

Guidelines for processing and
sterilising instruments

Table of contents

Underlying concept of the document	1–5	The hospital's responsibilities for instruments lent out by Mathys Ltd Bettlach	26
Purpose, scope, glossary, symbols			
General information concerning reprocessing	6–13	Customer service information	27
Preliminary notes			
Processing			
Warnings and precautions			
Checking of instrument sets on arrival for contents and proper working order			
Restrictions			
Processing instructions	14–20	Further reading	28
Tips for processing during and immediately after use			
Preparation for cleaning			
Preparation of the detergents			
Instructions for manual cleaning/disinfection			
Instructions for combined manual/machine cleaning and disinfection			
Instructions for machine cleaning/disinfection			
Inspection, maintenance, testing and treatment with lubricants			
Packaging, sterilisation, storage	21–25	Appendix	29–31
Packaging of single instruments		Example 1 Manual cleaning/disinfection procedure	
Packaging of instrument sets in stiff trays and containers with lids		Example 2 Combined manual/machine cleaning/disinfection procedure	
Instrument trays and containers with separated, pre-configured layouts		Example 3 Typical machine washing/disinfecting cycle for cleaning/disinfecting surgical instruments	
Sterilisation instructions			
Storage instructions			

Underlying concept of the document

Purpose

Instruments contaminated by handling present a considerable risk potential, both for medical personnel and for the patients being treated. The greatest danger is for doctors and their personnel in the form of cuts and stab wounds, while patients can be infected by cross-infection due to instruments not being correctly processed. Preparing the instruments is therefore one of the fundamental tasks of medical hygiene.

This document provides safe handling practices for all persons involved in the cleaning and sterilisation of re-usable instruments and helpful information for the effective reprocessing and maintenance of such instruments supplied by Mathys Ltd Bettlach.

Furthermore, these guidelines should make it easier for the administrative department and the persons responsible for hygiene in hospitals to develop procedures for processing Mathys Ltd Bettlach's instruments safely and effectively.


The hospital management and the management of the individual departments must be aware of these instructions and recommendations in order to ensure safe and effective reprocessing by the personnel responsible for this task. This is important in order to prevent damage to or misuse in respect of the environment, people and materials.

Scope

The contents of these guidelines concern the care, cleaning, disinfection, maintenance and sterilisation of instruments used in orthopaedic surgery. They apply both to all re-usable medical products and to non-sterile disposable medical products manufactured and/or sold by Mathys Ltd Bettlach.

Products for once-only use can be reprocessed provided they have not been used. This also includes disposable instruments supplied packaged and in sterile conditions which have been removed from the packaging and placed in kits.

WARNING: Any disposable products that have not been used but that have been contaminated with blood, bone, tissues or body fluids may not be reprocessed or re-sterilised and have to be disposed of.

Products that must not be re-used are identified by the following symbol: 

These guidelines refer in particular to functional accessories (reamers, drilling attachments, etc.), used together with electronic or pneumatic instruments.

Glossary

Processing/Reprocessing: This covers the whole period of time required for cleaning, disinfection, maintenance and sterilisation as well as for the preparation of a new medical product or one that has already been used.

Chemicals: These are industrially manufactured chemical substances. In this specific context they are used within the framework of the reprocessing of instruments.

N.B.: This includes detergents, surfactants, flushing agents, disinfectants, enzyme cleaners and sterilising agents.

Decontamination: The removal of infectious impurities known as contamination. This is carried out on objects or surfaces using physical or chemical means, until they are no longer capable of transmitting infectious particles. This enables safe handling of surfaces or objects.

Disinfection: Measures thanks to which the number of infective agents is reduced to such an extent that transmission and infection are no longer possible. A 100% reduction of the germs is not achieved, rather a reduction by a factor of at least 10^{-5} . This means that not more than a single germ capable of reproduction survives out of every original 100,000 germs.

N.B.: Cleaning and disinfection are usually carried out in one step.

Contaminated: Condition after a potential or actual contact with micro-organisms.

Manual cleaning: Cleaning by hand without using a washing/disinfecting machine.

Cleaning: This is a procedure for separating and removing undesired substances and dirt sticking to an object to the extent required for further processing.

Sterile: The term “sterile” is used when a product is free of all viable micro-organisms (see “Sterilisation”).

Sterilisation: This refers to validated procedures by means of which materials and/or products are freed of living micro-organisms able to form colonies. With sterilisation the germs are reduced by a factor of 10^{-6} .

N.B.: With sterilisation procedures, the degree of microbiological destruction is expressed as an exponential function, and is indicated in terms of probability. This can therefore be reduced to a very low number but never to nil. The degree of probability is only guaranteed by a validated procedure.

Washing/disinfecting machine: Used for cleaning and disinfecting medical products and items for use in the fields of medical, dental, pharmaceutical or veterinarian practice/clinical medicine.

