storz Ophthalmic Instruments | BAUSCH+LOMB Instruments Ear, Nose, Throat & Plastic Surgery

Angled Hydrodissection Cannula 27 Gauge - E405

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. Proper cleaning and sterilization using equipment, materials and personnel in the facility is the responsibility of the processer. 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 sterilization 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 device cleaning and sterilization. Products, unless stated otherwise, are supplied from Bausch + Lomb in a non-sterile state and are not to be considered sterile (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 procedures should be reserved for emergency reprocessing only and should not be employed for routine sterilization. Flash sterilization is not recommended for implants and may not be appropriate for other items that are to be held for later use. See AAMI/ANSI ST79, current revision, and your institution's policies for restrictions and limitations on flash sterilization.
- Long narrow cannulations and blind holes require particular attention during cleaning.
- Do not use this procedure for diamond lenses.

LIMITATIONS/RESTRICTIONS

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 to instruments.

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 for lumened instruments.
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 (Tergazyme®) 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 and soil challenge. Use 100% fresh water.
Minimum exposure conditions for thermal disinfection.
To cleaning frequently used instruments, monitor 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.

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

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. Additional rinsing may be necessary depending on the size and extent of soiling of the instrument.
3. Place the instrument into a suitable clean bowl or basin filled with fresh neutral pH 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 (Tergazyme®) 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 keeping 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. Additional rinsing 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 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 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 to 6 as necessary if visible soil remains on the instrument.
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. Ensure the instrument 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 in the desired direction.
   d. Connect the stopcock to the appropriate luer connector on the instrument.
   e. Push on the syringe plunger to flush the lumen. Repeat as needed to flush lumen beyond the proper disposal. Do not down flushing fluid back through the lumen. Disconnect the syringe. Disconnect the syringe 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, 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 (E2700) is a useful tool 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. Rinse the instrument with deionized or distilled 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 sprays on sterilizers 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 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 cycles:

- Pre-vacuum (High Temperature Autoclave: 132°C (270°F) for 4 minutes; wrapped.
- Standard Gravity Autoclave: 121°C (250°F) for 30 minutes; wrapped.
- Flash (Rapid) 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 instruments 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 be used immediately and not held for later use. 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 processed through a complete sterilization drying cycle as residual moisture from autoclaves can promote staining, discoloration, and rust.

WARNING: Although instruments have been validated to Type 1 (2°C Gravity, 30 Minute Full Cycle, the user must ensure that if using a sterilization tray, that instruments are not overloaded and that steam could reach all surfaces.

WARNING: Heat sensitive: Do not autoclave. Do not exceed 110°C (230°F) or 5 minutes. Silicone Tubing Tip Protectors should never be sterilized.

WARNING: Do not use chemicals to sterilize instruments or accessories.

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 disinfectant/cleaning agents and detergents, see http://www.storzinstrument.com/cleaning-care
- For information on cleaning powered instruments, consult the Instrument Owner's Manual.
- For additional information regarding the reprocessing of ophthalmic instruments, see: ASO05/ASO06 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, current revision, comprehensive guide to steam sterilization and sterility assurance.

ZAUJAMEMKA: Ninamapendekezo kwamba vifaa vinaweza kusafishwa CAFT/ZD (zinazoweza chemsha) ni mchanganyiko sawa, pudongzuo ya tovochaiwa na ya kimitambo ya kuondoa uchafu.

11. Tolmetre mpatanisha wa vitu vya, chakula, pokeza pokeza pokeza mpa ate detergent kuja, e kasoro ate mpatanisha wa vitu vya, chakula.
12. Tolmetre mpatanisha wa itua ntepe vaa't, chakula, pokeza pokeza pokeza ate detergent kuja, e kasoro ate mpatanisha wa vitu vya, chakula.
13. Ilatapata nuzolze ezizaawa ezizaawa na mpatanisha vitu zisetepa zisetapata ezizaawa ezizaawa ezizaawa ezizaawa na kuwa ezizaawa ezizaawa.

Dezinfekcja

Przed dezinfekcją należy przeprowadzić czyszczenie ręczne lub automatyczne.

UWAGA: Nie moczyć narzędzi w roztworach zawierających chlor lub chlorki.

