EN

Reprocessing of surgical instruments

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Contents

A. General guidelines

Recommended reprocessing, maintenance and care - please read before use!
Any manufacturer liability is excluded in the event of non-compliance with these instructions for use.

The complete reprocessing procedure pursuant to EN ISO 17664 is described in our instructions for use.

Reprocessing of surgical instruments

Prior to using a product distributed by Silony Medical, the surgeon and the staff members tasked with reprocessing are expected to closely study the following recommendations, warnings and advice as well as the product-specific information (description of the surgical technique, catalogue sheet, etc.). Baat Medical also recommends the attendance of corresponding user training courses.

Warning
All instruments provided by Baat Medical may be used only for the intended purpose. Use of instruments for purposes other than those intended leads to premature wear or to failure, which can in turn lead to serious patient injuries or even death.

Note regarding the use of this product in the United States of America and its territories (USA):
Caution: These instructions for use do not apply to the USA!

Field of application
Baat Medical instruments are intended for use in conjunction Baat Medical implant systems.

Combination with other products
Baat Medical instruments may not be combined under any circumstances with products, components and instruments from other manufacturers. Combinations with products from other manufacturers may adversely affect the outcome of the procedure and are not permissible as the components used may not be compatible with one another.

Using imaging devices to determine location
Prior to using instruments together with imaging devices, the compatibility should be verified in each individual case.

Handling
The instruments must not be overly stressed by twisting or using them as a lever, as this can result in damage or breakage of instrument parts.
All instruments must always be thoroughly cleaned, disinfected and sterilised prior to use as well as removed from the protective packaging and thoroughly cleaned, disinfected and sterilised before using for the first time. They must always be handled with the utmost care during transport, cleaning, care and sterilisation as well as during storage.
This applies in particular to blades, fine tips and other sensitive areas.
Surgical instruments are subject to corrosion and become functionally impaired following contact with aggressive substances (see also information on cleaning, disinfection and sterilisation from Section 3 onwards).

Risks
If instruments are not used as intended or if functional checks are not carried out, or in the event of improper cleaning and incorrect handling, the following hazards can occur:
- Damage to nerves, tendons, ligaments, vessels, tissue and bones
- Bleeding
- Infections

Repair
Defective instruments must be sent to Silony Medical customer service for repair. Customer service assesses the instrument and ascertains whether the instrument can be repaired. A consignment note must always be included with the defective instrument and must contain the following information:
- Hospital address, contact person and telephone number
- Article number of the instrument sent in
- Description of the problem

Reprocessing of surgical instruments

The exchange of instruments that cannot be repaired as well as the replacement of defective or missing parts is carried out by Silony Medical customer service.

Disposal
Should it no longer be possible to repair and reprocess the instruments, they must be transferred to the usual hospital disposal system with subsequent, proper reprocessing.

The return of instruments to Silony Medical is permissible only if the instruments have been cleaned, disinfected and sterilised in validated processes. It is essential to include corresponding proof (evidence of decontamination or batch protocols) with returned goods!

B. Cleaning, disinfection and sterilisation

1. Basics

Effective cleaning and disinfection with validated processes is an essential prerequisite for effective instrument sterilisation.
Within the scope of your responsibility for the sterility of the products in use, please note that only device and product-specific procedures for cleaning/disinfection and sterilisation may be used that are sufficiently validated, and that the validated parameters must be observed for each cycle.
Please also note the applicable legal provisions in your country as well as the operator's hygiene instructions.

Protection of staff members:
Staff members are required to wear protective gloves that meet the requirements of Directive 89/686/EEC especially when handling any used and unclean instruments. Used and contaminated instruments must be transferred to cleaning and disinfection as soon as possible so that maximum safety of staff members is ensured.

Advice
The instruments must be cleaned, disinfected and sterilised as soon as possible (at least within 4 hours of use).

2. Preparing the instruments

Open instruments
Open instruments with ratchet locks, speed locks and hinges.

Pointed and sharp instruments
To avoid injuries, all pointed or sharp instruments must be handled with extreme caution.

Disassemble instruments consisting of multiple parts
Instruments with removable parts must be disassembled. All small parts, such as screws, springs, sleeves, screw-nuts or bolts, etc. must be collected in a suitable container to prevent them from getting lost during cleaning. Please note the advice in the product-specific insert.

