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Processing Instruction

Processing Cleaning, Disinfection and Sterilization) of Products

General Principles

All products must be cleaned, disinfected and sterilized before each use; this particularly applies to the first use after delivery, as all products are delivered unsterilized (cleaning and disinfection after removing the transport protection packaging; sterilization after packaging). A thorough cleaning and disinfection is an indispensable requirement for effective sterilization.

Please note as part of your responsibility for the sterility of the products during use that
- generally, only suitable equipment and product-specific validated procedures are to be used for cleaning/disinfection and sterilization,
- the equipment used (WD, sterilizer, etc.) are to be regularly maintained and inspected, and
- the validated parameters are to be observed for each cycle.

Please ensure during use that contaminated instruments are collected separately and not placed back into the instrument tray in order to avoid further contamination of the loaded instrument tray. Clean/disinfect the contaminated instruments, then resort them back into the instrument tray and then sterilize the fully loaded instrument tray.

Please also adhere to the legal requirements applicable in your country as well as the hygienic requirements of the medical practice or hospital. This particularly applies to the various requirements (e.g. in Germany according to attachment 7 of KRINKO RKI BfArM recommendation for processing) regarding to an effective prion inactivation (not applicable for the USA).

Remark:
Application of the products is only admitted to qualified professionals.

Processing must performed only by qualified staff in the central sterilization service department of the hospital or in the processing room of the medical practice. Hospital or medical practice are responsible for selection and application of required of protective equipment and hygienic measures.

Please observe differing and/or additional requirements for several products in the “Special Instructions” section.

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Cleaning and Disinfection

Principles

For cleaning and disinfection, if possible an automated procedure [WD (washer-disinfector)] should be used. A manual procedure – even using an ultrasound bath – should only be used according to country specific requirements (e.g. in Germany for critical B products automated procedure binding) and if an automated procedure is not available due to the significantly lower effectiveness and reproducibility.

Pretreatment must be carried out in both cases.

Pretreatment

Immediately after use (within maximum 2 h), large impurities must be removed from the products. If observation of this time is not possible in consequence of duration of application or of organizational reasons, it is the responsibility of the user to define and validate measures in order to avoid complete drying of contamination.

Procedure

1. Disassemble the products as possible (see specific disassembly/assembly instructions).
2. Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Shift the movable parts back and forth at least three times during the prewash.
   If applicable (see "Special Instructions" section):
   Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).
3. Insert the disassembled products for the predefined soaking time in the pre-cleaning bath[1] (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the pre-cleaning by completely brushing all internal and external surfaces (at the beginning of the soaking time, see "Special Instructions" section for aids). The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel.
   Shift the movable parts back and forth at least three times during the pre-cleaning.
   If applicable (see "Special Instructions" section):
   Rinse all lumina of the products at least three times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).
4. Activate the ultrasound for an additional minimum soaking time (but not less than 5 min).
5. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Shift the movable parts back and forth at least three times when rinsing.
   If applicable (see "Special Instructions" section):
   Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).

When selecting the cleaning agent[1], ensure that
- it is generally suitable for cleaning invasive medical devices made of metals and plastics,
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- the cleaning agent is compatible with the products (see "Material Stability" section).

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent or the cleaning/disinfecting agent as well as the specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)[2] or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

[1] If you – e.g. for occupational safety reasons – use a cleaning and disinfecting agent for this, please ensure that this is aldehyde-free (otherwise it would fixate blood contaminants) and has verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), is suitable for disinfecting the products and is compatible with the products (see "Material Stability" section). Please keep in mind that the disinfecting agent used in pretreatment serves only for personal protection and cannot replace the disinfection step to be carried out later after cleaning.

[2] In case of consideration of a lower water quality as sufficient based on the background of national recommendations (e.g. in Germany KRINKO RKI BfArM recommendation for processing).

