

Instructions for Preparing Resterilisable Surgical American Eagle Hand Instruments



For medical devices of class I:



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Important Notes



Read these reprocessing instructions carefully before each use and keep them easily accessible for the user or the relevant technical personnel.



Carefully read the warnings indicated by this symbol. Improper use of the products may result in serious injury to the patient, users or third parties.

♦ **Intended use and area of application**

The devices may only be used for their intended use in medical specialties, by appropriately trained and qualified personnel. The devices are not intended for use on the central circulatory or nervous system. The attending physician or the user is responsible for the selection of the devices for specific applications or operative use, appropriate training and information, and sufficient experience for handling the devices.

◇ **Precautionary measures and warnings**

Medical devices have been designed for human use only and must not be used for any other purpose. Improper handling and care as well as improper use can lead to premature wear of the devices.

Treatment of brand new devices

Factory-new devices must have undergone the complete reprocessing process once before being used. Protective caps and protective nets for sharp-edged devices must be completely removed beforehand.

Load

Overloading of the devices must be avoided. Overloading can lead to bending or breaking and thus to the loss of functionality of the devices.

Functional impairment

The devices corrode and their function is impaired if they come into contact with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilisation instructions.

Operating conditions

To ensure the safe operation of the aforementioned devices, correct maintenance and care of the devices is essential. In addition, a functional or visual check should be carried out before each use. For this reason, we refer to the relevant sections in these reprocessing instructions.

Reprocessability

For the reprocessing of devices where TSE/CJD contamination is to be feared, the guidelines of the World Health Organisation (WHO), as well as the national requirements for hospital hygiene, must be followed. The safest and clearest way to ensure that there is no risk of residual infectivity from contaminated products and other materials is to dispose of them by incineration. In certain public health situations, a less effective method may be preferred, in compliance with national requirements. The steam sterilisation parameters recommended by WHO for prion inactivation, but with limited effectiveness, are: 134°C/273°F for 18 minutes.

Storage

There are no specific requirements for storing the devices before sterilisation. Nevertheless, we recommend storing the medical devices in a clean and dry environment.

◇ **Liability and warranty**

The devices may only be used for their intended purpose in the medical fields by appropriately trained and qualified personnel. The attending physician or the user is responsible for the selection of the devices for specific applications or operative use, for appropriate training and information, and for sufficient experience in handling the devices. The manufacturer does not take responsibility for damage resulting from repair or maintenance by unauthorized parties.

◇ **Obligation to report**

All serious incidents related to the devices must be reported to the manufacturer and the competent authority of the member state where the user and/or patient is established.

◇ **Sterility: Delivery condition**

The medical devices are delivered in a non-sterile state and must be processed and sterilized by the user in accordance with the following instructions before the first and each subsequent use.

◇ **Limitation of reprocessing, disposal**

Frequent reprocessing has little effect on the devices. Product life is limited by wear due to intended use and damage to the device. The device may no longer be used, among others, under the following aspects:

Corrosion, damage, fractures, cracks, deformation, porosity, functional limitations, devices with unrecognizable or missing labeling. Therefore, the corresponding instructions for functional testing by the reprocessor must be implemented. Please dispose of the devices properly or to a recycling system at the end of the product life. The national regulations and disposal guidelines must be observed!

◇ **Processing**

See the following points

◇ **Warning notes**

Tap water to be used must be of drinking water quality. If the device is not a one-piece device, the device must be disassembled as far as possible.

◇ **Place of use**

Coarse soiling, residues of e.g. hemostatic agents, skin disinfectants and lubricants as well as corrosive drugs should, if possible, be removed before discarding the device. Any contamination must be rinsed or wiped off immediately after use. The device should not be cleaned with physiological saline solution or stored before dry disposal. Wherever possible, dry disposal should be preferred, as prolonged exposure of medical devices to solutions during wet disposal can lead to material damage (e.g. corrosion). Long waiting times before reprocessing, e.g. overnight or over the weekend, should be avoided (< 6 hours drying time after contamination).

◇ **Transport**

The device is discarded after use without disinfectant or other additional liquids and transported to the reprocessing unit for medical devices. The device must be disposed of dry immediately after use. This means that the device must be transported in a closed container from the place of use to reprocessing without being placed in disinfectant solution or other liquids, so that no drying occurs on the device.

◇ **Pre-treatment**

If the device is not a one-piece device, it must be disassembled as far as possible.

- The device must be soaked in tap water (according to drinking water regulations) for 10 minutes while avoiding bubble formation on the surface of the device.
- Rinse the device under cold tap water of drinking water quality (< 40°C) until all visible dirt has been removed.
- Stubborn dirt must be removed with a soft brush.
- Additionally, fill the lumen with tap water (drinking quality < 40°C) using a disposable syringe (50 ml). The soaking time is 10 minutes.

