Cleaning and Maintenance of reusable surgical instruments

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Manufacturer

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REF Products

These instructions for use, processing and reprocessing of reusable surgical instruments are valid for all surgical instruments (e.g. eye retractors, knives, hooks, needle holders, forceps, scissors, canulas etc.) marked HERME CE and supplied by Bernhard Hermle GmbH.

Important hint

Read this instructions leaflet carefully before any application and keep it easily available to the user or to the appropriate specialist.

Read the warnings indicated by this symbol carefully. Inadequate use of the products may cause serious injuries to the patient, the user or third parties.

1 Field of application

The products supplied by Bernhard Hermle GmbH may only be used by suitably trained and qualified staff. The products are intended exclusively for temporary use in the medical field described below and must therefore be used in a suitable operating environment. It is mandatory that the user and the appropriate specialized staff familiarize themselves with the instruments before he / she applies them. Laypersons who use these products in exceptional cases must first obtain full information about the correct use from a doctor or another corresponding specialist.

2 Product description

These surgical instruments are intended for a surgical application in human medicine.

Materials

Surgical instruments are made of stainless steel (stainless steel alloys) according to DIN 7153-1. Mainly materials according these material numbers are used:

1.4021 (X20Cr13)
1.4024 (X15Cr13)
1.4034 (X46Cr13)
1.4104 (X14CrMoS17)
1.4116 (X50CrMoV15)
1.4117 (X38CrMoV15)
1.4197 (X22CrMoNiS13-01)
1.4301 (X5CrNi18-10)
1.4305 (X8CrNiS18-9)
1.4310 (X12CrNi17 7)
1.4401 (X5CrNiMo17-12-2)

Our silver instruments mainly consist of:

AgCu20
Ag935Cu065

Our titanium instruments mainly consist of:

Titan 3.7035
Titan 3.7165
Titanium Grade 2

3 Precautions and warnings

Attention!

The surgical instruments are designed for surgical use only and may not be used for any other purpose. Improper handling and care as well as improper use can lead to premature wear of the instruments.

Material incompatibility

The medical devices should under no circumstances be used if the user or the specialist staff obtains appropriate knowledge that the patient has material incompatibilities.

Functional impairment

Surgical instruments corrode and are impaired in their function as soon as they get into contact with aggressive substances. For this reason it is essential to follow the reprocessing and sterilization instructions.

Operating conditions

To ensure the safe operation of the aforementioned products proper maintenance and care of the products are essential. Additionally, a functional or visual check should be carried out before each application. For this reason we refer to the relevant sections in this instruction leaflet.

Storage

There are no specific requirements for the storage of the products. Nevertheless, we recommend to store the medical devices in a clean and dry environment.

Silver

Some cannulas and probes of our product range consist of pure silver. Care should be taken not to place silver cannulas and probes in physiological saline, as prolonged contact may cause discoloration.

Single-use instruments

Instruments determined for UNIQUE use may never be reprocessed and reused.

4 Liability and warranty

Bernhard Hermle GmbH as a manufacturer is not liable for consequential damages resulting from improper use or handling. This applies in particular to a non-compliant use for the defined purpose or a disregard of the preparation and sterilization instructions. This also applies to repairs or changes to the product made by unauthorized staff. These disclaimers also apply to warranty services.

5 Sterility

NON STERILE **Delivery condition**

The medical devices are supplied in a non-sterile condition and must be prepared and sterilized by the user according to the instructions below before the first and any further use.

6 Life time of the products

Since the medical products supplied by Bernhard Hermle GmbH consist of durable and proven materials in the field of medical technology, it is not possible to define an exact life time. The life time depends on the wear and frequency of use. Consider the instructions for functional testing before use.

7 Processing

Warnings

- Improper reprocessing can lead to wear of the products.
- The solutions and chemicals used must be suitable for the materials of the products to be treated and must be used in accordance with the manufacturer's instructions. Prescribed reaction times, concentrations and recommended times of use defined by the chemical's manufacturer have to be followed. Additionally, a prescribed water quality must be applied.
- The water must have drinking water quality except otherwise specified.
- This reprocessing statement specifies the cleaning and disinfecting agents used for the validation. The responsibility is at the reprocessor when he uses alternative cleaning agents or disinfectants (RKI or VAH listed).
- Reassemble disasssembled products before sterilization.