Symbols

STERILE R

Sterilised by radioactive radiation

STERILE 

Autoclaved

STERILE GP

Sterilised with gas plasma

STERILE EO

Sterile product, sterilised with gas (ethylene oxide)



Not for re-use / for private use only / use once only



CE marking



Warning: consult the accompanying documents



Use by ...



Manufacturing date

Mat.

Material



Non-sterile

General information concerning reprocessing

Preliminary notes

These guidelines refer to all Mathys Ltd Bettlach's surgical instruments and must be read thoroughly. Users in the various countries should comply with local laws and regulations to the extent that these call for application of stricter reprocessing requirements than those set forth in these instructions. New and used instruments are to be processed in accordance with these guidelines before use. During operations in the region of parts of the locomotor system, instruments become contaminated with blood, tissues, bone splinters and bone marrow. Furthermore, instruments may come into contact with body fluids containing the hepatitis virus, the HIV virus or other aetiological pathogens. All personnel involved must be trained in the required and generally recognised precautionary measures. Injuries caused by sharp instruments during and after surgical operations and during reprocessing can be avoided.

The saline solutions and other rinsing fluids used can have a corrosive effect on instruments, and their use must be taken into account when processing the instruments.

In orthopaedic surgery, heavy instruments with a number of components, articulating or revolving mechanisms, removable handles, synthetic replacement parts and a whole range of measuring instruments or other measuring equipment of various sizes are required. The instruments are usually supplied in sets, distributed among several instrument trays and/or containers. The products are arranged on the basis of their sizes

or in the order required for a given operation. The hospitals are responsible for cleaning, disinfecting, packaging and sterilising the instruments belonging to sets loaned to them by Mathys Ltd Bettlach. Upon receipt of the loaned sets, these must be re-checked for cleanliness and degree of contamination.

Only after this has been done may the reprocessing procedure for preparing the instruments for subsequent use be carried out. Mathys Ltd Bettlach cannot guarantee that sterility has been achieved by the previous user and that it has been maintained during transport. Partners of Mathys Ltd Bettlach open and check instrument sets for lending before they are despatched again, thus invalidating their sterility. Complete reprocessing before re-use is compulsory.

All instruments supplied by Mathys Ltd Bettlach can be safely and effectively reprocessed provided the instructions for manual or machine cleaning are followed. All medical instrument sets must be complete and in good condition, so as to ensure correct use.

Optional medical instruments are available from your local Mathys partner on request. To care for surgical instruments properly, it is important to comply strictly with the processing instructions provided below:

- Warnings and precautions
- Completeness and proper working order of the instrument set

- Restrictions applicable to reprocessing
- Preparations for reprocessing at the place of use
- Preparations for cleaning (including taking apart and putting back together again, where applicable)
- Cleaning, disinfection and drying
- Maintenance, inspection, testing and treatment with lubricants
- Sterilisation
- Sterile packaging
- Storage

Processing instructions

The instructions provided in these guidelines are helpful for implementing the reprocessing of instrument sets, whether they are the hospital's own or on loan, and should be of help for the hospital management and the management of the Sterilisation and Reprocessing Departments for developing procedures.

The information provided is based on Mathys Ltd Bettlach's experience and on studies and experiences in the field of materials science as well as the generally acknowledged recommendations of the following organisations:

- World Health Organization (WHO)
- Robert Koch Institute (RKI)
- Arbeitskreis Instrumenten-Aufbereitung (AKI)
- Swissmedic
- National Health Services (NHS)
- International Organization for Standardization (ISO)
- International Association of Healthcare Central Service Materiel Management (IAHCSCMM)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Dachverband der Schweizerischen Handels- und Industrie-vereinigungen der Medizinaltechnik (FASMED)

N.B.: These guidelines describe and define the required processing steps for new as well as for used instruments, in order to make them sterile.

Warnings and precautions

- Personnel coming into contact with potentially or actually contaminated surgical instruments must implement the generally acknowledged precautions. Special care is required when handling instruments with pointed parts or sharp edges.
- Personal protection equipment (overall, mask, safety goggles, visor, gloves, shoes, shoe covers, etc.) is necessary in order to avoid contact with contaminated or potentially contaminated materials, instruments and products.
- For manual cleaning procedures, Mathys Ltd Bettlach advises against the use of steel brushes or abrasive cloths as they can damage the surfaces and coatings of instruments. Brushes (e.g. synthetic brushes) and cleaning wires (e.g. pipe-cleaners) that do not damage the surfaces are recommended.
- Low-foaming detergents should be used for manual cleaning procedures in order to ensure visibility of the instruments. When cleaning manually with brushes, it is recommended that the instruments should be held constantly below the surface of the cleaning solution. This will ensure that no aerosols will form and avoid splashes that could spread contaminating substances. In order to avoid the accumulation of residues of detergents, all detergents must be removed completely from the product surfaces.
- Heavy objects may not be placed on top of delicate products.
- Do not dry contaminated instruments before reprocessing them. This is important, since all the steps described below for

cleaning and sterilisation will be facilitated where blood, body fluids, bone and tissue residues as well as saline solution or disinfectants are not allowed to dry onto the surfaces of used instruments.

