storz Ophthalmic Instruments

BAUSCH+LOMB Instruments Ear, Nose, Throat & Plastic Surgery

Irrigating Cannula Handpiece - MVS 1022

REPROCESSING INSTRUCTIONS

GENERAL COMMENTS

The following instructions have been validated by Bausch + Lomb as being CAPABLE of preparing a medical device for use in accordance with the responsibility of the processer to achieve the desired results. Effectiveness of cleaning using equipment, materials and personnel in the facility is under the desired results. This requires validation and routine monitoring and control. Likewise, any deviation by the processer from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and disinfection processes require validation at the point of use. These effectiveness will depend on many factors, and it is only possible to provide general guidance on proper, effective cleaning and sterilization. Products, unless stated otherwise, are supplied from Bausch + Lomb in a non-sterile state and are not to be considered sterile unless specified as such. If 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.

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

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

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

WARNING: Do not process single-use instruments.

WARNING: Flash sterilization procedures are reserved for emergency reprocessing only and should not be employed for routine sterilization of patient care items. Flash sterilized items should not be employed for routine sterilization and should be used immediately after the flash cycle. See AAMI/ANSI ST79, current revision, and your institution's policies for restrictions on flash sterilization.

WARNING: Long narrow cannulations and blind holes require particular attention during cleaning.

WARNING: Do not use this procedure for diamond knives.

LIMITATIONS TO 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 corrode 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, 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.

1. Follow the instructions of the washer manufacturer.
2. Use only neutral pH cleaning solutions.
3. If gross soiling is evident on the instrument, manual pre-cleaning with a neutral pH cleaning solution may be necessary.
4. Ensure that any hinged instruments are open and that instruments with lumens can drain effectively. Where the washer has provisions, ensure that lumens are irrigated with the appropriate adapters.
5. Place the instruments in suitable carriers such that they are not subject to excessive movement or contact with other instruments.
6. Process the instruments according to the conditions indicated below. The cleaning times and conditions may be adjusted based on the amount of soiling present on the instruments. The following conditions were validated using a neutral pH cleaning agent (Terg-A-Zyme) and a seven organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).

Phase	Time	Temperature
Pre-Wash	2 minutes	30°C (86°F)
Wash*	10 minutes	40°C (104°F)
Wash*	10 minutes	30°C (86°F)
Rinse	1 minutes	30°C (86°F)
Heated Final Rinse	5 minutes at 93°C (199°F) or 10 minutes at 90°C (194°F)	
Drying	By observation – Do not exceed 110°C (230°F)	

*Neutral pH detergent: Adjust concentration according to the detergent manufacturer's directions regarding water quality, soil load, and cycle length.

Minimum exposure conditions for thermal disinfection.

To cleaning frequently involve instruments with lumens, the efficacy of drying will vary based on the equipment and the nature and volume of the load being processed. Therefore, the drying parameters may need to be adjusted.

WARNING: Following processing, carefully inspect the instrument for cleanliness, any evidence of damage, and proper operation. If soiled or defective, return the instrument following processing, it should be reprocessed or manually cleaned.

Manual Cleaning

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 water for at least 30 seconds, rotating the instrument and flushing all surfaces and cavities to flushing out visible soil. Soaking may be necessary depending on the size and extent of soiling of the instrument.
3. Place the instrument into a suitable clean bowl filled with fresh water and prepared cleaning solution prepared according to the directions of the solution manufacturer. Use only cleaning solutions that are compatible with the instrument. Ensure that the instrument is fully immersed in the cleaning solution. The following conditions were validated using a neutral pH detergent (Terg-A-Zyme) and a seven organic soil challenge (Biomedical Instrumentation and Technology 2007;41(4):324-331).
4. Using a soft cleaning brush, gently scrub all surfaces and crevices while immersed in the instrument submerged in the cleaning solution for at least 5 minutes. Clean the instrument until all visible soil has been removed.
5. Rinse the instrument by holding it under cold running water for at least 30 seconds, rotating the instrument to expose all surfaces to flowing water. Manual flushing may be necessary depending on the size of the instrument and the amount of soil.
6. Place the instrument in an ultrasonic bath filled with fresh water and prepared cleaning solution and sonicate for 5 minutes. Use only cleaning solutions that are labeled for use with medical devices or surgical instruments. Ensure that instrument is fully immersed in the cleaning solution. Do not overheat 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.

7. 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 soiled is evident. Follow the instructions of the manufacturer for the care and cleaning of the ultrasonic bath.
8. Repeat steps 4 & 5 as necessary if soil is still present.
9. Rinse the instrument by holding it under warm (27°to 44°C/80° to 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.
10. The lumens should be flushed using a syringe filled with 50cc of water dedicated to manual water using a stopcock as follows:
   a. Place syringe tip into a beaker of warm (30° to 40°C/86° to 104°F) distilled or deionized water and fill to the 50cc mark.
   b. Connect the end of the syringe to the center stopcock fitting.
   c. Rotate the stopcock lever to the main luer fitting (irrigation) or to the female luer fitting (aspiration) to allow fluid to flow from the syringe into the lumen.
   d. Connect the stopcock to the appropriate luer connector on the instrument.
   e. Push on the syringe plunger to flush the lumen. Repeat the process flushing the lumen until the proper dispensed. Do not down flushing fluid back through the lumens. 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 50cc of air and repeat the flush, and push on the plunger to force air through each lumen. Disconnect the syringe/stopcock from the instrument.

