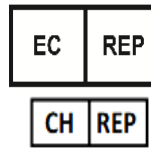




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PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 2

English

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DEVICE(S): All Ocular MaxField® Glass and MaxLight® CR-39 Indirect Diagnostic/Laser Lenses **NOTE:** See *Cleaning Method 3* for OI-20A, OI-20AS, and OI-28A.

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. Rapid cooling may damage devices.

POINT OF USE: Clean with alcohol wipe.

PREPARATION FOR DECONTAMINATION: Reprocess all devices as soon as reasonably practical following use.

CLEANING: AUTOMATED: Not recommended.

CLEANING MANUAL: 1) Clean with alcohol wipe. 2) Proceed with either disinfection or sterilization instructions.

DISINFECTION AUTOMATED: Not recommended.

DISINFECTION: 1) Perform manual cleaning per instructions. 2) Choose one of the following: Disinfectant Cidex, Activated Glutaraldehyde Solution or Steris Revital-Ox Resert (*Not compatible with OI-120M, OI-60M, OI-66M, OI-HM-78M, OI-78M, and OI-SP*). See manufacturer's instructions for Concentration and Contact Time. 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.

CAUTION: To avoid damage to the lens, do not exceed recommended exposure time.

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: 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. Not compatible with MaxLight CR-39 Indirects. Steris V-Pro maX: Lumen cycle & Non Lumen cycle | Steris V-Pro maX 2: Lumen, & Non Lumen cycle | Steris V-Pro 60: Lumen & Non Lumen cycle | Steris V-Pro s2: Lumen, & Non Lumen cycle (*See note 1*) Follow Steris instructions. Not compatible with: MaxLight CR-39 Indirects. STERIZONE® VP4 Sterilizer Low Temperature Sterilization System – Cycle 1(*See Note 1*) Follow STERIZONE® VP4 Sterilizer Low Temperature Sterilization System instructions. **NOTE:** 1. Colored aluminum will fade to a natural aluminum color within 25 cycles.

STORAGE: Ensure devices are cleaned, disinfected and dry before storage. Store in a clean and dry room temperature environment.

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.