- The chloride and iodide ions contained in detergents and disinfectants cause pitting corrosion. For this reason, contact of the instruments with these ions must be kept as brief as possible. Afterwards, rinse thoroughly with distilled water in order to remove all residues. Never leave wet instruments to stand. Rather, dry them immediately. The condensation of moisture resulting from sterilisation can be avoided by extending the drying phase. Excessively strong concentrations of detergents and disinfectants, as well as strong acid or alkaline detergents, can corrode the protective oxide layer and lead to pitting corrosion. When using such detergents, the concentrations and exposure times recommended by the manufacturers should be observed under all circumstances. Mathys Ltd Bettlach recommends using detergents with a pH of <9.5. For machine cleaning, the indications provided by the machine and detergent manufacturers must be complied with.

[NOTE CONCERNING THE USE OF OIL: The only oil that can be used for lubricating Mathys Ltd Bettlach's instruments (Paraliq 91) is a pure vegetable oil and is non-toxic. The use of other mineral oils is advised against.]

- Only instruments manufactured and/or sold by Mathys Ltd Bettlach may be placed in Mathys Ltd Bettlach's instrument trays and containers. The reprocessing instructions do not apply to Mathys Ltd Bettlach's instrument trays and containers used to contain instruments not manufactured and/or sold by Mathys Ltd Bettlach.
- No de-scaling agents containing morpholine may be used in steam sterilising apparatuses. These products leave residues that in time can lead to damage to polymer instruments.

Checking of instrument sets on arrival for contents and proper working order

- On arrival of the instrument sets at the hospital, they must be checked to ensure that they are complete. The completeness of the following must be checked: screws, screwed or other removable handles, exchangeable additional parts such as blades, right/left-handed accessories and heads. For most instrument trays there is a systematic layout arrangement of the instruments. This is illustrated in the form of diagrams, overview tables, catalogue numbers and/or instrument designations or sizes, screen-printed on the instrument tray and/or container or provided in some other way.
- During surgical procedures, the instruments are used in a pre-established order. Many instruments have measurements marked on them. These include, by way of example, the instruments for determining the positions of bone resections and so on. For this reason, it is necessary for all the required sizes of given instrument ranges to be at disposal. Certain instruments are removed from the instrument sets, due to the fact that they are used only sporadically (e.g. XL trial heads), unless otherwise requested by the user. Should any instruments be missing from an instrument set in any such a situation, please contact your local Mathys partner in order to arrange for these optional items to be added.
- Markings on the instruments that are used to measure anatomical sizes must be legible. These include, among others, measurement markings, angles, inside or outside diameters,

length or depth calibration marks and left and right indications. Should any scales or other markings no longer be legible, please inform your local Mathys partner immediately for an assessment of the instrument.

Restrictions

Patients who, in view of prion diseases such as Transmissible Spongiform Encephalopathy (TSE) or variant Creutzfeld-Jakob Disease (vCJD) and the associated infections, are considered to be a risk and must therefore be operated on using disposable instruments.

- **WARNING:** It is of the utmost importance that alkaline detergents should be completely neutralised and rinsed thoroughly off the instruments.

- If drilling attachments, reamers, rasps and other cutting instruments have been cleaned with alkaline detergents during processing, they must then be carefully inspected. In doing so, it is necessary to make sure that the cutting surfaces are sufficiently sharp for use. If you feel that this is no longer the case, contact your local Mathys partner. To decompose blood, body fluids and tissues, choose a suitable enzyme fluid. Some enzyme solutions are intended specifically for decomposing faecal matter or other organic contaminating substances, and are therefore not suitable for cleaning surgical instruments.

- There are no restrictions preventing repeated processing of Mathys Ltd Bettlach's instruments, since this has a limited impact on the useful life of the instruments. Their useful life is defined as a rule by wear and damage resulting from use (e.g. acetabular reamers).

- Mathys Ltd Bettlach recommends carrying out more thorough manual pre-cleaning or a combined manual/machine cleaning

procedure. Machine cleaning with an instrument washing/sterilising machine alone is insufficient for medical instruments featuring through holes, hollow needles, cavities, closely co-operating surfaces and other complex shapes.

- Instruments made up of several components must be completely taken apart in order to be cleaned.

As a rule it is easy to see when it is necessary to take instruments apart.

WARNING: Make sure that no small parts are mislaid. Any lost items must be reported immediately to your Mathys partner when returning the instruments.

