Reprocessing instructions

Reusable
surgical instruments / implants

FB-134

MANUFACTURER

Anton Hipp GmbH
Annastr. 25/1
78567 / Fridingen / Deutschland
Tel.: 07463 993030
E-Mail: info@anton-hipp.de
Website: www.anton-hipp.com

REPROCESSING – CLEANING, DISINFECTION, CARE AND STERILISATION – OF PRODUCTS

GENERAL REMARKS

All products must be cleaned, disinfected and sterilised before each use; this also applies in particular to the first use after delivery, as all products are delivered non-sterile (cleaning and disinfection after removal of the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

As part of your responsibility for the sterility of the products, please observe the following:
- that only sufficiently device- and product-specific validated procedures are used for cleaning/disinfection and sterilisation,
- that the devices used (CDU, sterilisers, etc.) are regularly maintained, checked and calibrated and
- that the validated parameters are adhered to in every cycle.

The user is responsible for ensuring compliance with the hygiene regulations of their facility, taking into account the reprocessing requirements applicable in the respective country.

WARNINGS

The products may only be used by trained specialists.

Reprocessing may only be carried out by trained specialist personnel in the central sterile supply department of the facility.

The organisation is also responsible for the selection and use of the necessary protective equipment and hygiene measures.

CLEANING AND DISINFECTION

An automated process (cleaning and disinfection unit – CDU) is preferable for cleaning and disinfection. A manual process – including the use of an ultrasonic bath – should only be used if an automated process is not available or in accordance with country-specific requirements (e.g. in Germany an automated process is mandatory for critical B products) due to the significantly lower effectiveness and reproducibility. However, this is not recommended and has not been validated.

Pre-treatment must be carried out in both cases. We recommend manual pre-cleaning using ultrasound before automated cleaning.

PRE-TREATMENT AT THE POINT OF USE

Immediately after use (within a maximum of 1 hour), coarse impurities, corrosive solutions or medicines must be removed from the products. If this time cannot be adhered to due to the duration of use or as a result of organisational aspects, the user must define and validate measures themselves to prevent the soiling from drying thoroughly.

Procedure

1. Dismantle separable products as far as possible.
   Note: For products where assembly/disassembly is not self-explanatory, specific instructions will be provided or created on request.
2. Wipe the medical device with a lint-free, damp cloth or similar. Rinse the products for at least 1 min under running water (temperature < 35°C/95°F). Move moving parts back and forth at least three times during pre-rinsing. Support the pre-cleaning process by completely brushing all internal and external surfaces with a suitable brush until no more soiling is visible.

DISPOSAL (transport for reprocessing (e.g. CSSD))

Dry disposal

Transport to the processing unit takes place in closed systems. Dry disposal is always preferable as a gentle method of preserving value, whereby drying of substances should be avoided.

Wet disposal

For wet disposal, the instruments are preferably placed in a cleaning agent solution or a combined cleaning agent and disinfectant solution that does not have a protein-fixing effect. Disinfectants containing aldehydes should be avoided as they have a fixing effect.
The manufacturer's instructions regarding concentration and contact time and, if necessary, the addition of cleaning boosters must be strictly adhered to.

MANUAL PRE-CLEANING

Before the products undergo automated cleaning in the CDU, we recommend manual pre-cleaning in an ultrasonic bath using a suitable cleaning agent or combined cleaning agent and disinfectant. To ensure effective cleaning, make absolutely sure that the products are disassembled as far as possible (if necessary according to the manufacturer's instructions), are completely covered and do not touch each other. Articulated instruments (scissors, clamps, forceps) must be open to minimise overlapping surfaces. The sieve trays, racks, holders, etc. used must be designed in such a way that manual pre-cleaning in the ultrasonic bath and subsequent cleaning in the CDU is not hindered by acoustic and/or rinsing shadows.

When selecting the cleaning agent to be used, ensure that
- this is fundamentally suitable for cleaning invasive medical devices made of metals and plastics,
- the cleaning agent is suitable for ultrasonic cleaning (no foam development),
- the cleaning agent is compatible with the products (see chapter "Material resistance"),
- the cleaning agent is aldehyde-free.