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Automated Cleaning/Disinfecting [WD (Cleaning and Disinfection Device)]

When selecting the WD, ensure that
- the WD generally has verified effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
- if possible, a tested program for thermal disinfection (A_0 value ≥ 3000 or – for older devices – at least 5 min at 90 °C/194 °F) is used (in chemical disinfection danger of disinfecting agent residues on the products),
- the program used is suitable for the products and contains sufficient rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents),
- for rinsing only sterile (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used,
- air used for drying is filtered (oil-free, low-bacteria and low-particle) and
- the WD is regularly maintained, inspected, and calibrated.

When selecting the cleaning system, ensure that
- it is generally suitable for cleaning medical instruments made of metals and plastics,
- providing no thermal disinfection is used – a suitable disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that it is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products (see “Material Stability” section).

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent and, if applicable, the disinfecting agent as well as specifications for rinsing must be adhered to.

Procedure

1. Disassemble the products as much as possible (see specific disassembly/assembly instructions).
2. Place the disassembled products into the WD. Ensure that the products do not touch.
   If applicable (see chapter "Special instructions"):
   Enable active rinsing by connecting to the WD rinse port.
3. Start the program.
   Validated cycle parameters as follows:

Step	Name	Medium	Temperature [°C]	Duration [Min.]
1	Rinse	Water	Not controlled (< 30°C)	1
2	Empty	-	-	-
3	Clean	Alkaline cleaner: Neodisher MediClean (Dr. Weigert GmbH & Co. KG, Hamburg) Concentration: 0.2 – 1% (as per manufacturer’s instructions)	55	10
4	Empty	-	-	-
5	Rinse	Deionized water	Not controlled (< 30°C)	1
6	Empty	-	-	-
7	Disinfection (thermal)	-	95	5
8	Dry	Hot air	100	25

4. Disconnect the WD (at the appropriate time) and remove the products after the program has completed.
5. Inspect and pack the products as soon as possible after removal (see “Inspection,” “Maintenance” and “Packaging” chapters, possibly after additional drying in a clean area).

Note on diamond knives
- Diamond blades must not come into contact with other instruments to avoid damaging the blade.
- Diamond blades are made of an extremely hard, but fragile, material. Handling these ultrasharp blades with caution can avoid damage.
- Mechanical contact must be avoided.

- After every use, the blade must immediately be returned to its titanium handpiece.

The verification of products' general suitability for effective automated cleaning and disinfecting was provided by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher MediClean pre-cleaning and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg). Here, the procedure described above was taken into consideration.

Manual cleaning and disinfection

When selecting the cleaning and disinfecting agent, ensure that
- it is generally suitable for cleaning and disinfecting medical instruments made of metals and plastics,
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- a disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products (see "Material resistance" chapter).

Combined cleaning/disinfecting agents should not be used if possible. Combined cleaning/disinfecting agents can be used only in cases of very low contamination (no visible impurities).

In case of manual cleaning and disinfection with a potential risk of injury and infection observation of measures of employment protection (e.g. protective clothing, protective glasses, gloves, air filtration) according to national requirements (e.g. in Germany TRBA 250) is required.

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning and disinfecting agent as well as specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)[3] or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

Procedure

Cleaning
1. Disassemble the products as much as possible (see specific disassembly/assembly instructions).
2. Place the disassemble products for the predefined soaking time in the cleaning bath (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the cleaning by completely brushing all internal and external surfaces with a soft brush. (Attention: Caution with products with narrow gaps, in which bristles of the brush can get stuck!) The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel. Shift the movable parts back and forth several times during cleaning.
   If applicable (see "Special Instructions" section): Rinse all lumina of the products at least five times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).
3. Activate the ultrasound for an additional minimum exposure time (but not less than 5 min).
4. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Shift the movable parts back and forth several times when rinsing.
   If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times (aids and minimum volume depend on the cavity to be rinsed).
5. Inspect the products (see "Inspection" and "Maintenance" chapters).

Disinfection
6. Place the disassembled and inspected products in the disinfection bath for the predefined soaking time so that the products are completely submerged. Ensure that the products do not touch. Shift the movable parts back and forth several times during the disinfection.
   If applicable (see "Special Instructions" section): Rinse all lumina of the products at least five times at the beginning and end of the exposure time (aids and minimum volume depending on the cavity to be rinsed).
7. Then remove the products from the disinfection bath and rinse them at least five times thoroughly (for at least 1 minute) with water. Shift the moving parts back and forth several times during the rinse.