- The instruments must be removed from the metal or polymer trays for manual and/or machine cleaning procedures. Cleaning of instruments inside metal or polymer trays is not permitted. The instrument trays, containers and lids must be cleaned separately.

- The synthetic materials used in Mathys Ltd Bettlach's instrument sets can be sterilised with steam/damp heat.

WARNING: Synthetic materials have a limited useful life. They must be replaced when their surfaces take on a "chalky" appearance or when they become too damaged (e.g. white colouring due to microcracks, flaking off the surfaces), when polymer instruments become excessively deformed or are visibly bent.

For replacements contact your Mathys partner.

- All polymers obtainable from Mathys Ltd Bettlach are unsuitable for use in washing/sterilising machines that work at temperatures of above 141°C and use jets of steam as aids for cleaning. The surfaces of polymer instruments can be badly damaged by these methods.
- Soaking polymer instruments in disinfectants can constitute a necessary step for eliminating certain viruses. Their use, however, can lead to discolouration and even to corrosion of the instruments. Disinfectants contain glutaraldehyde or other aldehydes and can alter the structural bonds of contaminating substances containing proteins, causing them to harden and making them difficult to remove. Mathys Ltd Bettlach therefore advises against soaking polymer instruments in disinfectants.
- Steam/damp heat, gas plasma and ethylene oxide (EO) are the recommended sterilisation methods for Mathys Ltd Bettlach's instruments.
- Dry heat is counterproductive as a sterilisation method for reusable instruments supplied by Mathys Ltd Bettlach.
- Instruments with removable polymer sleeves must be taken apart for sterilisation (e.g. adapters for acetabular reamers).
- Sterilisation with ethylene oxide can lengthen the serviceable life of some polymers (e.g. polysulphone). This sterilisation method can only be recommended if the manufacturer has indicated the corresponding aeration time on the packaging leaflet of the product in question. Large items made of formaldehyde

(POM) require very long degassing times (at least five days at high temperatures in a mechanical aerator), making gas sterilisation contraindicated for polyformaldehyde products.

- Due to its light weight, aluminium is used for the instrument trays and containers as well as for certain instrument parts. A resistant oxide layer is created on the aluminium by means of electrochemical surface treatments (eloxo-coating, the Ematal process or hard anodising), and is coloured. Surface-treated aluminium has good resistance to corrosion. In spite of this, contact with strong alkaline detergents and disinfectants and solutions containing iodine or certain metallic salts must be avoided since in such conditions the treated aluminium surface may undergo chemical corrosion. The oxide layer can even dissolve in solutions with a pH >11.

- Anodised titanium-based alloys are employed for a small number of applications (e.g. colour code rings). Pure titanium and titanium alloys are widely used as materials for making implants.

Titanium-based alloys are subjected to an electrochemical surface treatment (anodising) that forms a resistant oxide layer on the surface of the titanium. Various different shades of colour can be created depending on the thickness of this layer. The cleaning instructions for aluminium apply also to titanium. The protective oxide layer on titanium alloys can be corroded by treatment with detergents that have a pH >11.

- The use of hard water (°dH >14) must be avoided. Soft mains water is suitable for the initial rinsing. Rinse again thoroughly with distilled water to remove all residues. Normal water often contains high concentrations of minerals (e.g. calcium carbonate), recognisable on the surfaces of instruments in the form of patches with sharply defined edges.

TIP: Never leave instruments to stand in a wet condition. Dry them immediately.

Processing instructions

Tips for processing during and immediately after use

- First of all, any remaining body fluids and tissues must be wiped off the instruments with a non-linting disposable cloth. Then the instruments must be placed in a bowl with distilled water or covered with damp cloths. Saline solution, blood, body fluids, tissues, bone residues or other organic particles must be removed as soon as possible from instruments before cleaning, in order to prevent them from drying onto the surfaces.

TIP: Soaking instruments in proteolytic enzyme solutions facilitates cleaning, particularly in the case of instruments featuring complex shapes and areas difficult to access (e.g. cannulated and tubular designs, and so on). The enzyme solutions break down the substances containing proteins and thus prevent materials containing blood and proteins from drying on the instruments.

WARNING: Always follow strictly the manufacturer's instructions for preparing and using the solutions.

- Optimum cleaning is ensured if the instruments are cleaned within 30 minutes after use, in order to minimise the danger of substances and materials drying on their surfaces.
- In order to prevent contamination, used instruments must be taken to the Main Procurement Department in closed or covered containers.

Preparations for cleaning

- Instruments made up of several components must be taken apart first in order to clean them thoroughly. In doing so, care must be taken not to lose small screws or even small components. Should this happen for any reason in spite of your efforts, it is of the utmost importance that you inform your Mathys partner when returning the instrument sets.
- Instructions for use and brochures about surgical methods and/or procedures may be useful as an additional source of information illustrating certain complex, multi-component instruments supplied by Mathys Ltd Bettlach.