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and disinfectant as well as the instructions for rinsing must be strictly adhered to.

Example "Neodisher MediClean forte (Dr Weigert)":
Dosage: 0.5–2% (depending on the degree of soiling)
Temperature: max. 40°C
Exposure time: 10–30 min in an ultrasonic bath.
Rinsing: at least 10 seconds under running potable water

Only use freshly prepared solutions and purified water (deionised water, aqua purificata).

Note:
As part of the validation of these reprocessing instructions, manual pre-treatment was omitted in order to take a worst-case approach into account. We strongly recommend manual pre-cleaning.

AUTOMATED CLEANING / DISINFECTION IN THE CDU (= CLEANING AND DISINFECTION UNIT)

When selecting the CDU, make sure that
- the CDU has been tested for effectiveness (e.g. DGHM or FDA approval / clearance / registration or CE labelling in accordance with DIN EN ISO 15883),
- a tested programme for thermal disinfection (A0 value > 3000 or, for older appliances, at least 5 min at 90°C/194°F) is used (note: risk of disinfectant residues on the products if chemical disinfection is used),
- the programme used is suitable for the products and contains sufficient rinsing cycles (at least two rinsing steps after cleaning),
- only purified water (deionised water, aqua purificata) is used for rinsing,
- the air used for drying is filtered (free of oil/water, low in germs and particles) and
- the CDU is regularly maintained, checked and calibrated.

When selecting the cleaning agent system used, it must be ensured that
- this is fundamentally suitable for cleaning invasive medical devices made of metals and plastics,
- if thermal disinfection is not used (not recommended), a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval / clearance / registration or CE marking) is also used and that this is compatible with the cleaning agent used and
- the chemicals used are compatible with the products (see chapter "Material resistance").

Note: The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as the specifications for rinsing, must be strictly adhered to.

Procedure

1. Dismantle separable products as far as possible.
   Note: For products where assembly/disassembly is not self-explanatory, specific instructions will be provided or created on request.
2. Place the disassembled products in the CDU. Make sure that the products do not touch each other. If necessary, enable active flushing by connecting to the flushing connection of the CDU.
3. Start the programme. (See table “Cycle parameters”)
4. Remove the products from the CDU at the end of the programme.
5. Inspect and pack the products as soon as possible after removal (see chapter "Inspection", "Maintenance" and "Packaging", if necessary after additional drying in a clean place).

The basic suitability of the products for effective automated cleaning and disinfection was verified by an independent, DIN EN ISO 17025 accredited and ZLG-approved test laboratory using the WD PG8536 (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning and cleaning agent Neodisher MediClean forte (Dr Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account.

Validated cycle parameters

Step	Designation	Medium	Temperature (°C)	Duration (minutes)
1	Pre-rinsing	Water	Not tempered (< 30°C)	2
2	Emptying	-	-	-
3	Cleaning	Alkaline cleaning agent: Neodisher MediClean forte (Dr Weigert GmbH & Co. KG, Hamburg) Concentration: 0.5%	50°	10
4	Emptying	-	-	-
5	Rinsing I	Deionised water	Not tempered (< 30°C)	2
6	Emptying	-	-	-
7	Rinsing II	Deionised water	Not tempered (< 30°C)	2
8	Emptying	-	-	-
9	Disinfection (thermal)	A0 > 3000; or ⇨	at least 90°C	min. 5
10	Drying	Hot air	100°	20

INSPECTION / SERVICE LIFE OF THE PRODUCTS

Products that are still dirty must be cleaned and disinfected again.

Unless expressly labelled otherwise, the products can be used multiple times. The effect of repeated reprocessing was validated on the basis of 101 cycles. Validation has shown that repeated reprocessing does not damage the products. The product service life is therefore fundamentally determined by damage and signs of wear caused by use.

