

**REPROCESSING INSTRUCTIONS FOR STORZ[®]
NON-POWERED SURGICAL INSTRUMENTS
(OUTSIDE OF THE UNITED STATES)**

GENERAL COMMENTS

The following are instrument care instructions for all reusable Bausch + Lomb Storz[®] surgical instruments unless different instructions are supplied with the device.

The following instructions have been validated by Bausch & Lomb Incorporated as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the facility 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 Incorporated 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 specialist 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 powered Storz[®] Ophthalmic instruments in an ultrasonic cleaner.
- Do not reprocess single use instruments.
- 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 Storz[®] surgical instruments. The useful life of the instruments is determined by wear and damage during use.

**ADDITIONAL REPROCESSING INSTRUCTIONS
(OUTSIDE OF THE UNITED STATES)**

National and local guidelines for reprocessing ophthalmic surgical instruments vary by region. The following reprocessing instructions have been validated by Bausch + Lomb and may be applied as appropriate to the user's needs. The user should consult their institution's policies and national and local guidelines regarding the reprocessing of ophthalmic surgical instruments to determine the applicability of the following reprocessing instructions. It is the user's responsibility to ensure compliance with their institution's policies and national and local guidelines regarding the reprocessing of ophthalmic surgical instruments.

INSTRUCTIONS

POINT OF USE

- Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe as soon as possible.
- If possible, the instruments should be rinsed immediately after use by holding them under cold running tap water for at least 30 seconds, rotating the instruments to expose all surfaces and cavities to flowing water.
- The instruments should be kept moist following use 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.

DISINFECTION

WARNING: All disinfecting agents must be completely rinsed from the instrument and its lumens before use or further processing. Failure to adequately rinse chemical disinfecting agents from the instrument before use or further processing may

cause a severe ophthalmic reaction and inflammation.

WARNING: Do not use disinfectants containing glutaraldehyde, aldehydes or other protein cross-linking agents.

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

WARNING: Follow national and local regulations or guidelines and your institution's policies regarding the disinfection of ophthalmic surgical instruments and the use and handling of disinfectants.

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

1. Follow the instructions of the disinfectant manufacturer for the preparation of the disinfecting agent and the required water quality.

2. For the purposes of disinfection and transport Storz[®] Ophthalmic Instruments may be immersed in a suitable disinfectant solution compatible with the material properties of the instruments such as Dr. Weigert neodisher Septo PreClean (pH 12). Follow the instructions of the disinfectant manufacturer regarding immersion time and temperature, duration of use, and disposal of the disinfecting solution.

3. Following immersion in the disinfectant solution 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. Process the instrument by manual or automated cleaning as indicated below.

4. If the instrument is not to be further processed by automated or manual cleaning rinse the instrument for at least 60 seconds by holding it under warm (27°C – 44°C; 80°F to 100°F) running tap water, rotating the instrument to expose all surfaces and cavities to flowing water, followed by a 30 second rinse with distilled or deionized water.

CONTAINMENT AND TRANSPORT

- The instruments should be reprocessed as soon as possible.
- The instruments should be placed in a suitable covered puncture proof container to protect personnel from contamination and to keep the instruments moist during transport to the decontamination area. The container should be labeled in accordance with local procedures.

PREPARATION FOR DECONTAMINATION AND CLEANING

WARNING: Universal precautions should be followed including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to the manufacturer's directions and your institution's policies, particularly with regard to the handling and use of alkaline and acid cleaning solutions.

AUTOMATED CLEANING AND THERMAL DISINFECTION

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

WARNING: All detergents and neutralizing agents 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 and neutralizing agents 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/neutralizing agent 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. Follow the instructions of the washer manufacturer.
2. If gross soiling is evident on the instrument manual pre-cleaning may be necessary.
3. 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.
4. Place the instruments in suitable carriers such that they are not subject to excessive jostling or contact with other

instruments.

5. 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 combination of an alkaline pH detergent (Dr. Weigert neodisher Mediclean forte; pH 10.4 – 10.8) and an acid neutralization agent (Dr. Weigert neodisher Z; pH 2.6 – 3.0) and a severe organic soil challenge (BS 2745: Part 3:1993). Validation testing was performed in a Getinge 4656 washer disinfector equipped with lumen adaptors. The use of other automated washer disinfectors and alkaline/acid cleaning solutions may be acceptable. This must be determined by the user.

WARNING: Universal precautions should be followed including the use of suitable personal protective equipment (gloves, face shield, apron, etc.) according to the manufacturer's directions and your institution's policies, particularly with regard to the handling and use of alkaline and acid cleaning solutions.

PHASE	TIME	TEMPERATURE
Pre-Wash	3 minutes	30°C (86°F)
Alkaline Wash ¹	10 minutes	55°C (131°F)
Neutralization ¹	1.5 minutes	50°C (122°F)
Rinse	5 minutes	30°C (86°F)
Purified Water 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	

¹ Alkaline cleaning agent/Acid neutralizing agent - Adjust concentration according to the detergent manufacturer's directions, water quality and the extent of instrument soiling.

² Minimum exposure conditions for thermal disinfection. Higher thermal disinfection temperatures may be employed as appropriate to realize the desired thermal disinfection conditions.

³ As 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.

6. Neutral pH cleaning agents. The following conditions were validated using a neutral pH detergent solution (Getinge Neutrawash) and a severe organic soil challenge (Biomedical Instrumentation and Technology 2007; 41(4):324-331). Validation testing was performed in a Getinge 4656 washer disinfector equipped with lumen adaptors. The use of other automated washer disinfectors and neutral pH cleaning solutions may be acceptable. This must be determined by the user.

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

PHASE	TIME	TEMPERATURE
Pre-Wash	3 minutes	30°C (86°F)
Wash 1 ¹	10 minutes	40°C (104°F)
Wash 2 ¹	10 minutes	30°C (86°F)
Rinse	5 minutes	30°C (86°F)
Purified Water 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	

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

² Minimum exposure conditions for thermal disinfection. Higher thermal disinfection temperatures may be employed as appropriate to realize the desired thermal disinfection conditions.

³ As 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.

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>

MANUFACTURER CONTACT

 Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA



Bausch & Lomb Incorporated
106 London Road
Kingston-upon-Thames
KT2 6TN, UK

Storz is a registered trademark of Bausch & Lomb Incorporated or its affiliates.
All other product/brand names are trademarks of their respective owners.
© Bausch & Lomb Incorporated.
4118100

CE 0197