



Please observe the instructions for use

Field of application

Instruments for universal surgical use (all specialist areas)

Safe use and preparation

- Please read and observe the instructions for use and keep them in a safe place.
- Only use the product as intended
- Ex-factory products are delivered in a non-sterile condition.
- Always clean ex-factory products thoroughly (either manually or by machine) before the first sterilisation.
- Store ex-factory or unused products in a clean, dry and safe place.
- Before use always check the product for: loose, twisted, broken, cracked, worn and snapped off parts
- Do not use any products that are damaged or defective. Immediately remove any products that are damaged.
- Immediately replace any damaged parts with the manufacturer's replacement parts.

Validated disinfection and cleaning procedure

Note

Please ensure compliance with the relevant national statutory regulations and norms with regard to disinfection and cleaning.

Note

In the case of patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or possible variants, compliance with the relevant valid national regulations when disinfection and cleaning the products must be ensured.

Note

Disinfection and cleaning by machine is recommended rather than manual cleaning as the purification results are better and safer.

Note

It must be observed that the successful disinfection and cleaning of this medical product can only be guaranteed once it has been validated in the disinfection and cleaning process. The operator/processing officer is responsible for this. The manufacturer's instructions serve merely as a guideline for the processing officer's disinfection and cleaning procedure due to process tolerances.

Note

See www.a-k-i.org for current information on disinfection and cleaning.



Disinfection and cleaning of instruments

General information

Dried on and/or stubborn OP residues can make the cleaning process more difficult and/or ineffective and lead to corrosion in the case of stainless steel. Therefore the period of time between use and disinfection and cleaning should not exceed 6 hours, no fixing pre-cleaning temperatures of > 45 °C should be used nor any fixing disinfecting agent (active substance base: aldehyde, alcohol).

Too much neutraliser or basic cleaner can lead to a chemical attack and/or to the fading of the lettering in the case of stainless steel.

In the case of stainless steel chlorine and/or chloride-containing residues, such as are found in OP residues, tinctures, pharmaceuticals, saline solutions, industrial cleaning water and cleaning/disinfectant fluids lead to corrosion (pitting corrosion, stress corrosion) and thus to the destruction of the product. In order to remove these it is important that the instruments are properly rinsed with demineralised water and then dried.

Only those process chemicals that are recommended by the chemical manufacturer for cleaning and disinfecting and that are compatible with the materials should be used. All instructions for use, such as temperatures, concentrations, processing times, etc. must be strictly observed. If they are disregarded this can lead to follow-on problems:

- Optical changes in the material such as fading or colour changes in titanium or aluminium. In the case of aluminium visible changes to the surface can already appear with a pH value of >8 in the application/working solution or damage to the material such as corrosion, tears, breaks, premature aging or swelling.

For further detailed information on the hygienically safe care instructions for quality maintaining processing please see www.a-k-i.org Publications -> Red Brochure -> Proper Maintenance of Instruments.

Preparation for cleaning and disinfecting

- If necessary give the product an initial clean.
- Clean and disinfect product immediately after use.
- When using wet disposal it is advisable to use the appropriate detergent/disinfectant solution. Before using machine cleaning and disinfection rinse the product thoroughly under running water.
- If necessary, clean the product with ultrasound, see Cleaning/Disinfection

Wet cleaning and disinfection

When using wet disposal it is advisable to immerse the instruments in a combined detergent-disinfectant solution that has no protein-fixing effect. Disinfecting agents containing aldehyde should be avoided, because they have a fixing effect.

Dry disposal

In hospitals with a Central Sterile Supply Department (CSSD), closed systems are used to transport contaminated medical devices from the operating theatres and wards to the CSSD. Wherever possible, so-called "dry disposal" should be preferred.

Exposure time

Because of the corrosion risk and cleaning factors, long intervals between instrument use and processing for reuse. e.g. overnight or over the weekend should be avoided, irrespective of the disposal method used (i.e., wet or dry). Experience has shown that in the case of dry disposal, in practice intervals of up to 6 hours pose no problem.

1. Cleaning and disinfecting



IMPORTANT!

Damage to the product due to the use of inappropriate cleaning/disinfecting agents or too high temperatures!

Use cleaning/disinfecting agents that have been approved for surgical steel according to the manufacturer's instructions.

The instructions regarding concentration, temperature and exposure times must be observed.

Do not exceed the maximum cleaning temperature of 55°C

Ultrasonic cleaning and disinfecting

Use ultrasonic cleaning:

- as an effective mechanical method supporting the manual cleaning processes (recommended frequency 35 kHz).
- for removing tenacious encrustations from products before machine treatment.
- as an integral part of machine-based processing cycles.
- to remove tenacious encrustations from products after machine treatment.

