

Instructions for Use / Processing Instructions

Reusable Surgical Instruments

1. Function test and visual inspection

The functionality of all instruments must be checked prior to each use.

Instruments with surface damage, such as scratches, cracks, nicks, dents, etc., or bent parts must be repaired. Instruments with any damage of this kind must not be used.

Never use a damaged instrument under any circumstances!

2. Area of use

Surgical instruments are manufactured for use in surgical procedures and must not be used for any other purpose.

The physician in charge is responsible for determining which instruments are suitable for the particular surgical procedure. The physician is also responsible for ensuring that the staff in the operating theatre are adequately trained and informed and have sufficient experience in handling the surgical instruments.

3. Handling

Do not apply excessive stress to the instrument by twisting it or using it as a lever; such handling could damage or break the instrument or its parts.

4. Materials

Our surgical instruments are made from stainless steels in accordance with DIN EN ISO 7153-1; most instruments are polished to a matt or shiny finish prior to delivery.

5. Packaging/storage of surgical instruments

Some of the instruments are very delicate. They should therefore be stored individually in their packaging or in a protective container with individual compartments. To prevent corrosion, instruments should always be kept dry and stored away from chemicals.

6. Cleaning, sterilisation and maintenance

6.1 General

All new surgical instruments must be cleaned and sterilised prior to their first use.

All instruments must be cleaned **immediately** after each use. Never use metal brushes or steel wool.

If you are cleaning instruments in an automatic washer-disinfector or an ultrasonic cleaner, always ensure that the instruments are positioned securely in the device. Avoid any spray shadows or anechoic areas.

After cleaning and sterilisation, all hinged/jointed instruments must be treated with a paraffin-oil-based lubricant to ensure that the hinges/joints move freely and function properly.

All instruments can be sterilised in autoclaves. Instruments with plastic parts cannot be sterilised using radiation as this form of sterilisation destroys the plastic.

6.2 Preparation for disinfection and cleaning

If an instrument can be disassembled, it should be cleaned in the disassembled state.

The instruments should be disinfected and cleaned as soon as possible after use. **Contamination should not be allowed to dry on items** so disinfection and cleaning are not more difficult to carry out. Adhered contamination that is not removed immediately may also lead to it hardening and/or the instrument corroding.

6.3 Cleaning: (automatic cleaning is recommended)

Automatic preparation using thermal disinfection followed by steam sterilisation is the preferred procedure for thermostable medical devices.

6.3.1 Automatic cleaning

The wire baskets must not be overloaded so that the instruments are well rinsed. Spray shadows must be prevented.

Depending on their susceptibility to mechanical damage, the instruments must be placed or stored in such a way that no damage is caused to them.

Only washer-disinfectors (WD) that comply with the general requirements for WD should be used (described in part 1 of EN ISO 15883).

Pre-cleaning:

Remove any gross contamination and traces of blood under running water.

After use place the instrument in a suitable combination of cleaning solution and disinfectant (e.g. 2% Stabimed, BBraun). Remove all visible contamination with a sponge or soft brush. Move non-rigid components such as adjustment screws, joints, etc., during cleaning. Pay particular attention to cavities and hidden surfaces!

After the pre-cleaning, rinse the instruments off/out with powerful jets of water (spray guns are strongly recommended).

Recommended procedure in the WD:

a. Pre-rinse

Cold water with no additives to remove gross soil and foaming substances.

b. Cleaning

Cleaning at 55°C for at least 5 minutes. For automatic cleaning of thermostable and thermolabile instruments, we recommend the alkaline detergent neodisher® MediClean forte (0.5%).

If the water contains higher concentrations of chloride, pitting and stress corrosion can develop on the instrumentation. The use of alkaline detergents or demineralised water can minimise these types of corrosion.

c. Neutralisation

The addition of a neutralising agent based on acid makes rinsing off traces of alkaline detergents easier. The use of a neutraliser is also recommended when using neutral detergents with poor water quality, e.g. with high salt content, to prevent deposits forming. It is recommended to carry out the neutralisation with 0.1% neodisher® Z in cold water.

d. Intermediate rinse

Deionised water with no additives

e. Thermal disinfection / final rinse

Carry out the thermal disinfection at 92°C ± 2°C for at least 5 min (A0 value > 3000).

f. Drying

The washer-disinfector or other suitable methods are used to ensure the instruments are dried adequately. Dry the instruments at > 60°C for about 30 min. If residual moisture is still present, the instruments can be dried further in the drying cabinet at 60°C. The drying time is, however, dependent on both the load and the washed items.

6.3.2 Manual cleaning (not recommended)

a. Pre-rinse

After use rinse the instruments off/out with powerful jets of water using a spray gun.

b. Cleaning

After use place **the instrument** in a suitable combination of cleaning solution and disinfectant (e.g. 2% Stabimed, BBraun) for at least 15 min. Remove all visible contamination with a sponge or soft brush. Move non-rigid components such as adjustment screws, joints, etc., during cleaning.

Pay particular attention to cavities and hidden surfaces! These must be thoroughly cleaned until no contamination can be seen. If necessary, flush through using single-use syringes and cleaning solution.

c. Intermediate rinse

After cleaning, rinse the instruments off/out with powerful jets of water using a spray gun.

d. Immersion disinfection

Allow any remaining water to drain off sufficiently.

Completely immerse the product in a suitable disinfectant solution (e.g. 15 min Stabimed, B Braun). Ensure that all surfaces are wetted. The specifications of the manufacturer of the disinfectant regarding concentration and exposure time must be followed.

e. Final rinse

Thorough final rinse with low-microbe, demineralised water.

f. Drying

Drying with suitable aids (e.g. cloths, compressed air)

6.4 Sterilisation / autoclaving

STERILISER: Steam autoclave with fractionated pre-vacuum:

Sterilise all instruments before use.

Recommended sterilisation method:	Steam sterilisation with fractionated vacuum (3 vacuum cycles)
Recommended temperature:	134°C
Recommended pressure:	3 bar
Holding time:	≥ 5 min

The instructions for use provided by the manufacturer of the device regarding the recommended use must be closely followed for the sterilisation.

7. Creutzfeldt-Jakob disease and HIV infection

We assume no responsibility for the reuse of instruments that have been used on patients with Creutzfeldt-Jakob disease or HIV infection. If there is any reason to believe that the surgical patient is infected with Creutzfeldt-Jakob disease, we recommend the destruction of all instruments used. If instruments are used on patients with Creutzfeldt-Jakob disease or HIV infection, we do not assume any responsibility for reuse.

8. Warranty

All of our instruments are manufactured from high-quality steels and undergo rigorous inspection prior to delivery. No warranty can be given as to the suitability of the instruments for the respective surgery; the user is solely responsible for determining if instruments are suitable.

Any repairs performed on an instrument by a non-authorized service centre or technician shall render the instrument's warranty null and void.

We accept no liability whatsoever for consequential or incidental damages.

9. Additional instructions

Detailed instructions for the processing and maintenance of surgical instruments can also be found on the internet at: <http://www.a-k-i.org>

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