3. Automated cleaning process

The following general rule applies: **automated processing** (CDE cleaning and disinfecting equipment) must be used for cleaning/disinfection. Due to the often markedly lower efficacy of manual processing, manual processing must not be used if automated processing is available.
Sharp objects must not be used to remove residues. Metal brushes or steel wool must never be used. Instruments that are not completely clean must be cleaned and disinfected again.

Reprocessing of surgical instruments

3.1 Manual pre-wash

3.1.1 Place the instruments in cold water or in a suitable cleaning bath (Neodisher MediClean forte (Dr. Weigert)) for at least 5 minutes.

In doing so, ensure that all lumens are filled with water!

3.1.2 Brush until all visible residues have been removed

The entire surface of the instruments must be brushed with cleaning brushes while immersed in the water bath. They must then be brushed again under running water. It must be ensured that all surfaces, lumens, cannulations and openings have been cleaned without leaving residues. The use of steel brushes is prohibited. Movable parts, joints and hinges must be cleaned and brushed repeatedly (at least 5 times) while open and closed until all residues have been removed. The entire length of the insides of cavities must be brushed. Clean long, narrow cannulations and blind holes with particular care. It must be possible to flush cannulated instruments.

Cannulated instruments must be cleaned with particular care. To remove blood or tissue residues, suitable brushes of an appropriate size must be inserted repeatedly through the cannulated opening. Then flush thoroughly several times until all residues have been removed completely. Cleaning is only completed when no more residues (including inside the cavities) are visible!

Decontaminate and, if necessary, sterilise or dispose of cleaning brushes after use.

3.1.3 Rinsing

All instruments and instrument parts must then be thoroughly rinsed under running tap water to prevent any remaining media residues from drying and agglutinating and so that no adverse effects must be expected during subsequent automated processing. In doing so, it must be ensured that cannulations are flushed and blind holes are repeatedly rinsed with water and emptied. Instruments with hinges must be brushed under running tap water both when fully open and when fully closed.

Joints and cavities are rinsed for at least 15 seconds with a water gun at 3-4 bar flushing pressure using demineralised water. In doing so, instruments with hinges must be rinsed both when fully open and when fully closed.

Only water or aldehyde-free disinfectants or combination products may be used as rinsing fluid (undesirable fixing of blood stains occurs with aldehyde-based disinfectants). Be advised that disinfectants that are used for pretreatment are for the protection of staff members only and are not a substitute for subsequent disinfection.

3.1.4 Cleaning in an ultrasonic bath

To prevent the formation of air bubbles, the ultrasonic bath must be filled with cold water and degassed prior to use.
Workflow:

- Immerse the instruments in the ultrasonic bath. Insert hinged instruments in an open position!
- Ensure that lumened instruments are filled without air bubbles!
- Exposure time: 5 min. at 40°C (example: 0.5% Neodisher MediClean forte (Dr. Weigert)) in demineralised water.
- Note the instructions provided by the manufacturer of the chemical used.
- A temperature of 40° C must not be exceeded!
- Then rinse joints and cavities for at least 15 seconds with a water gun at 3-4 bar flushing pressure using demineralised water.
- Instruments with hinges must be rinsed using the water gun both when fully open and when fully closed.
- To finish, rinse off thoroughly under running water.

Note: In the event of contamination of the holders or of other parts of the storage system supplied by Baat Medical, this must be brushed off thoroughly and rinsed until no further soiling is visible.

Reprocessing of surgical instruments

3.2 Automated cleaning and disinfection

When selecting the cleaning and disinfecting equipment (CDE), you must make sure that
- the CDE meets the requirements of EN ISO standard 15883 and that the process used is validated,
- the CDE is serviced and checked regularly,
- the program used includes sufficient rinsing cycles,
- Demineralised water is used in the last rinsing step and
- the CDE has a program for thermal disinfection with an adequate A0 value.

When selecting the cleaning agent to be used, you must make sure that
- it is generally suitable for cleaning instruments,
- if thermal disinfection is not possible, a disinfectant with proven efficacy (e.g. VAH (German Association for Applied Hygiene) or CE mark) that is both listed and suitable for automated disinfection of instruments is used additionally and that the product is compatible with the cleaning agent used and
- the chemicals used are compatible with the instruments (see Section 10).