- Treat the lumens with a brush whose diameter and length are slightly larger than the diameter and length of the lumens. Brush through the lumens at least three times with the brush.
- If cleaning with a brush is not feasible due to the small lumen diameters, the lumens must be flushed three times with a 50 ml disposable syringe. Use tap water (drinking water quality < 40°C).
- By means of a water pressure gun,
 - Cracks
 - Holes
 - Edgesmust be rinsed intensively > 60 sec. with cold water (drinking water quality < 40°C)

◇ **Manual Cleaning/ Disinfection / Drying**

Note: Before ultrasonic cleaning, a pretreatment (see section 110) must be performed.

1. Ultrasonic cleaning

- Immerse the devices in an ultrasonic bath (< 40°C) with a mildly alkaline detergent and a frequency of approx. 35 kHz. Sonication time must correspond to the detergent manufacturer's specifications
- A detergent suitable for ultrasonic cleaning must be used. The instructions of the manufacturer of the detergent must be followed.
- Devices must be placed in such a way that all surfaces are covered.
- The devices must not touch each other.
- Rinse the devices thoroughly (at least 1 min.) three times under cold water (drinking water quality < 40°C).

2. Manual cleaning

Use a mildly alkaline detergent and prepare the cleaning solution according to the manufacturer's instructions.

- Immerse the devices completely in the cleaning solution.
- Carry out all further cleaning steps below the liquid level to avoid splashing of contaminated liquid.

The total exposure time in the cleaning solution must be in accordance with the manufacturer's instructions for the cleaning agent used.

- Brush the devices completely in the solution with a soft brush for at least 1 minute.
- Remove the devices from the cleaning solution and rinse it with water for at least 1 minute to completely remove the cleaning solution.
- Use a water pressure gun (or similar) (> 30 Sek.) to rinse:
 - Cracks
 - Holes
 - Edgesusing cold tap water (< 40°C, drinking water quality).
- Treat the lumens with a brush whose diameter and length are slightly larger than the diameter and length of the lumens. Brush through the lumens at least three times with a brush.
- If cleaning with a brush is not feasible due to the small lumen diameters, the lumens must be flushed three times with a 50 ml disposable syringe. Use tap water (drinking water quality, < 40°C).

3. Manual disinfection

The specific instructions of the manufacturer and the disinfectants must be observed. Only disinfectants suitable for disinfection of medical devices may be used.

- The devices must be completely immersed in disinfectants so that all surfaces are covered. The exposure time must be followed, as indicated by the manufacturer of the disinfectant.
- The devices must not touch each other.

Procedure after disinfection:

- Rinsing the devices in deionised water > 15 sec.
- The lumens must additionally be flushed with deionized water using a disposable syringe (50 ml) at least three times.

4. Manual drying

Dry manually with a lint-free disposable cloth until all surfaces are dry. The lumens must be ventilated using sterile and oil-free compressed air.

◇ Mechanical Cleaning / Disinfection / Drying

Note: Pre-treatment (see section 110) must be carried out before mechanical cleaning.

1. Ultrasonic cleaning

- Immerse the devices in an ultrasonic bath (< 40°C) with a mildly alkaline detergent and a frequency of approx. 35kHz. Sonication time must correspond to the detergent manufacturer's specification.
- A detergent suitable for ultrasonic cleaning must be used.
- The instructions of the manufacturer of the detergent must be followed.
- Devices must be placed in such a way, that all surfaces are covered.
- The devices must not touch each other.
- Rinse the devices thoroughly (at least 1 min.) three times under cold water (drinking water quality, < 40°C).

Procedure after ultrasonic treatment::

Rinse again using a water pressure gun (> 30 sec.) with cold tap water (< 40°C):

- Cracks
- Holes
- Edges
- Treat the lumens with a brush whose diameter and length are slightly larger than the diameter and length of the lumens. Brush through the lumens at least three times with a brush.
- If cleaning with a brush is not feasible due to the small lumen diameters, the lumens must be flushed three times with a 50 ml disposable syringe. Use tap water (drinking water quality, < 40°C).

Moving parts on the device must be moved back and forth at least ten times while applying the water pressure gun.

2. Preparation for decontamination

If present, the handle spring must be unhooked.

Rinse shadows must be avoided. The devices must be prepared in suitable strainer baskets or rinsing trays (select size to suit the devices). The devices should be placed with a minimum distance to other devices in the cleaning basket.

Overlapping must be avoided in order to exclude damage to the devices during the cleaning process. The quantity and type of load in the product trays selected for cleaning must be carried out in such a way that no impairment of the cleaning result is to be expected.

The device shall be positioned so that the water can flow into and out of the lumens.

3. Automated cleaning process

(washing machine, WD according to EN ISO 15883):

If a rinsing connection is available, the device must be connected to the designated fitting.

