

REPROCESSING INSTRUCTIONS FOR NON-POWERED INSTRUMENTS

GENERAL COMMENTS

The following are instrument care instructions for all reusable medical devices supplied by Bausch + Lomb, unless different instructions are supplied with the device.

The following instructions have been validated by Bausch + Lomb as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the facility to achieve the desired results. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and sterilization processes require validation at the point of use. Their effectiveness will depend on many factors and it is only possible to provide general guidance on proper device cleaning and sterilization.

Products unless stated otherwise are supplied from Bausch + Lomb in a non-sterile state and are not to be used without being cleaned, disinfected and sterilized.

These instructions are intended for use only by persons with the required knowledge and training.

Cleaning and Disinfecting Processing Equipment should be qualified and validated to ensure suitability for its intended purpose.

WARNINGS

- Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage the instrument.
- Do not process microsurgical instruments in an automated washer unless it has a delicate cycle.
- Do not process powered instruments in an ultrasonic cleaner.
- Do not process single use instruments.
- Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.
- Long narrow cannulations and blind holes require particular attention during cleaning.
- Do not use this procedure for diamond knives.

LIMITATIONS ON REPROCESSING

Reprocessing according to the instructions provided below should not adversely affect the functionality of instruments. The useful life of the instrument is determined by wear and damage during use.

INSTRUCTIONS

Point of Use

- Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
- The instrument should be kept moist to prevent soil from drying on the instrument.

WARNING: Do not soak instruments in solutions containing chlorine or chlorides as these may cause corrosion and damage the instrument.

WARNING: Single use instruments should not be reprocessed.

Containment and Transport

- The instruments should be reprocessed as soon as possible.
- The instruments should be placed in a suitable container to protect personnel from contamination during transport to the decontamination area.

Preparation for Decontamination and Cleaning

Universal precautions should be followed including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to your institution's policies.

Automated Cleaning and Thermal Disinfection

WARNING: Do not process microsurgical instruments in an automated washer unless it has a delicate cycle.

- Follow the instructions of the washer manufacturer.
- Use only neutral pH cleaning solutions.
- If gross soiling is evident on the instrument manual pre-cleaning with a neutral pH cleaning solution may be necessary.
- Ensure that any hinged instruments are open and that instruments with lumens can drain effectively. Where the washer has provisions for lumen adaptors these should be employed for lumened instruments.
- Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
- Process the instrument according to the conditions indicated below. The cleaning times and conditions may be adjusted based on the amount of soiling present on the instrument. The following conditions were validated using a neutral pH detergent (Getinge Neutrawash) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

| Phase | Time | Temperature |
|--------------------|---|----------------|
| Pre-Wash | 3 minutes | 30° C (86° F) |
| Wash ¹ | 10 minutes | 40° C (104° F) |
| Wash ¹ | 10 minutes | 30° C (86° F) |
| Rinse | 3 minutes | 30° C (86° F) |
| Heated Final Rinse | 50 minutes at 80° C (176° F) or 10 minutes at 90° C (194° F) ² | |
| Drying | By observation – Do not exceed 110° C (230° F) ³ | |

¹Neutral pH detergent: Adjust concentration according to the detergent manufacturer's directions regarding water quality and the extent of instrument soiling.

²Minimum exposure conditions for thermal disinfection.

³As cleaning frequently involves mixed instrument loads, the efficacy of drying will vary based on the equipment and the nature and volume of the load being processed. Therefore, the drying parameters must be determined by observation.

- Following processing carefully inspect the instrument for cleanliness, any evidence of damage, and proper operation. If visible soil remains on the instrument following processing it should be reprocessed or manually cleaned.

Manual Cleaning

- Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.
- Pre-rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.
- Place the instrument into a suitable clean basin filled with fresh neutral pH cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. The following conditions were validated using a neutral pH detergent (Steris ProKlenz NpH) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).
- Using a soft cleaning brush gently scrub all surfaces of the instrument while keeping the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
- Rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument and the amount of soil.
- Place the instrument in an ultrasonic bath filled with fresh neutral pH cleaning solution and sonicate for 5 minutes. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that the instrument is fully immersed in the cleaning solution. Do not overload the ultrasonic bath or allow instruments to contact one another during cleaning. Do not process dissimilar metals in the same ultrasonic cleaning cycle.

WARNING: Do not process powered instruments in an ultrasonic cleaner.