Place of use

The first steps of proper preparation already begin in the operating room. If possible, coarse dirt, residues of e.g. blood, hemostatics, skin disinfectants and lubricants and corrosive drugs have to be removed immediately. Drying of residues should be avoided! Lumen instruments (e.g., cannulas) should be handled with extra care. They may not dry and must be rinsed thoroughly after use immediately. Cleaning solutions should be used according to the manufacturer's instructions and must be renewed regularly.
Prefer wherever possible a dry disposal (humidified, closed system). Avoid at both kind of disposal a long waiting time before processing, e.g. overnight or over the weekend (<6 hours).

Transportation

The products must be disposed immediately after their use. This means that the products have to be transported in a moist condition in a closed container from the place of application to the place of processing or preparation, so that no drying may take place on the products.

Peparation for decontamination

If possible, the products should be disassembled before the subsequent treatment steps may take place, or if already in open state, sent for further processing steps. Avoid flush shadows. The products must be processed in suitable baskets or dishwashing trays. The products should be fixed with a minimum distance to each other in the cleaning basket and an overlapping should be avoided in order to prevent a damage due to the cleaning process.

Pre-cleaning

Flush/rinse the products under cold city water using drinking water quality (<40°C) until all visible contamination has been removed. All moving parts must be moved to ensure that all hidden surfaces are accessible for the cleaning. Snuggy dirt should be removed with a soft brush (not a wire brush). The instruments must not be damaged. Cavities, lumens are to be flushed intensively (> 30 sec) with cold city water drinking water quality (<40 ° C) by means of a water pressure gun (or similar). Irrigate instruments with Luer-Lock connections using a syringe (3 times 10 ml).

Cleaning / Desinfection

Automatic cleaning / disinfection process

Place the instruments at an open status into a cleaning tray and fix them if possible. Connect instruments with Luer-Lock connection to the machine.

(*Washing machine, RDG Vario TD program, device: company Miele)*

- 5 minutes pre-cleaning using cold demineralized water (possibly also softened water or drinking water) <40°C *(validated: drinking water, city quality)*
- Water drain
- 10 minutes cleaning using cold demineralized water 55 ± 2° C (company Dr. Weigert, neodisher® MediClean forte, alkaline cleaning media containing surfactants; pH-range 10,4 - 10,8; concentration 5-10ml/l, *(validated: 5ml/l*).
- Water drain
- 2 minutes intermediate rinsing I with cold demineralized water <40°C (optionally with

neutralizing agent, Dr. Weigert, neodisher® Z, for the neutralization of alkaline residues from the main cleaning cycle, free of phosphates, nitrogen and surfactants, pH-range 3.0 - 2.6, concentration 1-2ml / l, *(validated: 2ml/l*)

- Water drain
- 2 minutes intermediate rinse II with cold demineralized water <40 ° C
- Water drain
- 5 minutes final rinse incl. thermal disinfection with deionised water at 92°C ± 2°C, under consideration of the national requirements for the A0-value; e.g. A0-value >3000 in D (optionally with rinsing agent, Dr. Weigert, neodisher® MediKlar, to shorten the drying time during machine cleaning). *(Validated: without rinsing agent, Fa. Weigert, neodisher® MediKlar*
- Water drain
- Automatic drying according to the automatic drying process of the washing and disinfector machine for at least 30 minutes (at 60°C±5°C in the washing machine). *

If necessary, subsequent manual drying with lint-free cloth and blowing out of the lumen using sterile, oil-free compressed air.

Sterilization

Sterilization of the products by means of a fractionated pre-vacuum process (according to DIN EN ISO 17665-1) under consideration of the respective national requirements in a suitable sterilization packaging.

The sterilization has to be carried out by use of a fractionated pre-vacuum method, applying the following parameters:.

134°C / 273,2°F,

≥5 minutes holding time,

3 pre-vacuum-cycles

Drying in vacuum for at least 20 minutes.