If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times (aids and minimum volume depend on the cavity to be rinsed).

8. Dry the products with filtered compressed air.
9. Pack the products as soon as possible after removal (see “Packaging” section, possibly after additional drying in a clean area).

The proof of the general suitability of the products for effective manual cleaning and disinfecting was provided by an independent, governmentally accredited and respected (§ 15 (5) German Law for Medical Devices) test laboratory using the Cidezyme/Enzol pre-cleaning and cleaning agent and the Cidex OPA disinfecting agent (Johnson & Johnson GmbH, Norderstedt). Here, the procedure described above was taken into consideration.


NB

Category Aa products (see Special Instructions section) are not covered by the manual processing validation and must therefore be processed with the automated procedure only.

Care, maintenance and function check

General information

Following cleaning and disinfection, there must be a critical inspection of the cleanliness of the medical products. Sufficient cleanliness is a basic prerequisite for successful sterilisation! The instruments must be visually and tactically inspected and be macroscopically clean, i.e. free from visible residues. The inspection should be carried out for all instruments with the aid of a magnifying glass with magnification of at least 3 dioptres, preferably with a powerful light source.
Contaminated instruments are to be submitted to the entire cleaning process.

Tools to be used

- Magnifying glass with sufficient magnification power (min. 1:3 magnification) and a light source or a microscope
- Suitable scanning device (barcode scanner) to check the identification
- Maintenance oils: vapour-permeable, bio-compatible and intended for the maintenance of medical instruments by the manufacturer.
- Sterile / demineralised water
- Medical injections, min. 10ml volumes
- Consumables for function check: Plastic bag or plastic strips (max. 100g/m²) paper 180 – 250 g/m², cellulose, for example, gauze bandage

Maintenance

Maintenance measures should generally be carried out before the function check. For this, the instrument should be left to cool to room temperature.
Lightly lubricate moving parts (i.e. hinges and ends) with maintenance oil. Also see the chapter ‘Special instructions’, suitable oils should have a paraffin/white oil base, be valid according to European and United States pharmacopeia, biocompatible, vapour-sterilisation capable and vapour-permeable. The maintenance product must be manually applied directly in hinges and threads and on sliding surfaces. The maintenance product should be distributed evenly by moving the hinges/sliding surface. Excess maintenance product must be removed from the surface with a lint-free cloth.
Do not use maintenance products which contain silicon!
Plastic surfaces may not be treated with instrument maintenance products.

Maintenance and function check

Frequent treatment only has a minor influence on the lifetime of the product. The longevity and functional capability of the instrument is predominantly influenced by the appropriate treatment and maintenance of the instruments. If the products are subject to a limited number of times for repeated treatment, this is indicated accordingly in the chapter ‘Special instructions’. However, you should check the product carefully after every treatment cycle for functionality, damages and signs of increased wear and corrosion. Detailed information regarding the maintenance and function checks to be carried out can be found in the chapter ‘Special instructions’.

Function checks

Instruments which can be disassembled should be reassembled before the function check. After a successful check, the instruments are to be disassembled again before packaging for sterilisation.

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Products which demonstrate signs of increased wear or damages may not be reused under any circumstances and must be disposed of.
Defective products which are intended for return to a1 medical must have run through the entire repeated treatment process before they are returned.
Special instructions