Cleaning agents and disinfectants must not contain the following chemicals:
- Organic solvents (ketones, ester, ether, phenols, haloalkanes, ethyl alcohol, cyclohexanone)
- Highly alkaline solutions
- Strong acids
- Hypochlorite
- Organic, mineral and oxidising acids
- Lyes (only mild alkaline cleaning agents are recommended)
- Halogenated hydrocarbons, chlorine, iodine
- Organic solvents (alcohols, acetone, etc.)
- - Ammonia

No defined limits for the pH value of the cleaning agent can be given. Cleaning agents with a pH value in the cleaning step of < 10.5 are recommended. We recommend using MediClean forte. It is essential that the concentrations indicated by the manufacturer of the cleaning agents and, where applicable, disinfectants are observed.

The cleaning process was validated as follows (in accordance with Table 1):

Level	Water	Cleaning agent	Temperature	Hold time
Pre-wash	Tap water	-	unheated	2 min.
Emptying				
Main cleaning	Tap water	DOS 0.5**	55°C	5 min
Emptying				
Neutralisation	Demineralised water*	-	cold	3 min
Emptying				
Rinsing	Demineralised water*	-	cold	2 min
Emptying				
Thermal disinfection	The CDE program on thermal disinfection must have a A0 value of at least 3,000. In addition, the country-specific national requirements must be taken into account.			
Drying	Program with sufficient drying of the products and at least 20 minutes holding time. Please also note the instructions of the CDE device manufacturer.			

* Demineralised water
** Neodisher MediClean forte (Dr. Weigert)
*** A laboratory examination was not performed due to the specification of the A0 value.

Workflow:

1. Carefully place the instruments into a tray basket onto the loading rack of the cleaning and disinfecting equipment (CDE) in such a way that all surfaces are exposed during cleaning. Place instruments with ratchet locks, speed locks and hinges into the tray basket in an open position. For instruments with

cavities make sure that they are flushed and emptied during the cleaning process inside the CDE; flushing connections or MIC racks may be necessary for this.
2. Start the program (based on Table 1).
3. Once the program has ended, remove the instruments from the cleaning and disinfecting equipment (CDE) using clean disposable gloves.
4. Check cleanliness: after automated cleaning, check whether residues are visible. If residues are visible, the cleaning/disinfecting processes must be repeated.
5. Check the function of the instruments (see Section 7).
6. Package the instruments as soon as possible (see Section 8, if necessary after additional drying in a clean location).

Proof of basic suitability of the instruments for effective automated cleaning and disinfection was provided by an independent, accredited test laboratory using the cleaning and disinfection equipment (CDE) Miele G7735 CD / Miele G7836 CD (thermal disinfection), the cleaning agent Neodisher MediClean forte and demineralised water for neutralisation. The procedure outlined above was taken into consideration.

When using other procedures, their basic suitability and efficacy must be confirmed within the scope of a validation.

4. Manual cleaning and disinfection

In order to meet our obligations as an initial distributor, a completely manual procedure is described below.

Caution: We nevertheless strongly advise against the use of completely manual processing!

4.1 Place the instruments in cold water or in a suitable cleaning bath (Neodisher MediClean forte (Dr. Weigert)) for at least 5 minutes.

In doing so, ensure that all lumens are filled with water!

4.2. Brush until all visible residues have been removed

Brush the entire surface of the instruments with cleaning brushes while they are immersed in the water or cleaning bath (0.5% Neodisher MediClean forte (Dr. Weigert) cleaning solution with demineralised water at 20°C +-2°C). Ensure that all surfaces, lumens, cannulations and openings are cleaned without any residues.
Do not use steel brushes. Movable parts, joints and hinges must be cleaned and brushed repeatedly (at least 5 times) while open and closed until all residues have been removed. Brush the entire length of the insides of cavities. Clean long, narrow cannulations and blind holes with particular care.
Cannulated instruments must be cleaned with particular care. To remove blood or tissue residues, insert a suitable brush of an appropriate size repeatedly through the cannulated opening and then rinse thoroughly several times until all residues have been removed completely. Cleaning is not complete until no more residues, including inside the cavities, are visible! It must be possible to flush cannulated instruments.