NOTE: The 27/30 Luer Stopcock Adapter (REF 1022-SA) is a useful accessory for cleaning instrument lumens.

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

Lubrication

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 lubricants or disinfectant or sterilants with instruments. See Automated Cleaning and Thermal Disinfection above for procedures for the disinfection of instruments in an automated washer/disinfector.

Drying

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

Maintenance, Inspection and Testing

Clean, lubricate, 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, Central Supply Room (CSR) wrap or rigid container.

Sterilization

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

- Pre-vacuum (High Temperature Steam) 132°C (270°F) for 4 minutes; wrapped.
- Standard Gravity Autoclave: 121°C (250°F) for 30 minutes; wrapped.
- High Speed (Flash) Autoclave: 132°C (270°F) for 3 minutes; unwrapped but covered.

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 instruments. Do not pile instruments on top of each other as this may block steam penetration and undermate drainage. Do not overload the tray. Heavily loaded instrument trays should be processed by high temperature pre-vacuum steam sterilization.

Flash (Immediate Use Steam) Sterilization: Flash sterilization processing should be used for emergency reprocessing only and should not be employed for routine processing of the instrument. Instruments processed by flash sterilization should be processed individually or in trays specifically designed for use with flash sterilization. Flash sterilized items should not be stored for later use. Follow manufacturer's instructions. See AAMI/ANSI ST79, current revision, and your institution's policies for restrictions regarding the use of flash sterilization.

WARNING: Single-use instruments should not be reprocessed.

WARNING: The instrument and/or instrument tray must be identified with a sterilization indicator.

WARNING: Sterilizing instruments in a closed container will result in sterilization failure

Χρησιμοποιείτε μόνο Αυτόκλειστο Γκέλας, Υπεξάλωσης από τη Βίωση και Ρύθμιση Θερμοκρασίας.

WARNING: Σφραγίστε τον δοκιμαστικό δίσκο Γκέλας Υπεξάλωσης από τη Βίωση μόνο αφού τοποθετήσετε τον δοκιμαστικό δίσκο Γκέλας Υπεξάλωσης από τη Βίωση στο αυτόκλειστο.

WARNING: Μη χρησιμοποιείτε τον δοκιμαστικό δίσκο Γκέλας Υπεξάλωσης από τη Βίωση εάν παρουσιάζει ρωγμές ή φθορές.

WARNING: Μη χρησιμοποιείτε τον δοκιμαστικό δίσκο Γκέλας Υπεξάλωσης εάν δεν τοποθετηθεί σωστά στο αυτόκλειστο

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INSTRUCȚIUNI DE UTILIZARE

Instrucțiuni de utilizare și de siguranță

Citiți cu atenție instrucțiunile de utilizare și de siguranță înainte de prima utilizare a produsului. Păstrați instrucțiunile de utilizare și de siguranță pentru o utilizare ulterioară. Respectați toate avertismentele și instrucțiunile de siguranță. Dacă nu respectați avertismentele și instrucțiunile de siguranță, poate apărea o electrocutare, un incendiu și/sau o rănire gravă. Nu folosiți niciodată produsul dacă acesta este deteriorat sau dacă unele componente ale produsului sunt deteriorate. Dacă aparatul sau cablul de alimentare este deteriorat, acesta trebuie înlocuit de producătorul sau de un specialist calificat pentru a evita orice pericol.

Utilizarea conformă cu destinația

Acest produs este destinat numai pentru uz casnic și nu este destinat pentru uz în spații comerciale. Produsul este destinat numai pentru uz în interior. Nu folosiți produsul în alte scopuri decât cele menționate în prezentele instrucțiuni de utilizare și de siguranță. Nu folosiți produsul în aer liber. Nu folosiți produsul în spații umede, de exemplu în apropierea unei piscine sau a unei cabine de duș. Nu folosiți produsul în spații cu pericol de explozie.

Siguranța copiilor și persoanelor vulnerabile

Produsul nu este o jucărie pentru copii. Nu lăsați ambalajul produsului la îndemâna copiilor. Ambalajul poate deveni periculos în mâinile unor persoane care se joacă cu acesta. Nu lăsați copiii fără supraveghere în apropierea produsului. Nu permiteți persoanelor care au o capacitate redusă de a percepe pericolele sau care au o capacitate redusă de a se proteja de pericole (de exemplu persoanele cu dizabilități fizice, senzoriale sau mintale) sau persoanelor care nu au experiență și cunoștințe în ceea ce privește utilizarea produsului, dacă nu sunt supravegheate de o persoană responsabilă care le-a oferit instrucțiuni privind utilizarea produsului și care este responsabilă de siguranța acestora. Nu lăsați ambalajul la îndemâna copiilor. Ambalajul poate deveni periculos în mâinile unor persoane care se joacă cu acesta.

Siguranța la utilizare

Nu folosiți niciodată produsul dacă acesta este deteriorat. Dacă aparatul sau cablul de alimentare este deteriorat, acesta trebuie înlocuit de producătorul sau de un specialist calificat pentru a evita orice pericol. Nu folosiți niciodată produsul dacă unele componente ale produsului sunt deteriorate. Nu folosiți niciodată produsul dacă este ud. Nu folosiți niciodată produsul în apropierea unei piscine sau a unei cabine de duș. Nu folosiți niciodată produsul în spații cu pericol de explozie. Nu folosiți niciodată produsul în alte scopuri decât cele menționate în prezentele instrucțiuni de utilizare și de siguranță. Nu folosiți niciodată produsul în aer liber. Nu folosiți niciodată produsul în spații umede, de exemplu