Product group	Lifespan restriction?	Checks to be carried out?	Tools
ALL INSTRUMENTS		**- Surface, generally sound** **- Check the identification**	**- Magnifying glass** **- Barcode scanner**
Vessel and tissue clamps	No	- Check container and tissue clamps	- Magnifying glass - Plastic bag
Needles, foreign body needles, cataract extraction instruments	No	- Cutting	- Magnifying glass - Plastic strips max. 100g/m²
Retractor, micromanipulator retractors, elevators, spatula, probes, dilators	No	No specific tests required	No specific tools required
Cannulas, suction tips*	No	Test of cannulas, instruments with lumen	- Sterile / demineralised water - Medical injection
Silicone tubes	max. 10 cycle	No specific tests required	No specific tools required
Needle holder, clamps, forceps	No	- Test of hinges, ratchets, moving parts - Test working ends / jaws	No specific tools required
Tweezers	No	Test working ends / jaws	No specific tools required
Knives, keratomes, scalpels	No	- Cutting	- Magnifying glass - Plastic strips max. 100g/m² or cellulose
Chisels, surgical scoops, curettes, dissectors	No	- Cutting	- Magnifying glass - Plastic strips max. 100g/m²
Clippers	No	- Test of hinges, ratchets, moving parts - Cutting	- Magnifying glass - Plastic strips max. 100g/m² or cellulose
Punches	No	- Test of hinges, ratchets, moving parts - Test of sliding sheath instruments	- Paper 180 – 250 g/m²
Expander springs	No	No specific tests required	No specific tools required
Trepans	No	- Cutting	- Magnifying glass - Light source - Microscope
Ocular marker	No	No specific tests required	No specific tools required

* Corresponding information about a numerical limit for the lifespan was verified in the scope of pre-clinical investigations taking into consideration the most realistic conditions possible during the application and treatment of the products. However, the lifespan of the products can be abruptly shortened due to improper application and treatment or insufficient maintenance and care of the instruments. Therefore, you should carry out a complete maintenance and function check after every application. a1 medical accepts no liability for instruments which do not achieve the indicated lifespan if these are improperly used, treated, maintained or cared for.

Check of the surface, general integrity
If possible, use a magnifying glass with sufficient magnification as well as a light source or ensure there is sufficient lighting in the test environment when checking the surfaces and the general integrity of the instruments.
Visually check the instruments for damaged surfaces, splitting, deformations and burrs - in particular on the working ends, as well as hairline cracks. If such defects are identified, the products are to be rejected.
Check the products for wear, particularly on moving parts, such as hinges or latches as well as on the working ends.
Check the products for loose parts (hinges, rivets or screw connections)
Check the products for corrosion or surface alterations which could encourage the formation of corrosion (for example, yellow-brown to dark brown restricted discolouration on instruments, particularly on hard to reach parts such as locks, drag lines and hinges).
Possible appearances of corrosion could be:

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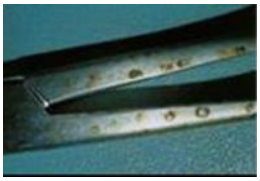
Surface corrosion

Stress crack corrosion

Hole corrosion

Rust film



Wear corrosion

Reject instruments with:

- Any type of corrosion
- Damaged surfaces, splitting, burrs
- Hairline cracks-
- Deformations which impair functionality (see also specific functionality checks in the following sections)
- Excessive wear which impairs the functionality, for example, to hinges (see also specific functionality checks in the following sections)

Checking the identification

Check that all the identification elements on the instruments, in particular the elements which are necessary for identification and traceability of the instruments (batch number, item numbers), are clearly legible.
If the instrument has a barcode identification, check this using a suitable scanner (barcode scanner). Instruments must be rejected in the event of a scanner error.
In an emergency, compare the results with your records for identification / traceability of the instruments. If the instrument cannot be identified with certainty it should be rejected.

Check vessel and tissue clamps

Vessel and tissue clamps may not demonstrate any damages or alterations to the jaws which could lead to damage to tissues when enclosing soft tissues. Therefore, you should carry out a careful check of the jaws using a magnifying glass. Pay attention to burrs, sharp edges and drag lines.
Fill a plastic bag with water to check the clamping functionality. Now apply the clamp to one of the bottom corners so that the water is forced upwards when closing. Then open the clip or clamp and check the plastic bag for impressions and perforations. The clip and clamp should leave impressions but not perforations.
Instruments which demonstrate damages or alterations to the jaws or which do not pass the plastic bag test must be rejected.