If microsurgical products can be securely fixed in machines or on racks so that they can be thoroughly cleaned, use machine cleaning and disinfection methods.

2. Manual cleaning and disinfecting

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemicals
I	Pre-cleaning	RT (cold)	3	-	DW	-
II	Disinfecting cleaning	RT (cold)	15	2	DW	Borer Chemie; deconex 53 INSTRUMENT, mid-alkaline, aldehyde-free, Product information sheet for Borer Chemie at: www.borer.ch
III	Intermediate rinse	RT (cold)	1	-	DW	-
IV	Final rinse	RT (cold)	1	-	DMW	-
V	Drying	RT	-	-	-	-

DW: Drinking water

DMW: Demineralised water

RT: Room temperature

Following manual cleaning/disinfecting check for any dirt residues that may still adhere to the visible surfaces of the instruments. If necessary, repeat the manual cleaning process.

Phase I

- Rinse the product thoroughly (all accessible surfaces) under running water.

Phase II

- Immerse the product completely in the disinfecting solution. Make sure that all the accessible surfaces are wetted.
- Clean the product with the designated cleaning brush until no residues remain on the surface.
- Brush hidden surfaces, such as in products with hidden crevices, lumen or complex geometries for at least 5 minutes and/or until no further residues can be removed. Manipulate articulated components such as adjusting screws, joints, etc. during cleaning.
- Finally thoroughly rinse these areas (at least 5 times) with the cleaning solution using a disposable syringe (20 ml)
- Do not use a metal brush or other scouring agents that will damage the surface when cleaning as this creates a corrosion risk.

Phase III

- Rinse the product thoroughly (all accessible surfaces) under running water.

Phase IV

- Rinse the product thoroughly (all accessible surfaces) under running water.
- Ensure that the product has fully drained.

Phase V

- Dry the product with compressed air.

3. Machine-based cleaning/disinfecting with manual pre-cleaning

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemicals
I	Pre-cleaning	>25/77	3	DW	-
II	Cleaning	55/131	10	DMW	Borer Chemie; deconex POWER ZYME Product information sheet for Borer Chemie at: www.borer.ch
(III)	(Neutralisation, only when cleaning with alkaline cleaning products. When using deconex POWER ZYME neutralisation is not necessary!)	20/68	2	DMW	- Concentrate, acid: Basis: Citric or phosphoric acid Always observe the manufacturer's instructions for use!
IV	Intermediate rinse	70/158	1	DMW	-
V	Thermal disinfection	94/201	10	DMW	-
VI	Drying	90/194	40	-	-

DW: Drinking water

DMW: Demineralised water



- Place the product on the appropriate cleaning tray (avoid areas inaccessible to water).
- Connect individual parts with lumen and channels directly to the special connector in the injector tray.
- Place products with joints on the tray in such a way that the joints are open.
- Following the machine cleaning/disinfecting check for any dirt residues that may still adhere to the visible surfaces of the instruments.
- If necessary, repeat the cleaning process.

Control, maintenance and checks

- Allow the product to cool to room temperature.
- After each cleaning and disinfecting check the product for: cleanliness, functionality and damage, e.g. isolation, loose, twisted, broken, cracked, worn and snapped off parts.
- Check compatibility with related products.
- Immediately remove any products that are damaged.

Packaging

- Protect products with a delicate working end appropriately.
- Sort the product into the correct storage area or tray. Ensure that any blades are protected.
- Pack the trays according to the sterilisation process (ensure that the packaging prevents any recontamination of the product between cleaning/disinfecting and re-use).

4. Sterilisation

- Ensure that the sterilisation agent has access to all the external and internal surfaces (e.g. by opening the valves and taps).
- Validated sterilisation process
 - Steam sterilisation using fractionated vacuum process
 - Steam steriliser in accordance with EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST 46-1993 and validated in accordance with EN 554/ISO 13683
 - Steam sterilisation using fractionated vacuum process at 134 °C / exposure time 5 minutes
- When sterilising several products in a steam steriliser at the same time: Ensure that the maximum load for the steam steriliser according to the manufacturer's instructions is not exceeded.

5. Storage

- Cleaned and disinfected products should be stored in germ-tight, dust-free packaging in a dry, dark environment and temperature fluctuations should be avoided.

6. Disposal

- Surgical instruments must be disposed of professionally.



Technical service

For repairs and reprocessing please contact Ulrich AG. Any modifications can lead to the loss of entitlement to guarantees/warranty claims.

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