After that, brush again under running water.

Clean, disinfect and sterilise or dispose of cleaning brushes after use.

4.3 Rinsing

All instruments and instrument parts must then be rinsed thoroughly under running tap water for at least 10 seconds to prevent residues from drying and agglutinating. In doing so make sure that cannulations are flushed and blind holes are repeatedly rinsed with water and emptied. Instruments with hinges must be brushed under running tap water both when fully open and when fully closed.

Joints and cavities are rinsed for at least 15 seconds with a water gun at 3-4 bar flushing pressure using demineralised water. In doing so, instruments with hinges must be rinsed both when fully open and when fully closed. Use only water or aldehyde-free disinfectants as rinsing fluid (undesirable fixing of blood stains possible with aldehyde-based disinfectants!).

Please note that disinfectants that are used for pretreatment are for the protection of staff members only and cannot fully replace subsequent automated disinfection.

4.4. Place instruments into the ultrasonic bath

To prevent the formation of air bubbles, the ultrasonic bath must be filled with cold water and degassed prior to use.

- Immerse the instruments in the ultrasonic bath. Insert hinged instruments in an open position
- Ensure that lumened instruments are filled without air bubbles
- Exposure time: 10 min. at 40°C (example: 0.5% Neodisher MediClean forte (Dr. Weigert)) in demineralised water
- A temperature of 40° C must not be exceeded.
- Joints and cavities are then rinsed for at least 15 seconds with a water gun at 3-4 bar flushing pressure using demineralised water. In doing so, instruments with hinges must be rinsed both when fully open and when fully closed.
- To finish, rinse thoroughly under running water for at least 10 seconds in each case.

Note: In the event of contamination of the holders or of other parts of the storage system supplied by Baat Medical, this must be brushed off thoroughly and rinsed until no further soiling is visible.

4.5 Manual disinfection

Manual disinfection must be performed in accordance with the disinfectant manufacturer's instructions. When selecting the disinfectant to be used, strictest attention must be paid to ensuring that it is suitable for the intended use, product group and materials and has e.g. been authorised by the VAH (German Association for Applied Hygiene) and is listed in VAH's disinfectant list for efficacy-tested products.

The indicated concentrations, exposure times, rinsing and secondary rinsing cycles must be observed in order to ensure efficient disinfection. The following general rule applies: automated processing is superior to manual processing and preference must always be given to automated processing.

5. Inspection, functional check and care

5.1 Visual inspection and functional check

- Inspect the instrument for visible residues immediately after cleaning.
    - The instrument must be free from any visible residues.
    - Cannulations must be free from any residues.
- Check critical areas, such as hinges, joint connections, cavities, lumens, handles and connectors, with particular care.
- Inspect the instrument for signs of parts that have become loose, e.g. loose screws, immediately after cleaning.
- Check instruments for intact surfaces as well as for correct alignment and function. It is essential for poorly functioning, damaged, corroded or blunt instruments to be repaired or replaced.
- Always check that the instrument is complete and functional before use and that there are no cracks or signs of breakage. Areas such as blades, tips, Torx, hinges, locks and catches in particular as well as all movable parts must be checked carefully.
- Do not use damaged instruments. Do not carry out repairs yourself.
- Servicing and repairs may be carried out only by Silony Medical members of staff.
- The employees of Silony Medical will be happy to answer your questions.

5.2 Care

In order to retain the functionality of the instruments, we recommend the application of maintenance oils to prevent friction corrosion.

Only biocompatible oils authorised for this purpose may be used. The oil must be suitable for steam sterilisation and vapour-permeable. Please note the requirements of the valid European and other applicable guidelines.

The oil is applied to the critical areas of the instruments prior to sterilisation. Critical areas include joints, friction surfaces, threads and hinges of forceps with a scissor function. After that, move the joints and connections to ensure that the oil is distributed evenly. Excessive or superfluous oil must be carefully removed with a lint-free cloth. Please note the advice in the product-specific insert.

The oil must always be applied manually as an automated process does not offer sufficient protection. Immersion baths must not be carried out.

The maintenance oil may be used only on metal instruments. Plastic surfaces must not be treated with maintenance oil.