Cutting check

Check the blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Pay attention to blunt blades as well as drag lines, cracks or splits. You can recognise blunt blades as they do not give off any light reflection under direct lighting.
Carry out a cut test on cellulose (for example, gauze bandages) or plastic strips (max 100g/m²) in order to check the cutting ability of knives, scalpels or clippers. The material should be cut over 2/3 of the blades and a straight, homogeneous cut should be created without tearing or chewing.
Test tips of needles or cannulas by piercing a plastic strip. In this test, the tip must be able to perforate the plastic strips without requiring excessive force. Then slowly pull the instrument back out. The tip may not catch when it is being withdrawn.

Instruments which demonstrate damages or alterations to the cutting surface or do not pass the cutting test must be rejected.

Test trephine cutting
Special instructions to test trepan cutting. Carefully check the cut under a magnifying glass or microscope with a light source for the smallest reflections, burr formation or damages to the cutting edge. If there is even the smallest light reflection on the blade then it is not at its maximum sharpness. Event the smallest burr formation or damages to the blade means a clean cut can no longer be guaranteed. Damaged, blunt trepans must be rejected.

Check of hinges, ratchets, moving parts
Check the hinges and the metallic sliding surfaces / instrument parts which move against each other carefully for excessive wear ('metal eating') as well as loose connecting screws or rivets.
Ratchet locks should close securely and not open independently under counter-pressure.
Hinges must open and close evenly and without friction. However, scissors, clamps and needle holder hinges must demonstrate minimal resistance. Determine this by carrying out a clasping test of the hinge for these instruments. Hold the instrument horizontally by both handles, in a fully open position and then release the upper handle. The instrument should now close approx. two thirds, however not completely, nor 'fall' in the closed position
Test working ends / jaws
Check the working ends / jaws of the instruments carefully for deformations as well as splits, burrs, scoring or hinge loosening. Test the symmetrical and correct position of the jaw by holding the instrument against a light source and closing the jaw. No light should penetrate through the jaws.
Teeth on jaws should close cleanly and not catch or be difficult to open. Check the closure of the toothed jaws by closing the instrument securely and ensuring that the teeth close and open again cleanly and symmetrically without catching or tilting.

Test of cannulas, instruments with lumen
Instruments with lumina such as cannulas must be checked for consistency. In order to achieve this, lumen must be rinsed with sterile water immediately after cleaning / disinfection - in order to prevent blockages. Ensure the interior is dried carefully after the rinsing process. This is achieved by blowing through with a dry injection until no more drops of moisture come out.
Damaged, blunt, bent and impassable cannulas must be rejected.

Checking sliding sheath instruments
Check the punches carefully for a clean run of the carriage. The carriage must run over the complete range cleanly and with consistent resistance. The blades must run cleanly into the foot plate when the instrument is closed.
Check the jaws of rongeurs according to the specifications in the chapter 'Test working ends / jaws'
Check the cutting surfaces of punches and rongeurs carefully with a magnifying glass and appropriate lighting. The cut of the instruments may not demonstrate any burrs, scoring or splitting, nor nay arching.
Use paper with 180 – 250g/m² to check the cutting performance. Introduce the test material with punches at approx. 2/3 of the cutting surface and carry out a cut. The cut must be completely clean, without tearing or 'chewing'. If the cut is not fully clean, the instruments are to be rejected.

Additional note on non-metallic materials:
Products or parts made of plastic, e.g. seals, or glass, e.g. glass obturators, must also be checked for damage. Look in particular for deformations, damage and tears/splitting. Products with this or comparable damage must be rejected.

Packaging

Sort the cleaned and disinfected products into the corresponding sterilization tray. (see the **MIS item number range** in the a1 medical catalogue).

Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) in accordance with the following requirements (material/process):
- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature stability up to at least 138 °C (280 °F) sufficient steam permeability)
- sufficient to protect the products or sterilization packaging from mechanical damage
- undergo regular maintenance according to the manufacturer's specifications (sterilization containers)
- do not exceed a maximum weight of 10 kg per package/contents of the sterilization container.

Sterilization

For sterilization, only the following sterilization methods may be used; other sterilization methods are not allowed.