- Pre-rinsing for 5 minutes with cold tap water (drinking water quality) < 40°C
- Water drainage
- 10 minutes cleaning with deionised water of 55°C with mild alkaline detergent
- Water drainage
- 1 minute rinse with deionised water
- Water drainage
- 1 minute rinse with deionised water
- Water drainage

The special instructions of the manufacturer of the cleaning machine and the cleaning agents must be observed. Use a cleaning agent that is suitable for a washer-disinfector.

4. Automated disinfection

Automatic thermal disinfection in washer-disinfectors, taking into account the national requirements for the A0 value; e.g. A0 value 3000:

- 5 minutes disinfection with deionised water 90°C
- Water drainage

5. Automated drying

Automatic drying according to the automatic drying process of the washer-disinfector for at least 15 minutes (at 90°C in the rinsing room).

If necessary, subsequent manual drying with a lint-free cloth if wetness can be detected on the device.

◇ Inspections

The devices must be macroscopically clean after each cleaning, i.e. free of visible dirt.

- A stained device (corrosion, discoloration) must be sorted out immediately and subjected to special treatment.
- A contaminated device must be reprocessed.
- In the event of errors or damage, the device must be sorted out immediately.

The following components must be checked with particular attention:

- Notches
- Blades
- Points

◇ Care of the devices

The section is not relevant for the devices.

◇ Packaging

If not yet done, the disassembled device must be reassembled.

The device is placed in a suitable, standard-compliant packaging for the respective device or in sterilisation trays for sterilisation in accordance with DIN EN ISO 11607 or DIN EN 868 and sealed.

The packaging must meet the following requirements:

- Suitable for steam sterilisation (temperature resistance up to at least 138°C (280°F) sufficient vapour permeability).
- Sufficient protection of devices or sterilisation packaging against mechanical damage.
- Regular maintenance according to the manufacturer's specifications (sterilisation containers).
- A maximum weight of 10 kg per package/contents of the sterilisation container must not be exceeded.

◇ Sterilisation

Sterilisation of the devices using the fractionated pre-vacuum method (according to DIN EN ISO 17665-1) taking into account the respective national requirements. The devices must be sterilised in suitable sterilisation packaging. Sterilisation must be carried out using a fractionated pre-vacuum process with three pre-vacuum cycles and drying in a vacuum for at least 10 minutes. The following parameters must be taken into account:

	Temperature	Time
Europa	134°C (273°F)	≥ 3 Min.
USA	132°C (270°F)	≥ 4 Min.

◇ **Additional information**

The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilisation material must be observed. The autoclave must be installed, maintained, validated and calibrated according to regulations. The reprocessor is responsible for ensuring that the reprocessing carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the process and equipment used.

◇ **Service, repair and return transport**

Service and repair

Do not carry out any repairs or modifications to the devices yourself. This is the sole responsibility of the manufacturer's authorised personnel. Please contact us if you have any complaints, claims or information regarding our devices.

Return transport

Defective or non-conforming devices must have gone through the entire reprocessing process before being returned for repair/service.

◇ **Storage and transport**

- Protect against mechanical damage
- Store dry and dust-free
- Store and transport in safe containers/packaging
- Handle, do not throw or drop with great care

Appropriate approved sterilisation packaging (e.g. according to DIN EN 868, ISO 11607) must be used for sterilisation, subsequent transport and storage.

◇ **Inspection instruction**

Before each use of the device, it must be checked for fractures, cracks, deformations, damage and functionality. Worn, corroded, deformed, porous or otherwise damaged devices must be sorted out.

The following components must be checked with particular attention:

- Notches
- Blades
- Points






The stainless steels used for manufacturing of the devices form specific passive layers as protective layers due to their alloy. These steels show only limited resistance to the attack of chloride ions and aggressive media and liquids! In addition to the efforts made by the manufacturer in the selection of the right materials and in their careful processing, devices must be subjected to professional and continuous care and the correct preparation at the user's end.






◇ **Material resistance**

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

- Organic, mineral and oxidising acids (minimum permissible pH value 5,5)
- Alkalis/strong alkalis (neutral/enzymatic (max. permissible pH value 8.5, mandatory for devices made of aluminium or other alkali-sensitive materials) or alkaline cleaning agents (max. permissible pH value 11, mandatory for devices intended for use in prion-critical areas, e.g. in accordance with Appendix 7 of the KRINKO RKI BfArM recommendation for reprocessing))
- Organic solvents (z.B. alcohols, ethers, ketones, benzines)
- Oxidising agents (z.B. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

◇ Description of symbols used

	Symbol for "Manufacturer"
	Symbol for "Article Number"
	Symbol for "Batch Code"
	Symbol for "Follow Instructions For Use"
	Symbol for "CE Marking of Conformity"

	Symbol for "Quantity"
	Symbol for "Unsterile"
	Symbol for "Attention"
	Symbol for "Medical Device"
	Symbol for "Keep Dry"