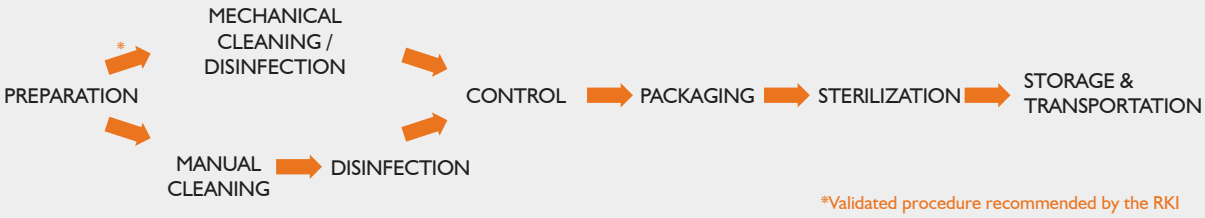
EN

Instructions for reprocessing (cleaning, disinfection and sterilization) of medical devices from Hager & Meisinger GmbH in accordance with DIN EN ISO 17664

85SH006 - EN1123



*Validated procedure recommended by the RKI

General information

AREA OF APPLICATION

This information applies in principle to all medical products in the Hager & Meisinger GmbH product range. Special features that only apply to individual items are indicated separately. Improper reprocessing can lead to patient infection. In addition, the functionality and service life of the product can no longer be guaranteed.

For the safe use of the products, please refer to the separately available application and safety instructions (see also www.meisinger.de). Please observe the product-specific information in the labeling and instructions for use (IFU) supplied with the product.

All items (reusable and disposable instruments) labeled as "non-sterile" are delivered non-sterile and must be processed according to the following instructions before first use. All reusable instruments must also be reprocessed after each further use.
Serious incidents that have occurred in connection with the device must be reported to the manufacturer and the competent authority of the Member State in which the user, patient and/or third parties are established.

PROCESS REQUIREMENTS

For cleaning, disinfection and sterilization, only sufficiently device- and product-specific validated procedures may be used. The washer-disinfector (WD) and sterilizer used must be regularly maintained and checked and the validated parameters must be adhered to for each cycle. The user must ensure that the reprocessing procedure (including resources, materials and personnel) is in place. If this is not the case, it is the user's responsibility to validate their process accordingly.

Notes on cleaning agents and disinfectants

For health and safety reasons, cleaning agents and disinfectants must be used that

- are aldehyde-free, especially for pre-cleaning (risk of fixing blood stains),
- should have proven efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance or CE marking),
- is suitable for cleaning and disinfecting the instruments and should be compatible with the instruments (see section "Material resistance").

Cleaning agents and disinfectants must be used strictly in accordance with the manufacturer's instructions (concentration, exposure time, etc.). Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or only filtered air (oil-free, low in germs and particles) for drying. Combined cleaning agents and disinfectants should not be used if possible.
A neutral enzymatic cleaner is recommended for manual cleaning.

The disinfectant used during pre-treatment is for personal protection and cannot replace the subsequent disinfection step to be carried out after cleaning.

Steam sterilization

1. The specified times and temperatures must not be undercut (minimum requirements). If a deviation downwards is necessary for procedural reasons, this is the sole responsibility of the user and must be validated by the user.
2. It is generally possible to exceed the specified times and temperatures. However, longer sterilization times and higher temperatures lead to increased stress on the material, which can have a negative impact on product life.
3. When using steam sterilizers, it must be ensured that sterilization steam without impurities is used.
4. The fractionated vacuum method with a steam sterilizer (in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 and validated in accordance with DIN EN ISO 17665) with sufficient product drying must be used for sterilization. Other sterilization methods must be validated by the user.

LIMITATION / RESTRICTIONS DURING REPROCESSING

The products must not be reprocessed in the original packaging of any kind.

Unless expressly stated otherwise, the products can be used multiple times. The product service life is generally determined by damage and signs of wear caused by use. The user alone is responsible for deciding on the frequency of use. In case of doubt, the products should always be sorted out and replaced at an early stage. The maximum number of validated reprocessing cycles is 100 cycles. Single-use articles (indicated ⊗ on the label) are not approved for reuse. If reused, the safety and performance of the products can no longer be guaranteed due to the risk of infection.
If a patient is diagnosed with a prion disease (e.g. Creutzfeld-Jakob disease), there is a potentially high risk of infection after a surgical procedure. The decision to reprocess and continue using the product is the sole responsibility of the user.