- The cleaning solution should be changed before it becomes visibly soiled. The ultrasonic bath should be drained and cleaned each day it is in use or more frequently if visible soiling is evident. Follow the instructions of the manufacturer for the cleaning and draining of the ultrasonic bath.
- Repeat steps 4-6 as necessary if visible soil remains on the instrument.
- Rinse the instrument by holding it under warm (27° C – 44° C/80° F – 111° F) running water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water. Additional rinsing may be necessary depending on the size of the instrument.
- If the instrument has lumens the lumens should be flushed using a syringe filled with 50cc of warm distilled or deionized water using a stopcock as follows:
 - Place syringe tip into a beaker of warm (30° C – 40° C/86° F – 104° F) distilled or deionized water and fill to the 50cc mark.
 - Connect the end of the syringe to the center stopcock fitting.
 - Rotate the stopcock lever to the male luer fitting (irrigation) or to the female luer fitting (aspiration) to allow fluid flow to the appropriate luer fitting.
 - Connect the stopcock to the appropriate luer connector on the instrument.
 - Push on the syringe plunger to force fluid through the lumen into another beaker for proper disposal. Do not draw flushing fluid back through the lumen. Disconnect the syringe. Disconnect the syringe/stopcock from the instrument.
 - Repeat steps A-E at least three times, for each lumen.
 - Fill the syringe with 50cc of air, reattach the stopcock, and push on the plunger to force air through each lumen. Disconnect the syringe/stopcock from the instrument.

NOTE: The CX7120 Universal Maintenance Kit contains a syringe and stopcock suitable for cleaning instrument lumens.

- Immerse the instrument in clean basin containing fresh deionized or distilled water and soak the instrument for at least three minutes.
- Immerse the instrument in second clean basin containing fresh deionized or distilled water and soak for at least three minutes.
- Perform a final rinse of the instrument with sterile distilled or deionized water for at least 30 seconds, rotating the instrument to expose all surfaces and cavities to flowing water.

Disinfection

Due to the potential for residual chemicals to remain on the instrument and cause an adverse reaction Bausch + Lomb does not recommend the use of liquid chemical disinfectants or sterilants with instruments. See Automated Cleaning and Thermal Disinfection above for procedures for thermal disinfection of instruments in an automated washer/disinfecter.

Drying

Carefully dry the instrument with a lint free surgical wipe or blow the instrument dry with micro filtered forced air.

Maintenance, Inspection and Testing

Following cleaning inspect the instrument to ensure that all visible soil has been removed and that the instrument operates as intended.

Packaging

Package the instrument in a suitable sterilization pouch or instrument tray.

Sterilization

Unless otherwise indicated in the Directions for Use provided with the specific instrument, instruments and instrument trays may be sterilized by the following moist heat (steam) sterilization methods:

- Pre-vacuum High Temperature Autoclave: 274° F (134° C) for 3 minutes; wrapped.
- NOTE:** As per ANSI/AAMI ST79:2010 and A1:2010 270° F (132° C) for 4 minutes and 275° F (135° C) for 3 minutes are acceptable minimum cycle times for dynamic-air-removal steam sterilization cycles.
- Standard Gravity Autoclave: 250° F/15.2 psi (121° C/104.8kPa [1.048 bar]) for 30 minutes; wrapped.
- High Speed (Flash) Autoclave: 270° F/27.1 psi (132° C/186.8kPa [1.868 bar]) for 10 minutes; unwrapped, but covered.
- High Vacuum (Pre-vacuum) Autoclave: 274° F/30.0 psi (134° C/206.8kPa [2.068 bar]) for 3 minutes.

WARNING: Instruments processed in a wrapped instrument tray should be placed within the tray in a manner that allows steam to contact all surfaces of the instrument. Do not pile instruments on top of each other as this may block steam penetration and condensate drainage. Do not overload the tray. Heavily loaded instrument trays should be processed by high temperature pre-vacuum steam sterilization.

WARNING: Flash sterilization processing should be reserved for emergency reprocessing only and should not be employed for routine sterilization processing of the instrument. Flash sterilized items should be used immediately, and not stored for later use. See ANSI/AAMI ST79:2010 and A1:2010 and your institution's policies for restrictions regarding the use of flash sterilization.

WARNING: Single use instruments should not be reprocessed.

The instrument and/or instrument tray should be processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.

Storage

Following sterilization processing packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your institution's policies.

ADDITIONAL INFORMATION

- For additional information regarding the reprocessing of instruments and information regarding the reprocessing of diamond knives and other specialty instruments see <http://www.storzeye.com/instrument-care>
- For information on cleaning powered instruments consult the Instrument's Owner's Manual.
- For additional information regarding the reprocessing of ophthalmic instruments see:
 - ASCRS/ASORN Special Report Recommendations for the cleaning and sterilization of intraocular cataract surgical equipment. J. Cataract Refract Surg. 2007; 33(6):1095-1100.
 - ANSI/AAMI ST79:2010 and A1:2010 Comprehensive guide to steam sterilization and sterility assurance.

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