Steam sterilization
- Fractionated vacuum procedure[4, 5] (with sufficient product drying[6])
- Steam sterilizer 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 (commissioning) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

Country	Fractionated vacuum procedure	Gravity displacement
Germany	at least 5 min[7] at 134 °C (273 °F)	Not permitted[4]
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]	not recommended[4]
France	at least 5 min at 134 °C (273 °F) if required for prion inactivation sterilization time 18 min	Not permitted[4]
other countries	at least 5 min[7] at 132 °C (270 °F) / 134 °C (273 °F)	Not permitted[4]

Verification of the general suitability of the products for effective steam sterilization was provided by an independent, governmentally *accredited and respected* (§ 15 (5) MPG) *test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum procedure, as well as the instrument oil LAWTON MEDOIL. Here, the typical conditions in the clinic and medical practice and the procedure described above were taken into consideration.*

The flash sterilization procedure is generally not permitted.

Do not use dry head sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

Storage

After sterilization, the products must be stored dry and free of dust in the sterilization packaging.

Material Stability

When selecting the cleaning and disinfection agents, please ensure that they do not contain the following components:
- Organic, mineral and oxidizing acids (minimum permitted pH value 5.5)
- Alkalis/strong alkalis (neutral/enzymatic (max. permitted pH 8.5, mandatory requirement for products made of aluminum or other alkali-sensitive materials, see “Special Instructions” section) or alkaline cleaner (max. permitted pH 11, mandatory requirement for products with intended application in prion-critical areas, e.g. in accordance with Annex 7 of KRINKO RKI BfArM recommendation for treatment) recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

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

All products, sterilization trays and sterilization containers can only be exposed to temperatures under 138 °C (280 °F).

Safety and warning information

- Ensure that all equipment used during processing is eligible and serviced according to the manufacturer’s instructions.
- There is a risk of injury or infection when removing transport packaging for the processing of sharp or pointed medical products. This also applies in case of carelessness during manual cleaning/disassembly, or when loading or emptying a cleaning/disinfection device loading trolley.
- Repairs may only be carried out by the manufacturer (Attention: Otherwise, whoever carries out the repair automatically becomes the manufacturer with responsibility for the product!)

[3] at least three vacuum steps
[4] The use of the gravity displacement procedure is not permitted in the European Union. The use of the less-effective gravity displacement procedure outside the European Union is only permitted if the fractionated vacuum procedure is not available, requires significantly longer sterilization times and is subject to product, device, procedure and parameter-specific validation by the user.
[5] The actual required drying time depends directly on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer status) and must, therefore, be determined by the user. Nonetheless, drying time should not be under 20 min.
[6] or 18 min (prion inactivation, not relevant for the USA)

- In case of use of unsuitable process parameters or media, or unsuitable loading of cleaning/disinfection devices (including ultrasound devices), processing residues may remain on the medical product.
- When cleaning in an ultrasound bath, the applicable general rules (no overloading, degassing, etc.) must be observed.
- Media used for the function check must not cause recontamination or cross-contamination. Test facilities must be included in regular hygiene measures.
- For instrument surfaces optimised for ultrasound imaging (e.g. wave-reflecting surfaces on biopsy cannulas), deposits, surface roughening and deformations can reduce the level of reflection and thus the level of contract on ultrasound images.
- Electric radiation: MR-compatible systems can produce artifacts on magnetic resonance images due to changes in their properties in terms of magnetisation or changes to internal resistance, or damage tissue due to the induction of eddy currents.
- Appropriate, hygienically specified and regularly tested media must be used for drying.

Reusability

With proper care, the products can be reused if they are undamaged and uncontaminated. Each additional use or using damaged and/or contaminated products is the user's responsibility.

If disregarded, any liability is excluded.

Symbol key as per DIN EN ISO 15223-1

CE marking with identification number of designated body:

CE 0483

mdc medical device certification GmbH
Kriegerstrasse 6
70191 Stuttgart, Germany

Item number

Batch number


Observe warnings!


Observe information for use


Manufacturer

Non sterile delivery


Keep dry


Keep out of direct sunlight


Fragile, handle with caution

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Do not use if packaging is damaged.
Observe instructions for use.