6. Packaging

Prior to sterilisation, the instruments must be packaged with a suitable sterile goods barrier system (sterilisation in the PE protective packaging in which the instruments are supplied is not permissible).

The sterile goods barrier system:

- must be suitable for the packaging systems and the sterilisation procedures used in accordance with the applicable standards and requirements
- must be taken into consideration accordingly in process validation

7. Sterilisation

Only cleaned and disinfected instruments packaged in a suitable sterile goods barrier system may be sterilised.
Only the sterilisation procedures listed below are permitted for use in sterilisation; other sterilisation procedures are not permissible:
Steam sterilisation

- Fractionated vacuum procedure[1] (with sufficient drying of the products at the end of the process)
- Steam steriliser in accordance with EN 13060 and EN 285
- Procedure validated in accordance with EN ISO 17665-1 (valid commissioning and product-specific performance evaluation)
- Minimum sterilisation temperature 134°C
- Maximum sterilisation temperature 137°C (value corresponds to minimum temperature plus tolerance of + 3°C in accordance with EN 285)
- Minimal sterilisation time 3 min.
- Sufficient drying (at least 20 min.)

1 When using the less effective process of downward displacement, corresponding proof must be provided by additional validation (longer sterilisation times may be necessary).

Proof of basic suitability of the instruments for effective steam sterilisation was provided by an independent, accredited test laboratory using the fractionated vacuum procedure (Selectomat HP 666-1 HRED from MMM Münchener Medizin Mechanik GmbH, Planegg). The procedure outlined above was taken into consideration.
The use of other sterilisation procedures (e.g. ethylene oxide or low-temperature plasma sterilisation) is beyond the manufacturer's responsibility. In this case, please observe the respective applicable standards (EN ISO 14937/ANSI AAMI ISO 14937 and/or procedure-specific standards) and provide proof of the suitability and principal efficacy of the procedure in consideration of the specific product geometry as part of the validation.
Sterilisation with hot air must not be used (instruments may be destroyed).

8. Reusability

Provided no functional or surface damage is visible, the instruments may be reprocessed and reused. The longevity of the instruments depends on how often they are used, on how they are cared for, and on whether

the reprocessing procedures are observed and maintained. As it is the duty of the operator to check the instruments before each use, the operator bears the responsibility as well as the risk if dirty or damaged instruments are used (no compensation for damages).

Restrictions on repeated reprocessing
There are no restrictions: repeated reprocessing has little impact on the service life of the instruments. As a general rule, the service life is determined by wear and damage resulting from use.

Stability/material resistance
The instruments must not be exposed to temperatures higher than 137°C. When selecting the cleaning agents and disinfectants, please ensure that they do not contain the chemicals listed in Section 3.2. The quality of the water can influence the results of the cleaning and disinfection of instruments. High concentrations of chlorine and other minerals in running water may cause corrosion or other damage. If corrosion occurs and all other causes of corrosion have been ruled out, the quality of the media should be checked.

Overstressing of instruments
Instruments were designed only for the intended purpose and must also be used accordingly. Improper use and reprocessing can lead to overstressing and permanent impairment and can make the instrument more susceptible to corrosion.

9. Storage

Sterility of the medical devices is only guaranteed if the instruments were packaged and are also stored in accordance with the current standards. All of the process and expiry dates relevant for the user must be indicated on the packaging. Instruments should be used in the same order in which they were received.

10. Labelling and symbols

Each instrument is labelled using laser inscription with
- Article number
- Article designation
- Lot no.
- CE

The symbols used on labels and in the product-specific inserts are explained below:


Legal manufacturer


Production date in YYYY-MM-DD

Quantity


Follow instructions for use

Order number / article number

Lot number


Store in a dry place

Content in unsterile packaging


Protect from sunlight


Caution: Additional notes must be observed.


Do not use if the packaging is damaged


Next service
Including the year and month in accordance with the following format: "YYYY-MM-DD"


Number of annual service cycles required


Number of reprocessing cycles permitted

11. Additional information

The national guidelines apply. Furthermore, internal hospital instructions and the recommendations of the manufacturers of cleaning agents and disinfectants and of CDE and sterilisation machines must be observed. Baat Medical has validated that the above instructions are suitable for the preparation of the instruments for reprocessing. The person reprocessing the instruments is responsible for ensuring that the reprocessing actually performed with the equipment and materials used and by the staff members in the reprocessing facility achieves the desired results. For this it is necessary to validate and routinely monitor the workflow. Any deviation from the instructions provided must also be carefully evaluated in terms of its efficacy and possible negative consequences by the person performing the reprocessing.

