short Cycle | STERRAD 50** **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. **3.** Devices containing coated mirrored surfaces may exhibit minor accumulative changes with repeated cycling. 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:	**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 (e.g. Asepti-Wipe II, Cavicide, DisCide Ultra, Envirocide, Tristel Wipes System and Opti-Cide-3) and Medical disinfectant solutions such as Cidex OPA. 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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