Preparation of the detergents

- Excessively strong concentrations of detergents, as well as very acid or very alkaline detergents, can corrode the protective oxide layer and lead to pitting corrosion. When using such detergents, the concentrations and exposure times recommended by the manufacturers must be observed under all circumstances. Detergents with a pH <9.5 are recommended. Treatment with a neutralising agent and thorough rinsing are absolutely necessary after treatment with alkaline detergents. For machine cleaning, always follow the instructions of the manufacturers of the machines and of the detergents.
- When using dry detergents in powder form, it is necessary to make sure that the detergents are completely dissolved before use, to avoid discoloration or corrosion of the instruments.
- Very dirty cleaning solutions (containing blood and/or that have become cloudy) must be replaced with freshly prepared solutions.

Table 1: Cleaning/disinfection options

Method	Description
Manual cleaning	Soaking and brushing in an enzyme solution, followed by ultrasonic cleaning
Combined manual/ machine cleaning	Soaking and brushing in an enzyme solution, followed by a machine washing/disinfecting cycle
Machine cleaning (washing/disinfecting machine)	Washing/disinfecting cycle, remembering that this procedure without manual pre-cleaning is not recommended

Instructions for manual cleaning/disinfection

1. The instruments must be immersed completely in an enzyme solution and left to soak in it for 15 to 20 minutes. The whole surface of each instrument must be immersed in the water bath and brushed with synthetic brushes and cleaning wires until all the visible dirt has been removed. Decontaminate and sterilise the brushes and wires after use or dispose of them. Steel brushes must never be used for this task.

Brush hinges both in the open and the closed position, as well as the complete insides of any cavities. Cavities should be thoroughly rinsed out with water.

2. Then remove the instruments from the enzyme solution and rinse thoroughly for at least 3 to 4 minutes, so that any remaining residues cannot dry or stick on the surfaces. While doing this, make sure that any through holes are rinsed and any blind holes are repeatedly filled and emptied.

3. Place the prepared detergents in an ultrasonic cleaning system. Immerse the instrument completely in the cleaning solution and expose to ultrasonic waves at a water temperature of at least 40°C for at least 3 minutes at a frequency of between 35 kHz and maximum 47 kHz. Temperatures in excess of 50°C can cause crusts of blood to form.

4. Either rinse the instrument for at least 3 minutes with pure water or continue the procedure just described until no more signs of blood or other types of dirt can be seen on the instrument

or in the rinsing water. Take special care to rinse thoroughly any cavities or other areas that are difficult to reach.

5. Repeat the steps listed above for ultrasonic cleaning and rinsing again.

6. Then wipe off the excess moisture with a clean, absorbent and non-linting disposable cloth.

WARNING: If only manual cleaning and disinfection are possible, written instructions in this respect must be provided. In this case, chemical disinfection is particularly important.

Instructions for combined manual/machine cleaning and disinfection

1. Immerse the instruments completely in an enzyme solution and soak initially for 15 to 20 minutes. The whole surface of each instrument must be immersed completely in the water bath and brushed with synthetic brushes and cleaning wires until all the visible dirt has been removed. Decontaminate and sterilise the brushes and wires after use or dispose of them. Do not use steel brushes.

Brush hinges in both the open and the closed position, as well as the insides of any cavities. Cavities should be thoroughly rinsed out with water.

2. Then remove the instruments from the enzyme solution and rinse thoroughly for at least 3 to 4 minutes, so that any remaining residues cannot dry or stick on the surfaces. While doing this, make sure that any through holes are rinsed and any blind holes are repeatedly filled and emptied.

3. Place the prepared detergents in an ultrasonic cleaning system. Immerse the instrument completely in the cleaning solution and expose to ultrasonic waves at a water temperature of at least 40°C for at least 3 minutes at a frequency of between 35 kHz and maximum 47 kHz. Temperatures in excess of 50°C can cause crusts of blood to form.

4. Either rinse the instrument for at least 3 minutes with pure water or continue the procedure just described until no more signs of blood or other types of dirt can be seen on the instrument

or in the rinsing water. Take special care to rinse thoroughly any cavities or other areas that are difficult to reach.

TIP: Areas that are difficult to access or closely co-operating surfaces can be rinsed better with a syringe or a jet of water.

5. Then place the instruments in a suitable rack in the washing/disinfecting machine and run them through a standard instrument cycle in the machine. Follow the instructions of the washing/disinfecting machine manufacturer carefully.