In order to prove that the products are suitable for reuse, they should be checked after each reprocessing in accordance with the specifications of DIN 96298-4. The following characteristics must be inspected:

– Cleanliness
– Missing parts
– Breakage
– Deformation
– Surface changes such as corrosion, discolouration, cracks, changes to coatings
– Marking

The service life of the products ends when

– it can no longer fulfil its intended purpose and thus its function (e.g. breakage or severe deformation)
– traceability is no longer guaranteed (e.g. labelling, UDI code no longer legible)
– the surface is damaged to such an extent that the product can no longer be used safely (e.g. rust formation, burrs, sharp edges)

If the end of the product's service life has been reached, the products must be labelled as no longer functional and removed. After the products have been reprocessed, they must be repaired by the manufacturer or disposed of in accordance with standard hospital practice.

MAINTENANCE

Reassemble disassembled products.
Note: For products where assembly/disassembly is not self-explanatory, specific instructions will be provided or created on request.

Instrument oils or grease must not be used. An exception applies in the case of lubrication of joints; care must be taken to ensure that only instrument oils (white oil, without further additives) are used that are approved for steam sterilisation – taking into account the maximum sterilisation temperature used – and have tested biocompatibility and that only a small amount is applied to the joints.

PACKAGING

Standardised packaging that meets the following requirements (material/process) must be selected:

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilisation (temperature resistance up to at least 138°C (280°F), sufficient steam permeability)
- adequate protection of the products or sterilisation packaging against mechanical damage
- regular maintenance in accordance with the manufacturer's specifications (sterilisation container)
- a maximum weight of 10 kg per packaging/content of the sterilisation container must not be exceeded.

STERILISATION

NOTE: Only the sterilisation methods listed below may be used for sterilisation; other sterilisation methods are not permitted.

Steam sterilisation

- fractionated vacuum process (at least 3 vacuum steps), (with sufficient product drying)
- steam steriliser in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated in accordance with DIN EN ISO 17665 (valid IQ/OQ and product-specific performance assessment (PQ))
- maximum sterilisation temperature 134°C (273°F; plus tolerance according to DIN EN ISO 17665)
- sterilisation time (exposure time at the sterilisation temperature):

Country	Fractionated vacuum process
Germany	at least 5 minutes at 134°C (273°F)
USA	at least 4 minutes at 132°C (270°F), drying time at least 20 minutes
France / Switzerland	at least 5 minutes at 134°C (273°F) if required for prion inactivation, sterilisation time 18 minutes
Other countries	at least 5 minutes at 132°C (270°F) / 134°C (273°F)

Procedure

1. Place the packaged product in the steam steriliser.
2. Start the sterilisation programme.
3. Remove the product after the end of the programme and successful steam sterilisation.

NOTE: Do not use gravitational sterilisation, flash sterilisation, hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.

Proof of the fundamental suitability of the products for effective steam sterilisation was provided by an independent, DIN EN ISO 17025 accredited and ZLG-approved test laboratory using the steam steriliser 3870 EHS (Tuttnauer) and using the fractionated vacuum process as well as the instrument oil "RUCK Instrument Care Oil" (oiling of the joints and friction surfaces). Typical conditions in clinics and medical practices as well as the procedure described above were taken into account.

STORAGE

After sterilisation, the products must be stored dry and dust-free in the sterilisation packaging.

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)
- alkaline/strong alkaline solutions (neutral/enzymatic cleaner (maximum permissible pH value 8.5, mandatory for products made of aluminium or other alkali-sensitive materials) or alkaline cleaner (maximum permissible pH value 11, mandatory for products intended for use in prion-critical areas, e.g. in accordance with Annex 7 of the KRINKO RKI BfArM recommendation for reprocessing) recommended)
- organic solvents (e.g. alcohols, ethers, ketones, petrols)
- oxidising agents (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

Never clean products, sterilisation trays and sterilisation containers with metal brushes or steel wool.

All products, sterilisation trays and sterilisation containers may only be exposed to temperatures not exceeding 138°C (280°F).

REUSABILITY & LIMITATION

The products can be reused, provided they are undamaged and uncontaminated. Any further use beyond this or the use of damaged and/or soiled products is the responsibility of the user. The user alone is responsible for deciding on the frequency of application. If in doubt, the products should always be rejected and replaced at an early stage.

In the case of non-compliance, any liability is excluded.

The above instructions have been validated by the medical device manufacturer as suitable for preparing a medical device for reuse. The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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