Material resistance

When selecting cleaning agents and disinfectants, please ensure that they do not contain the following ingredients:

- Organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- Strong alkaline solutions (maximum permissible pH value 11, neutral/enzymatic cleaner, slightly alkaline or alkaline cleaner recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzenes) - Oxidizing agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

When selecting detergents, please also take into account that corrosion inhibitors, neutralizing agents and/or rinse aids may leave critical residues on the instruments.
To prevent corrosion, the instruments should not be placed or temporarily stored in a NaCl solution.

Anodized aluminium bur block
Please pay attention to the suitability of the cleaning agent, it must be specifically suitable for aluminum.

Instruments made of tool steel (tungsten-vanadium)

- The instruments are not suitable for sterilization without appropriate pre-treatment.
- Instruments made of tool steel are not suitable for automated cleaning/disinfection.

For additional information on the procedure, please refer to the instructions on "Manual reprocessing of tool steel instruments from Hager & Meisinger GmbH" in the download area at www.meisinger.de

PLACE OF USE

Effective hygiene measures in accordance with country-specific requirements in the medical facility must be observed. Different specifications regarding effective prion inactivation (not applicable for the USA) must be observed.

Classification according to KRINKO BfArM

Uncritical Medical devices

Touch only with intact skin

uncritical

No special requirements for preparation

Semi-critical Medical devices

Contact with the mucous membrane or pathologically altered skin

Semi-critical A	Semi-critical B
No special requirements for preparation	Increased requirements for reprocessing (e.g. medical devices with cavities)
Preferred: Mechanical cleaning (preferably alkaline) and thermal disinfection, Sterilization if necessary (with moist heat)	Pre-cleaning immediately after use Preferred: Mechanical cleaning (preferably alkaline) and thermal disinfection, Sterilization if necessary (with moist heat)

Critical Medical devices

Penetration of skin or mucous membrane, contact with blood
Use on internal tissues, organs or other other sterile medical devices

Critical A	Critical B	Critical C
No special requirements for preparation	Increased requirements for reprocessing (e.g. medical devices with cavities)	Particularly high reprocessing requirements (e.g. critical B medical devices that cannot be steam sterilized)
Preferred: Mechanical cleaning (preferably alkaline) and thermal disinfection. In principle: Sterilization (with moist heat)	Pre-cleaning immediately after use Mandatory: Mechanical cleaning (preferably alkaline) Thermal disinfection and sterilization (with moist heat)	Further reprocessing only in facilities with an externally certified quality management system in accordance with DIN EN ISO 13485 in conjunction with the KRINKO/BfArM recommendation

Preparation

Personal protective equipment	Personal protective equipment (sturdy gloves, water-repellent protective gown, face mask or mask and safety goggles) must be worn.
Initial treatment at the place of use	Dry disposal (recommended): Remove surface contamination with a disposable cloth/paper towel, then direct transportation to the reprocessing area. Wet disposal: Placing the instruments in a drill bath, so-called wet disposal
Storage and transportation within max. 2h	Storage and transportation should take place in suitable, closed containers (e.g. trays, bur blocks, instrument trays) in order to avoid contamination of the environment and damage to the instruments. Cleaning and disinfection should be carried out immediately after preparation (within 2 hours at the latest). To avoid increased contamination of the loaded instrument trays, soiled products should be stored separately and must be stored separately and cleaned and disinfected in the tray before reloading.
Preparation before cleaning	**Cleaning location** Cleaning in the "non-clean area" of the processing room **Necessary materials** • Drill bath neodisher Mediclean forte 0.5 % (or other suitable cleaning and disinfecting agents), s. Section "Process requirements" • Ultrasound device • Brush (e.g. figure 431) • Disposable syringes • Illuminated magnifier **Dismantling** Instruments must be dismantled as far as possible. For the following products, separate manufacturer's instructions must be observed: • Benex pull rope and extractor (85FLBM01) • Torque ratchets (85FLBM29, 85GADRMP, 85FLBM1) **Pre-cleaning** 1. Removal of residues (blood, tissue residues and drugs). The drying of residues on the instruments residues on the instruments must be prevented 2. The use of fixing agents and/or hot water (>40 °C) is prohibited during pre-treatment 3. Pre-cleaning takes place with the aid of ultrasonic (12 minutes, at 25-50 kHz, temperature <30 °C) 4. The instruments are removed from the preparation bath and then rinsed (3x for at least 1 min with continuously flowing deionized water). Movable parts must be moved back and forth at least 5 times. Instruments with lumen are rinsed at least 3 times with a disposable syringe (minimum volume 10 ml).

