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PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 4

English

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DEVICE(S): ALL Ocular Tonometers.

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. Sterilize all devices before surgery. Never soak in Acetone or Other Solvents. Reassemble after reprocessing but before use. In the absence of the O-ring, a false reading will occur. 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: Tonometers have a lifetime of 5 years. After a period of 2 years of purchase, check for the following: Any visual damage. Easy gliding and turning without any resistance. No complete rip of the white 'O' type joint ring. Scratches on applanation (contact surface). Complete visibility of engraved white ring on the applanation (contact) surface. Contact customer service for any such concern. NOTE: Cosmetic changes such as slight discoloration and rings from water spotting can occur even with the shorter steam autoclave cycles that we recommend. These cosmetic issues do not affect the function of the Tonometer.
INSTRUCTIONS - POINT OF USE: Rinse: Immediately upon removal from patient's eye, thoroughly rinse in cool or tepid water.
PREPARATION FOR DECONTAMINATION: Reprocess all devices as soon as reasonably practical following use. See specific Product Sheets for disassembly/reassembly instructions.
CLEANING AUTOMATED: Not recommended.
CLEANING MANUAL: Disassemble lens and place a few drops of low foaming mild soap (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. Thoroughly rinse lens in cool or tepid high purity water (at least 100 milliliters) for 1 minute. Carefully dry with a non-linting tissue or hospital grade compressed air. 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. 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.

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PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 4 (cont.)

STERILIZATION: STEAM AUTOCLAVE - Place all three parts in a tray taking care to protect the tonometer from damage by contact with other instruments. Note: Force from contact with tray, lid or other devices will damage the lens and void warranty. Pre-Vacuum Cycle (wrapped/unwrapped): Temperature: 270°F (132°C). Time: 4 minutes. Dry Time: 20 minutes. Or. Temperature: 273°F (134°C). Time: 3 minutes. Dry Time: 20 minutes. Gravity Cycle (unwrapped): Temperature: 270°F (132°C). Time: 4 minutes min. No Dry Time. WARNING: REMOVE PROMPTLY, longer exposures will damage lens. The intense heat for an extended time will cause the plastic to cloud. Reassemble before use. In the absence of the ring, a false reading will occur. 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. EO (ethylene oxide): Minimum Time: 1 hour. Temperature: 130°F (54°C). Aerations Time: 12 Hours. Concentration: 600mg/L. Humidity: 100%. Steris SYSTEM 1E. Follow Steris Instructions. STERIZONE® VP4 Sterilizer Low Temperature Sterilization System – Cycle 1 (See note 1). Follow STERIZONE® VP4 Sterilizer Low Temperature Sterilization System instructions. Notes: Colored aluminum will fade to a natural aluminum color within 25 cycles. Devices will have limited life after 10 cycles. 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.
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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