1. Postępować zgodnie z instrukcjami producenta pralnio-myjki.
2. Stosować wyłącznie roztwory o obojętnym pH.
3. Jeśli na narzędziu widoczne są zanieczyszczenia, zanim zostanie umieszczone w pralnio-myjce zalecane jest ręczne wstępne czyszczenie roztworem o obojętnym pH.
4. Upewnić się, że narzędzia z zawiasami są otwarte i że narzędzia z prześwitem są w stanie efektywnie odprowadzać ciecze. Jeśli pralnio-myjka posiada odpowiednie wyposażenie, należy zadbać o płukanie prześwitu narzędzi z prześwitem.
5. Umieścić narzędzia w odpowiednich koszach, tak aby nie ulegały nadmiernemu ruchowi i nie dochodziło do ich wzajemnego kontaktu.
6. Narzędzia poddać przemianie cieplnej zgodnie z poniższymi parametrami. Czas i warunki mogą być zmodyfikowane w zależności od ilości zanieczyszczeń.
7. Po przeprowadzeniu czyszczenia dokładnie zbadać narzędzia pod kątem ich czystości, uszkodzeń, prawidłowego działania. Jeśli na narzędziu widoczne są zanieczyszczenia, narzędzie powinno zostać ponownie poddane procesowi czyszczenia lub ręcznie wyczyszczone.

Faza	Rodzaj	Temperatura
Przepłukanie wstępne	2 minuty	30°C (86°F)
Mycie*	10 minuty	40°C (104°F)
Mycie*	10 minuty	30°C (86°F)
Płukanie	1 minuty	30°C (86°F)
Końcowe gorące płukanie	5 minuty na 93°C (199°F) lub 10 minuty na 90°C (194°F)	
Suszenie	Przetrzymanie – nemoże przekroczyć 110°C (230°F)	

*pH neutralny detergent: Dostosować koncentrację zgodnie z zaleceniami producenta detergentu w zależności od jakości wody i zanieczyszczenia narzędzia. Minimalne wymogi ciśnienia i temperatury.
Zmniejszenie wydajności suszenia w zależności od rodzaju i ilości narzędzi może wymagać zmiany parametrów suszenia.

8. Zanieczyszczenia pozostałe po procesie należy usunąć ręcznie.
9. Ponownie przeprowadzić proces czyszczenia.

UWAGA: Nie przetwarzać narzędzi z prześwitem za pomocą ultradźwięków.

10. Stosować wyłącznie środki czyszczące przeznaczone do narzędzi medycznych lub chirurgicznych.
11. Zanieczyszczenia pozostałe po procesie należy usunąć ręcznie.
12. Ponownie przeprowadzić proces czyszczenia.
13. Ilatapata nuzolze ezizaawa na mpatanisha vitu vya, chakula, pokeza pokeza pokeza ate detergent kuja, e kasoro ate mpatanisha wa vitu vya, chakula.

Sterylizacja

Jeśli nie określono inaczej w instrukcjach dotyczących konkretnego instrumentu, narzędzia i tacze na narzędzia można sterylizować następującymi cyklami sterylizacji parowej (ciepłem wilgotnym):

- Autoklaw z grawitacyjnym usuwaniem powietrza: 121°C (250°F) 30 minut; owinięte.
- Standardowy grawitacyjny autoklaw: 121 °C (250 °F) 30 minut; owinięte.
- Autoklaw z wysokotemperaturowym usuwaniem powietrza: 132°C (270°F) 4 minuty; owinięte.
- Standardowy grawitacyjny autoklaw: 121 °C (250 °F) 30 minut; owinięte.
- Szybki (Natychmiastowy) autoklaw: 132°C (270°F) 3 minuty; nieopakowane, ale pokryte.

UWAGA: Narzędzie sterylizowane w opakowaniu powinno być ułożone w taki sposób, aby para wodna miała dostęp do wszystkich powierzchni narzędzia. Nie przeładowywać tacy z narzędziami. Tacy z ciężkim ładunkiem narzędziowym powinny być sterylizowane parowo z wysokotemperaturowym usuwaniem powietrza.

Sterylizacja szybkiego (natychmiastowego) parowa: Sterylizacja szybkiego powinna być stosowana wyłącznie w przypadkach nagłych i nie powinna być stosowana w rutynowej sterylizacji narzędzi. Narzędzia sterylizowane szybko powinny być przetwarzane indywidualnie lub w specjalnie przeznaczonych tacach do szybkiego sterylizowania. Produkty sterylizowane szybko powinny być natychmiast użyte i nie powinny być przechowywane. Sterylizacja szybka nie powinna być stosowana w celach rutynowych. Sterylizacja szybka nie powinna być stosowana w celach rutynowych. Sterylizacja szybka nie powinna być stosowana w celach rutynowych

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

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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