

nature and volume of the load being processed. Therefore, the drying parameters must be determined by observation.

7. 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

WARNING: All detergents must be completely rinsed from the instrument before use or further processing.

WARNING: Follow the manufacturer's instructions regarding use of suitable personal protective equipment (gloves, face shield, apron, etc.) when handling detergents according to your institution's policies.

WARNING: Be certain to observe any national or local regulations or guidelines and your institution's policies regarding the reprocessing of ophthalmic surgical instruments.

WARNING: Observe the detergent manufacturer's recommendations regarding the compatibility of the detergent with the materials of construction of surgical instruments. The use of an inappropriate detergent or neutralizing agent may damage the instrument and cause harm to the patient.

1. Disassemble the instrument as applicable and inspect the instrument for damage or corrosion.

2. Pre-rinse the instrument by holding it under cold running tap 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.

3. The following conditions were validated using an alkaline pH detergent (Dr. Weigert neodisher Mediclean forte; pH 10.4 – 10.8) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007; 41(4):324-331). Storz™ Ophthalmic Instruments are compatible up to a pH of 10.8 when the detergent is completely rinsed from the instruments as indicated below. The use of other alkaline cleaning solutions may be acceptable. This must be determined by the user.

4. Place the instrument into a suitable clean basin filled with fresh alkaline 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

5. 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. Thoroughly clean and sterilize the cleaning brush according to the directions provided by the manufacturer of the cleaning brush and your institution's policies.

6. Rinse the instrument by holding it under cold running tap 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.

7. Place the instrument in an ultrasonic bath filled with fresh alkaline 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 Storz™ Ophthalmic Instruments in an ultrasonic cleaner.

8. 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.

9. Repeat steps 5-7 as necessary if visible soil remains on the instrument.

10. Rinse the instrument by holding it under warm (27°C – 44°C; 80°F to 100°F) running tap 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.

11. 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 – 40°C/85-105°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.

d. Connect the stopcock male Luer fitting (irrigation) or female Luer fitting (aspiration) to the appropriate lumen on the instrument.

e. 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.

f. Repeat steps A-E at least three times, for each lumen.

g. Fill the syringe with air, reattach the stopcock, and push on the plunger to force air through each lumen. Disconnect the syringe/stopcock from the instrument.

NOTE: The Storz™ CX7120 Universal Maintenance Kit contains a syringe and stopcock suitable for cleaning the lumens of Storz® Ophthalmic Instruments.

12. Immerse the instrument in clean basin containing fresh deionized or distilled water and soak the instrument for at least three minutes.

13. Immerse the instrument in second clean basin containing fresh deionized or distilled water and soak for at least three minutes.

14. 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.

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 and is suitable for its intended use. The use of a suitable magnifying device (1.5 X or greater) is recommended for visual inspection.

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, Bausch + Lomb Storz™ Ophthalmic Instruments and Instrument Trays may be sterilized by the following moist heat (steam) sterilization methods:

- Prevacuum High Temperature Autoclave: 274°F (134°C) for 3 minutes; wrapped.
- Prevacuum High Temperature Autoclave: 274°F (134°C) for 5 minutes; wrapped
- Prevacuum High Temperature Autoclave: 274°F (134°C) for 18 minutes; wrapped
- Standard Gravity Autoclave: 250°F (121°C) for 30 minutes; wrapped.

WARNING: Single use instruments should not be reprocessed. The exposure times and temperatures specified are minimum requirements. 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 Storz™ Ophthalmic Instruments see <http://www.storzeye.eu>

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