The following steps at least must be carried out during the washing and disinfecting process (e.g. Miele G 7836 CD):

Instructions for machine cleaning/disinfection

Start Programme 1: Vario FA

4 mins	Pre-rinse 1
4 mins	Pre-rinse 2
14 mins	Start cleaning process Neodisher FA starting at 45°C / 0.3% Cleaning: 55°C / 5 minutes
6 mins	Start neutralising process Neodisher Z / 0.1% Neutralisation: 10°C / 2 minutes
4 mins	Intermediate rinse
30 mins	Thermal disinfection process Holding time: 93°C / 5 minutes
25 mins	Drying process 110°C

1. It is not recommended to clean surgical instruments solely with machine washing/disinfecting systems. Rather, unless otherwise specified, the instruments should undergo the cleaning process (manual or combined manual/machine) indicated at the beginning of this section.

2. Optionally, a washing/disinfecting machine may be used for manual cleaning, even though this is not strictly necessary for the process.

3. Instruments consisting of a single component and with no complex shapes can be cleaned and disinfected thoroughly using a typical cleaning/disinfecting cycle for surgical instruments, such as that illustrated in the example on page 18.

N.B.: In order to ensure effective cleaning, the products are to be checked once again thoroughly for cleanliness prior to sterilisation.

The detergents recommended by this manufacturer are, by way of example, Neodisher FA, Neodisher Midiclean Forte, Neodisher Z or Neodisher Oxivario.

Inspection, maintenance, testing and treatment with lubricants

1. In order to make sure that all dirt has been removed, top priority must be given to checking each instrument carefully. Should any dirt be discovered sticking to any instruments, the cleaning/disinfection process must be repeated without delay.

WARNING: Instruments judged clean on the basis of a visual inspection may still have proteins on them.

2. Check the instruments and instrument sets for completeness, correct alignment, damage and/or intact surfaces. Damages or signs of wear that might have a negative impact on the functioning of the instrument must be reported to your local Mathys partner, who is responsible for deciding whether to repair and/or replace instruments or instrument sets.

3. The proper functioning of mobile parts (e.g. hinged joints and so on) must also be checked in order to ensure that the complete movement they were designed to perform can be carried out in full.

4. Instruments provided with hinged, revolving or articulating mechanisms should be treated with the oil specified by Mathys Ltd Bettlach (e.g. Paraliq 91). Alternative products must be oil-free (e.g. instrument cream or an equivalent lubricant) and envisaged specifically for surgical instruments requiring sterilisation. With regard to stored products diluted to the appropriate concentration for use, take care to observe the expiry date indicated by the manufacturer.

WARNING: These instructions concerning lubricants do not ap-

ply to compressed-air or electrical instruments. For such products, proceed in accordance with the manufacturer's instructions with regard to treatment with lubricants.

5. Check long and slender instruments (in particular rotatable instruments) for deformations.

6. Instruments made up of several individual components must be checked to ensure simple and correct assembly.

Packaging, sterilisation, storage

Packaging of single instruments

- To double-pack single instruments it is possible to use steam sterilisation bags for medical applications available on the market (e.g. paper bags according to EN 868-5, heat-sealing and self-sealing transparent bags, or other equivalent material) of the appropriate size.

What is important is that the inner bag should have enough room to contain the instrument completely, without damaging the seal or the packaging material. At the same time, however, the bag must be small enough to be packed without danger inside a second bag (integrity of the packaging as a whole).

WARNING: If sterilisation fleece is used, this must be free of any residues of detergents. Mathys Ltd Bettlach advises against re-usable fleece.

Packaging of instrument sets in stiff trays and containers with lids

In accordance with general guidelines, the overall weight of a wrapped instrument tray or container may not exceed 11.4 kg. The overall weight of a sterilisation container with a sealed lid for instrument trays may reach a maximum of 16 kg. In countries in which the maximum weight is below 16 kg, these latter specifications must be complied with. The weight of 16 kg must in any case not be exceeded.

- Instrument trays and containers with lids can be packed in a double layer of medical steam sterilisation fleece or using an equivalent method. As an alternative, instrument trays and containers with lids can also be placed for sterilisation inside an approved sterilisation container with a sealed lid.

WARNING: When installing or replacing a sterilisation filter, it is imperative to comply with the manufacturer's instructions.

Instrument trays and containers with separated, pre-configured layouts

- The areas intended specifically for given instruments must be used exclusively to hold such instruments. Optional instruments by Mathys Ltd Bettlach may be placed only in pre-configured instrument trays and containers designed with special universal areas or special universal compartments, using the guidelines for instrument trays and containers without separated layouts or universal areas.

WARNING: Only instruments manufactured and/or sold by Mathys Ltd Bettlach may be placed in Mathys Ltd Bettlach's instrument trays and containers. These validated reprocessing instructions do not apply to Mathys Ltd Bettlach's instrument trays and containers used to contain instruments not manufactured and/or sold by Mathys Ltd Bettlach.