For more advice about reprocessing medical devices, visit:
Internet: http://www.rki.de / http://www.a-k-i.org

Warranty:
The products are fabricated in accordance with EN ISO 13485, manufactured using high-quality materials and are subject to quality control prior to delivery. Should errors nevertheless occur, please contact our service. Any liability for products that are modified, used for other purposes or used improperly compared to the original is excluded. Silony does not assume liability if violations of these instructions for use are demonstrated.

vCJD advice:
We do not accept any responsibility for reuse in the event that the instruments are used in patients with Creutzfeldt-Jakob disease. It is not possible to take back such instruments without prior agreement and coordination of the measures to be performed.

C. Material science

In order for the instruments to be reprocessed and maintained correctly, the user must be familiar with the used materials and their properties.

Stainless steels

Reprocessing of surgical instruments

Baat Medical instruments are manufactured predominantly from corrosion-resistant steels. Thanks to their high chromium content, stainless steels form a protective layer on the surface of the metal. This passive layer protects the instrument from corrosion. Incorrect handling (e.g. damage of the surface) and exposure to chemical, physical or thermal wear can impair the resistance to corrosion.

Titanium alloys

Anodised titanium base alloys are used for a small number of applications (e.g. colour coding ring). Pure titanium and titanium alloys are widely used as materials in implant devices. Titanium base alloys are subject to an electrochemical treatment of the surface (anodisation) which forms a resistant oxide film on the surface of the titanium. Different shades of colours can be set via the thickness of the layer. The protective oxide film of the titanium alloys can become corroded by treatment with cleaning agents with pH values above 11.

Silicone rubber

All handles are manufactured using Elastosil® silicone. Silicone rubber is highly resistant to high and low temperatures. There is almost no change in the physical properties between –50°C and +180°C. Resistance to chemicals and environmental factors is also typical of this material. The handles can be repeatedly reprocessed without problems using the hospital's usual reprocessing procedure. However, as with other instruments, they must also be inspected for damage and material wear after and before each use for safety reasons.

Causes of superficial changes and corrosion

Incorrect handling or contact with physical, thermal or chemical agents can damage the surface of the instruments. In order to prevent the development of corrosion and material deterioration, the possible causes and remedial measures are listed below.

Secretions, blood, pus

Tissue residues contain chloride ions. If they adhere to or are left to dry on an instrument for longer periods of time, this can lead to corrosion. For this reason, instruments must always be cleaned and dried immediately after use.

Water, saline solutions

Saline solutions contain sodium chloride ions, which can cause pitting. Contact with these ions must be kept to a minimum. To ensure that all residues are removed, thoroughly rinse instruments with distilled water. Normal tap water often contains concentrations of minerals that are visible on the surfaces of instruments as stains. In most cases, these stains and rings can be removed with non-abrasive stainless steel cleaning agents. Dry instruments immediately and do not allow them to remain wet for extended periods. Condensation develops during sterilisation. This can be prevented by prolonging the drying time.

Cleaning agents and disinfectants

Concentrations of cleaning agents and disinfectants that are too strong as well as highly acidic and alkaline cleaning agents can damage the protective oxide film and cause pitting. When these agents are used, it is essential to observe the concentration and exposure time recommended by the manufacturer. For further details, see Section 6. When automated cleaning is used, the instructions provided by the cleaning agent and device manufacturer must be followed.

Steel wool, steel brushes

The use of steel wool, steel brushes or files to clean surgical instruments is not permitted. The mechanical, abrasive treatment of the instruments damages the passive layer, which leads to corrosion.

Contact between instruments

Stainless steel instruments that come into contact for longer periods of time with other materials such as non-stainless steels with damaged surfaces can develop rust near the contact points if these are coated with an electrolyte at the same time, such as water, steam or ultrasonic cleaning solutions. It is essential to remove and replace instruments on which rust has formed. Instruments must always be cleaned while open and after disassembly in order to prevent crevice and frictional corrosion.