Automated cleaning / disinfection (validated procedure recommended by the RKI)

For machine cleaning, use the appropriate program with the corresponding number of rinsing cycles for the products.

Procedure description

Products must not touch each other!

Cleaning location
Cleaning in the "non-clean area" of the processing room

Necessary materials
- WD with CE mark or FDA clearance, validated according to ISO15883
- Suitable mild alkaline cleaning agent: e.g. Neodisher Mediclean Forte
- Suitable neutralizing agent: e.g. Neodisher Z
- Bur block

Procedure
1. In general, product-specific instructions for use, if available, must be observed
2. The pre-cleaned instruments are sorted into suitable cleaning containers, such as a stainless steel bur block. The products do not touch each other and the manufacturer's instructions regarding arrangement, connection and accessories are followed
3. If available, all lumens of the products must be connected to the rinsing connection of the WD using a suitable rinsing adapter
4. The cleaning containers are positioned in the baskets so that rinsing shadows are avoided
5. The program is then started
6. At the end of the program, the parts must be removed and a visual inspection carried out in accordance with the section "Inspection, maintenance and packaging"

Prescribed cleaning phases

Process steps	Conditions
Pre-rinsing	Cold city water Temperature <40 °C Time 60 s
Cleaning	Concentration 0.5 % RKI recommendation: Temperature 55 °C Time 600 s
Sinks	City water Temperature 40±2 °C
Neutralization	Concentration 0,10 %
Rinsing	Demineralized water Temperature 40±2 °C Time180 s
Disinfection (thermal)[1]	Demineralized water Temperature 90 °C Time 300 s A_0 3000
Drying	Temperature 120 °C

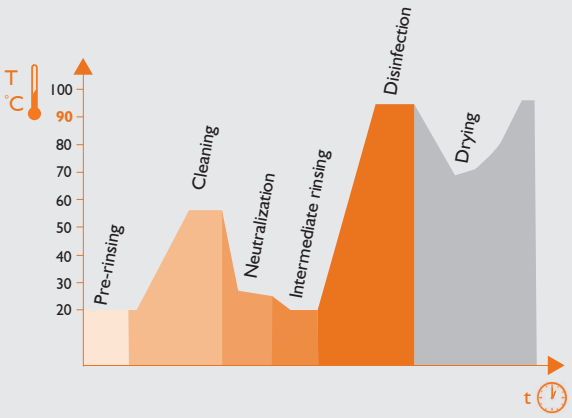


Fig. 1: Overview of the cleaning procedure
(Source: Springer, Central Sterile Supply Department (CSSD))

[1] Thermal disinfection must be carried out in accordance with the A0 value and national regulations (DIN EN ISO 15883).

Notes on removal
The products must be removed immediately after the end of the program and must not be left in the WD overnight. If post-drying is necessary, this should be carried out with filtered air (preferably with medical compressed air in accordance with KRINKO recommendations)

Product features

For the following products, separate manufacturer's instructions may need to be observed for reprocessing:
- Benex pull rope, extractor and quadrant support (85FLBM01)
- Torque ratchets (85GADRMP, 85FLBM29)

Manual cleaning (alternative method to machine cleaning)

When reprocessing by hand, please ensure that no damage is caused by metal brushes, abrasive cleaners or excessive force.