The following conditions apply to universal instrument trays and containers without separated, pre-configured layouts or with undefined universal areas or compartments:

- In accordance with general guidelines, the overall weight of a wrapped instrument tray and container may not exceed 11.4 kg. The overall weight of a sterilisation container with a sealed lid for instrument trays may reach a maximum of 16 kg. In countries in which the maximum weight is below 16 kg, these latter specifications must be complied with. The weight of 16 kg must in any case not be exceeded.

- Instruments made up of several components must be taken

to pieces before being placed in the instrument trays and containers.

- The instruments must not be placed one on top of another or come into contact with one another, and must be arranged in such a way that the steam can reach every part of the surfaces of the instruments.

- Before starting sterilisation, it is necessary to make sure that the contents are tidily arranged and have not slipped out of place, and that the instrument container is not tilted.

Silicone mats designed specifically for this purpose can be used to prevent the instruments from slipping out of place.

WARNING: Only instruments manufactured and/or sold by Mathys Ltd Bettlach may be placed in Mathys Ltd Bettlach's instrument trays and containers. These validated reprocessing instructions do not apply to Mathys Ltd Bettlach's instrument trays and containers used to contain instruments not manufactured and/or sold by Mathys Ltd Bettlach.

Sterilisation instructions

- The hospital is responsible for the in-house procedures for implementing all the steps specified above in order to guarantee complete penetration of the sterilising steam through the instruments. The hospital must furthermore implement protective measures with regard to sharp or potentially dangerous places on instruments.
- Instructions given by the manufacturer of the sterilising equipment must always be followed. If several instrument sets are sterilised in one and the same sterilisation cycle, the maximum capacity of the sterilising equipment as specified by the manufacturer may not be exceeded.
- For optimum sterilisation the instrument sets must be properly prepared and packed tidily in the instrument trays and containers provided for this purpose. Only if this is done can the steam spread and penetrate so as to reach all the surfaces.
- Ethylene oxide sterilisation should only be used when this method of sterilisation is referred to explicitly in the packaging leaflet of the product in question.

National recommendations/guidelines for sterilising instruments must be followed in all cases. The following steps at least must be taken (e.g. Zirbus Autoclav LSA 346):

Sterilisation steps

1. ***Vacuum ($p > 120$ mbar)***
2. ***Steam ($136^{\circ}\text{C} / p > 3350$ mbar / 18 minutes)***
3. ***Dry ($p > 120$ mbar / 5 minutes)***
4. ***Cool down to room temperature***

Storage instructions

- The packaged and sterile instruments must be stored in a dry and cool room, protected from dust, insects, vermin and direct sunlight. The room may be accessed by authorised personnel only. The equipment for storage and transport must be designed in such a way as to avoid any muddling, overstuffing or falling of items. Sterile medical products may never be stored directly on the floor.

The instruments will be used in order of arrival of the goods, and the sterile packaging must be checked very thoroughly to ensure that it is intact before it is opened.

WARNING: Should the packaging or a sterile fleece have got torn, punctured, visibly damaged or damp, the instrument set must be repackaged and re-sterilised. Also, if there are signs on a sterilisation container that the lid seals or filters have been opened or damaged, the instrument set must be re-sterilised and the sterile filter replaced. In the case of re-usable filters, these must undergo a thorough visual inspection.

The hospital's responsibilities for instruments lent out by Mathys Ltd Bettlach

- As a rule, medical instruments have long working lives if they are used correctly and properly cared for. Instruments that due to wear, misuse or improper care no longer function as they should are to be returned to Mathys Ltd Bettlach to be disposed of. Please report any problems with instruments to your local Mathys partner immediately.
- Loaned instrument sets must undergo cleaning, disinfection, inspection and final sterilisation before being returned. Documentation of the decontamination is to be provided at the time of return.
- In order to ensure that the next hospital receives an instrument set that is complete and in proper working order, any damaged or missing instruments from the loan instrument set must be reported to the local Mathys partner by the Operating Theatre or central Sterilisation and Reprocessing Department, through the person in charge at the time.
- The hospital is responsible for implementing these instructions. It is the hospital's duty to ensure that the appropriate equipment and materials are used for reprocessing and that the personnel involved has been properly trained. This can only be achieved by means of regular validation and monitoring of the equipment and processes.

In order to ensure reprocessing of instruments is in accordance with the regulations, regular validation and monitoring of the equipment and processes are necessary. In the event of

deviations of any kind from the procedures described here, same must be checked for effectiveness in order to exclude possible undesired consequences.

