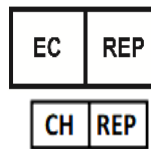




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## PRODUCT CARE INSTRUCTIONS: CLEANING METHOD 1

### English

## 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.\* 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. **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:** 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 OMRA-WFEX, OG4MG All types, OG3MHD All types, OLIV-WFNA, OLIV-EQNA, OWIV-HMNA, & OIV-132*). 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.* **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 - \*Note:** Devices containing Grey paint will have limited life after 25 cycles.: Follow Steris Instructions (not compatible with OMRA-HM, OMRA-HM-2).

**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](http://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.