Process description Cleaning  **Products must not touch each other!**	**Cleaning location** Cleaning in the "non-clean area" of the processing room **Necessary materials** • Suitable mild alkaline cleaning agent: e.g. cleaning agent Neodisher Mediclean Forte, concentration 0.5% (according to manufacturer's instructions) • Nylon brush (e.g. brush Fig. 431) • Disposable syringes • Ultrasound device • Illuminated magnifier **Procedure** 1. Rinse for 1 min under running water (< 40 °C) 2. Remove all macroscopically visible impurities with a suitable brush for at least 15 seconds 3. Work with an illuminated magnifier if necessary 4. If lumen available: • Thorough rinsing of the lumen at the beginning and end of the cleaning agent exposure time using a disposable syringe (at least 3 times, minimum volume 10 ml) • Thoroughly move the moving parts back and forth (at least 5 times) 5. Ensure that the instruments do not touch each other in the cleaning bath 6. Subsequent ultrasound application (5 min) 7. It must be possible to reprocess the brush, otherwise it must be disposed of properly after each cycle 8. Visual inspection: • The instructions in section "Inspection, maintenance and packaging" must be observed • The instruments must be checked for residues. An illuminated magnifying glass may be used for this • If residues are present (especially dentin and bone residues), the previous steps are repeated • If proper cleaning is not possible, dispose of the instrument properly
Process description Disinfection	**Necessary materials** • Suitable disinfectant: e.g. Cidex OPA (ready-to-use solution) • Ultrasound device • Disposable syringes **Procedure** 1. Cover the instruments with a suitable disinfectant solution for the specified exposure time. All air bubbles must be eliminated 2. Ensure that the instruments do not touch each other 3. If lumen available: • Thorough rinsing of the lumen at the beginning and end of the cleaning agent exposure time using a disposable syringe (at least 3 times, minimum volume 10 ml) • Thoroughly move the moving parts back and forth (at least 5 times) 4. Disinfection using ultrasound (5 min) 5. Removing the instruments from the disinfection bath 6. Rinse instruments thoroughly after the specified exposure time 7. Move the moving parts back and forth at least 5 times 8. If lumen available • Rinse 3 times with a disposable syringe (minimum volume 10 ml) 9. Drying the instruments (preferably with medical compressed air in accordance with KRINKO recommendations) 10. Visual inspection: • see section "Inspection, maintenance and packaging"
Product features	For the following products, separate manufacturer's instructions may need to be observed for reprocessing: • Benex pull rope, extractor and quadrant support (85FLBM01) • Torque ratchets (85GADRMP, 85FLBM29)

Inspection, maintenance and packaging

Check and pack the products as soon as possible after removal in the "clean area" of the processing room.

Control Visual inspection!	1. Ensure that the instruments are completely dry 2. Check instruments after cleaning or cleaning/disinfection (use a magnifying glass if necessary): • Residues • Corrosion • Damaged surfaces/blank spots • Blunt or chipped cutting edges/chipping • Damage to shape (e.g. bent, not running round) • Soiling 3. Sort out damaged products 4. If residues are present (especially dentin and bone residues), the previous steps are repeated 5. If proper cleaning is not possible, dispose of the instrument properly
Maintenance	Disassembled products must be reassembled (see specific instructions if necessary) and maintained if necessary. Instrument oils or greases must not be used.
Packaging	Cleaned and disinfected products must be sorted into the corresponding sterilization tray (e.g. bur block). The products or sterilization trays must be packed in single-use sterilization packaging (single or double packaging) and/or sterilization containers that meet the following requirements (material/process): • DIN EN ISO/ANSI AAMI ISO 11607-1/-2 (for USA: FDA clearance) • suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F) sufficient steam permeability vapor permeability) • Adequate protection of the products and sterilization packaging against mechanical damage (choose double packaging if necessary) • for individual packaging: the packaging must be large enough to ensure that the seal is not under tension

Sterilization

Procedure description

Cleaning location
Products may only be handled for sterilization in the "clean area" of the reprocessing room.

Necessary materials
Steam sterilizer
(in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 and validated in accordance with DIN EN ISO 17665)

Sterilization process
Only the sterilization procedures listed below are recommended for sterilization.
Steam sterilization:
- Fractionated vacuum process[1] (with sufficient product drying[2])
- Maximum sterilization temperature 138 °C (280 °F; plus tolerance according to DIN EN ISO 17665)

Procedure
1. Only cleaned and disinfected products may be sterilized.
2. The properly packaged instruments are placed in the sterilization chamber and the program is started.
3. At the end of the program, the instruments are removed.
4. After complete cooling, the packaging must be checked for damage. Leaking or damaged packaging must be considered non-sterile, meaning that the "Packaging" and „Sterilization“ steps must be carried out again.