CE-Symbol

UDI Symbol

Medical Device

a1 medical GmbH
Liptinger Str. 88
78532 Tuttlingen
Germany
info@a1-medical.com
emergency@a1-medical.com
www.a1-medical.com

CE
0483
CE

Standards referenced

Annex 7 of the KRINKO RKI BfArM Recommendation
Steam sterilizer DIN EN 13060/DIN EN 285 and ANSI AAMI ST79 (for USA: FDA clearance)
DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA-Clearance)
DIN EN ISO 17665
DIN EN ISO 15223-1
DIN EN ISO 17664
DIN EN ISO 15883

Specific aspects

Geometric aspects		rinsing volume	brushes	specific/additional procedure in case of			maintenance/ packaging	sterilization
worst case type Example item number	**specific geometric aspects**			**pretreatment**	**manual cleaning/ disinfection**	**automated cleaning/ disinfection**		
Aa2 C-0360-C-0530 VR-0010-23- VR-1610 VR-5000T	tube shaft products with self-closijng jaw without LuerLock or rinsing port no dismantling possible	-	standard brushes	brush outside least 5times during soaking and rinsing	brush outside least 5times during soaking and rinsing	jaw in open position	lubricate joint	lubricated
Ad2 C-0750	tube shaft products with LuerLock no dismantling possible	10 ml (single-use syringe)	standard brushes	brush outside rinse inside at least 5times articulate joint at least 5times during soaking and rinsing	brush outside rinse inside at least 5times articulate joint at least 5times during soaking and rinsing	connect to rinsing port jaw in open position	lubricate joint open Luer-Lock close jaw	lubricated protection cap opened jaw closed
B4 All cannulas	small cannula-like products, with LuerLock	5 ml (single-use syringe)	standard brushes	brush carefully outside rinse inside at least 5times	brush carefully outside rinse inside at least 5times	connect to rinsing port	assemble again no lubrication admitted	standard
C4 F-4440	segmented products with longer/narrow ringlike cannulation dismantling for cleaning/disinfection possible direct connection not possible	-	standard brushes	dismantle brush inside and outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled small pieces basket	assemble nearly closed, but still a little bit loosely lubricate threads	nearly closed, but still a little bit loosely mounted lubricated
Ea2 ES-0271	segmented products with blind cavities without Luer Lock	10 ml (single-use syringe) with fitted extra long cannula (for post-rinsing of the blind cavity)	standard brushes	dismantle brush outside (do not brush inside!) back-rinse inside at least 5 times	dismantled brush outside (do not brush inside!) back-rinse inside at least 5 times	dismantled in small pieces basket	assemble loosely lubricate thread	loosely mounted lubricated

Fa3 L-0010 – L-0070	Sliding shaft instruments no dismantling possible	-	standard brushes	brush outside open and close at least 5times during soaking and rinsing for ultrasonic treatment joint in opened position	brush outside open and close at least 5times during soaking and rinsing for ultrasonic treatment joint in opened position	standard basket joint in opened position	in opened position lubricate the joint	in opened position joint lubricated
G1 L-0001-L0006	instruments with joints dismantling possible	-	standard brushes long brushes (length > 400 mm, diameter approx. 12 mm)	dismantle (removal of the grip tubes) brush outside and inside open and close at least 5times (including lock) during soaking and rinsing soak grip tubes by dipping and taking out for ultrasonic treatment joints in half opened position	dismanted(grip tubes removed) brush outside and inside open and close at least 5times (including lock) during soaking and rinsing soak grip tubes by dipping and taking out for ultrasonic treatment joints in half opened position	standard basket joints in half opened position	assemble (grip tubes) lubricate the joints	mounted lubricated
G4 All needle holders, tweezers, clippers and articulated specula	rectractors with several joints and open threads	-	standard brushes	brush outside and in the gaps open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joints in half opened position	brush outside and in the gaps open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joints in half opened position	standard basket joints in half opened position	not completely closed lubricate the joints and the thread of the spindle	not completely closed

G6 L-0010 – L-0070	instruments with joints self-closing (with lock)	-	standard brushes	brush inside and outside open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joint in half opened position	brush inside and outside open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joint in half opened position	standard basket joint in half opened position	in slightly opened position lubricate the joints	in slightly opened position joints lubricated