Flash sterilization is not suitable for lumen products!

The instructions for use of the autoclave's manufacturer and the recommended guidelines for the maximum loading of items to be sterilized must be followed/noticed. The autoclave must be properly installed, maintained, validated and calibrated.

HERMLE CE marked surgical instruments can also be processed by use of other devices, device settings and cleaning chemicals, different to the upper mentioned and by Bernhard Hermle GmbH validated reprocessing procedure listed above. The reprocessor/conditioner is responsible for ensuring that the treatment procedure used by him achieves the same results as the treatment procedure validated by Bernhard Hermle GmbH.

* As an alternative to the period of at least 30 minutes (at 60°C ± 5°C in the washing machine/space) being validated, the automatic drying process in the washing and disinfector machine can also be applied for a period of at least 20 minutes (at 90°C ± 5°C in the washing machine/space) or at least 15 minutes (at 110°C ± 5°C in the washing machine/space). However, the higher applied thermal stress to the material (even during a shorter period of time) can lead to an at present undetermined reduction of lifetime, especially at components made of plastics.

⚠ Creutzfeldt-Jakob-disease (CJD)

Regarding the reprocessing of medical devices used at patients with Creutzfeldt-Jakob disease (CJD) or their variant (vCJD) or at any suspect, the requirements defined in the relevant hospital hygiene guideline and infection prevention directive and the publications (e.g. the Bundesgesundheitsblatt) of the national health authority need to be followed. The medical devices used in this group of patients must be safely disposed by incineration (according to European Waste Catalog EAK 180103) (Cat. IB). Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but no inactivating effect on TSE pathogens. Of the sterilization methods available, limited effect has been demonstrated only for steam sterilization (especially 134 ° C, 18 minutes).

⚠ Additional information

It is the responsibility of the reprocessor/conditioner to ensure that the treatment actually carried out with the equipment, materials and staff available in the treatment facility achieves the desired results. This usually requires validation and routine monitoring of the process and the equipment used.

8 Functional check

Check products after preparation / reprocessing and prior to sterilization for the following aspects:

- Cleanliness
- Damages including e.g. signs of corrosion (rust, pitting), discoloration, deep scratches, peeling, cracks or wear.
- Proper function, including e.g. sharpness of the cutting tools, flexibility of flexible products, flexibility of hinges / hinges / box locks and moving parts, such like e.g. handles and ratchets.
- Missing or removed (abraded) part numbers.
- Clearly readable marks
- Correct assembly

Check products for flawless surfaces, correct assembly and functionality. Do not use heavily damaged products, products with unrecognizable markings, signs of corrosion or blunt cutting edges.
Reassemble disassembled products correctly before sterilization. Applied care products should be applied in the thinnest possible layer after cleaning and before sterilization and must be approved as biocompatible and for the sterilization process.

9 Service and repair

⚠ Service and repair

Do not carry out any repairs or changes to the product on your own. Only authorized manufacturer's staff is responsible and intended for this purpose. We ask you to contact us in case you have complaints or comments regarding our products.

⚠ Return of products

Defective or non-compliant products must have undergone the entire reprocessing process before being returned for repair / service.

10 Packaging, storage and disposal

Standard packaging of products for sterilization according to ISO 11607 and EN 868.

Store sterile products in a dry, clean and dust-free environment, protected from damage, at moderate temperatures. When doing so, pay attention to the details of the sterile barrier systems used.

The manufacturer's medical devices should be stored in individual packaging, boxes or protective containers. Please handle the instruments during transport, storage and processing with the utmost care. The maintenance of the sterile state after the sterilization process is to be ensured by the user or the specialist staff provided for this purpose.

The disposal of the products, the packaging material and the accessories must be carried out in accordance with national regulations and laws. A specific instruction for this is not made by the manufacturer.

11 Symbols

⚠	Attention!
📖	Read information
REF	Item number
LOT	Batch code
CE	CE-marking
NON STERILE	No sterile product
🏭	Manufacturer's name und address
	Manufacturing date
MD	Medical device

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