Sterilization cycle	
Process steps	**Conditions**
Backing vacuum	according to DIN EN ISO 17665-1 and DIN EN 285 Quantity: 3x
Sterilization	Temperature 134 °C Holding time 5 min Pressure 2-2.5 bar
Postprocessing	Drying time 30 min

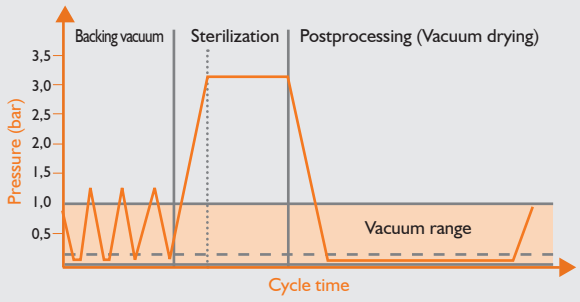


Fig.2: Overview of the sterilization cycle

Important information

- The flash sterilization procedure is generally not permitted
- No hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization may be used
- To prevent staining and corrosion, the steam must be free of ingredients (see limit values in DIN EN 13060)
- The maximum load of the sterilizer must not be exceeded (observe the appliance manufacturer‘s instructions)
- If prions are suspected, national guidelines should be observed and a holding time of 18 minutes should be used

[1] At least three vacuum steps
[2] The actual drying time required depends directly on the parameters that are the sole responsibility of the user (e.g. load configuration and density, sterilizer condition) and must therefore be determined by the user. However, drying times of 20 minutes should not be exceeded.

Sterilization procedures in other countries	**Fractionated vacuum process**
USA (note ANSI AAMI ST79)	min. 4 min at 132 °C (270 °F), Drying time min. 20-30 min
Other countries	min. 3 min at 132 °C (270 °F) / 134 °C (273 °F) min. 20 min at 121 °C (250 °F)

Storage, transportation and disposal

Storage 	• In original packaging until initial preparation • Recontamination-protected storage of sterile products in suitable hygienic and maintained containers under the following conditions: - Room temperature - Protected against dust and moisture • The storage period depends on the type of packaging
Transportation	There are no special requirements for transportation. Until the product is used, it is safe from recontamination in accordance with the "Storage" section.
Disposal	When disposing of the instruments (at the end of their service life or after expiry of the specified shelf life), ensure that the product is disposed of in the waste for biohazardous substances. All packaging components are disposed of in accordance with national regulations (e.g. dual waste system).

General information on validations and verifications

Validation by	CleanControlling Medical GmbH & Co. KG
Materials used, equipment and parameters	1. Laminar Flow Thermo Fisher Scientific Safe 2020 2. Incubator Binder BD 115 3. Autoclave Lautenschläger ZenralCert (half-cycle mode) 4. Shaking incubator Infors Ecotron 5. Sartorius filtration unit 6. Photometer Biotek Epoch Reader 7. Ultrapure water system ELGA Veolia PURELAB flex 2 8. TOC-Analyzer Shimadzu Total Organic Carbon Analyzer TOC-LCPH FA, E200 9. Interlok cleaning brush – double sided REF 09098 green 10. Washer-disinfector (WD) Miele PG 8535 11. All devices and common equipment of a biological laboratory
Validation result	The above instructions have been validated as SUITABLE by the medical device manufacturer for the preparation of a medical device for reuse. The reprocessor is responsible for ensuring that the actual reprocessing performed with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Similarly, any deviation from the instructions provided should be carefully evaluated by the reprocessor for effectiveness and potential adverse consequences.
Evidence	Proof of basic suitability for effective reprocessing procedures was provided by an independent, officially accredited and recognized test laboratory, officially accredited and recognized test laboratory. Typical conditions in clinics and medical practices as well as the procedures described above were taken into account.
Manual cleaning and disinfection	Cleaning agent Neodisher Mediclean forte 0.5 % (10 min at 0.5 % solution) Cidex OPA disinfectant (15 min in the US bath, ready-to-use solution) (Johnson & Johnson)
Automated cleaning and disinfection	WD PG8535 (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) Pre-cleaning and cleaning agent Neodisher MediClean forte 0.5 % (5 min at 95 °C) (Dr. Weigert GmbH und Co. KG, Hamburg)
Steam sterilization	Systec V-150 steam sterilizer (Systec GmbH Labor-Systemtechnik, Wettenberg) Fractionated vacuum process