Customer service information

Address

Mathys Ltd Bettlach

Güterstrasse 5

P.O. Box

CH-2544 Bettlach

Switzerland

Phone number

Tel. +41 32 644 1 644

Fax +41 32 644 1 161

E-mail

info@mathysmedical.com

Further reading

1. EN 285 + A1, Sterilization – Steam sterilizers – Large sterilizers
2. DIN 58946-7 Sterilisation – Dampf-Sterilisatoren – Teil 7: Bauliche Anforderungen und Anforderungen an Betriebsmittel
3. EN ISO 11135, Sterilization of health care products – Ethylene oxide
4. ISO 14161, Sterilization of health care products – Biological indicators – Guidance for the selection, use and interpretation of results
5. EN ISO 14937, Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
6. EN ISO 11138, Sterilization of health care products – Biological indicators
7. EN ISO 11137, Sterilization of health care products – Radiation
8. EN ISO 11737, Sterilization of medical devices – Microbiological methods
9. EN 556, Sterilization of medical devices – Requirements for medical devices to be designated “STERILE”
10. ISO 15223 and Amendments 1 and 2, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
11. DIN 58953, Sterilisation – Sterilgutversorgung
12. EN 868, Packaging materials and systems for medical devices which are to be sterilized
13. ASTM F 565, Standard Practice for Care and Handling of Orthopedic Implants and Instruments
14. German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung, Proper Maintenance of Instruments, 8th Ed, 2004
15. ISO 15883, Washer-disinfectors: General requirements, terms and definitions and tests
16. ISO 17664, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
17. Robert Koch Institute (RKI), Hospital Supplies and Instrument Sterilization in Light of CJD Patients and Suspected CJD Cases, Federal Health Gazette, 7/1998
18. UK Department of Health, Health Technical Memorandum (HTM) 2010, Sterilization, Part 5 – Good Practice Guide
19. UK Department of Health, Health Technical Memorandum (HTM) 2030, Washer-Disinfectors – Validation and Verification
20. World Health Organization (WHO), WHO/CDS/CSR/APH 200.3, WHO Infection Control Guidelines for TSE
21. FASMED, MebV_812.213

Appendix

Cleaning/disinfection procedures

Example 1: Manual cleaning/disinfection procedure

Step 1

Leave the instruments to soak for 10 to 15 minutes completely immersed in an enzyme solution. Clean each instrument gently with a soft-bristled brush intended specifically for this purpose, until all visible dirt has been removed. Particular attention must be paid to cavities, through holes, closely co-operating surfaces, connecting pieces and other areas that are difficult to reach. Through holes must be cleaned with a long, thin wire (e.g. a pipe-cleaner) with soft bristles.

Step 2

Remove the instruments from the enzyme solution and rinse for at least 1 minute with pure water. Rinse thoroughly all openings and other areas that are difficult to reach, until all foam has been completely removed from the instruments.

Step 3

Place the instruments in a suitable rack of the washing/disinfecting machine and run them through a standard instrument cycle.

Example 2: Combined manual/machine cleaning/disinfection procedure

Step 1

Immerse the instruments completely in an enzyme solution and leave them to soak for 15 to 20 minutes. Clean each instrument gently with a soft-bristled brush intended specifically for this purpose, until all visible dirt has been removed.

Step 2

Remove the instruments from the enzyme solution and rinse for at least 1 minute with pure water. Rinse thoroughly all openings and other areas that are difficult to reach, until all foam has been completely removed from the instruments.

Step 3

Place the prepared detergents at a temperature of over 40°C in an ultrasonic cleaner (temperatures in excess of 50°C can cause crusts of blood to form). Immerse each instrument completely in the cleaning solution and clean by exposing to ultrasonic waves at 35–47 kHz for at least 5 minutes.

Step 4

Rinse the instrument for at least 1 minute with pure water. Rinse thoroughly all openings and other areas that are difficult to reach, until all foam has been completely removed from the instrument.

Step 5

Repeat steps 1 to 4 referring to ultrasonic cleaning and rinsing.

Step 6

Dry the excess moisture with a clean, absorbent and non-linting disposable cloth.

Example 3: Typical machine washing/disinfecting cycle for cleaning/disinfecting surgical instruments

Step 1	4 minutes – pre-rinse 1	Step 8	4 minutes – intermediate rinse
Step 2	Spray with enzyme solution, hot soft mains water, 20 seconds	Step 9	30 minutes – thermal disinfection process Holding time: 93°C / 5 minutes 25 minutes Drying process 110°C
Step 3	Soak in enzyme solution, 1 minute		
Step 4	4 minutes – pre-rinse 2		
Step 5	14 minutes – start cleaning process – Neodisher FA starting from 45°C / 0.3% Cleaning: 55°C, 5 minutes		
Step 6	Rinse (twice), hot soft mains water, 15 seconds		
Step 7	6 minutes – start neutralising process – Neodisher Z / 0.1% Neutralisation: 10°C / 2 minutes		

CE 0123

Mathys Ltd Bettlach
Robert Mathys Strasse 5 • 2544 Bettlach • P.O. Box • Switzerland
Tel. +41 32 644 1 644 • Fax +41 32 644 1 161
info@mathysmedical.com • www.mathysmedical.com