MATHYS
a company of enovis

GUIDELINES

for the processing and sterilisation of instruments

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1. Area of application

The present processing instructions pursuant to the requirements of SN EN ISO 17664 apply to instruments that are reusable and therefore need to be reprocessed, as well as to medical devices (implants and instruments) that are sold non-sterile, but to be used in sterile condition.
The surgical instruments manufactured by Mathys Ltd Bettlach belong to this group.

The parameters of the process chemistry as well as of the equipment in the present processing instructions are recommendations resulting from findings of instrument processing validations performed by Mathys Ltd Bettlach.

The processor shall be responsible for ensuring that the processing actually carried out achieves the desired results with the individual equipment, process chemistry, and staff in the processing facility. It is not necessary to use absolutely identical chemicals, parameters or technical equipment as in the validation process of Mathys Ltd Bettlach. Equivalent or alternative products may be used with which a successful validated cleaning and sterilisation process can be demonstrated as a result. If the user has a method that is already established and validated and demonstrably leads to the desired result, there is no need for the user to change the method.

2. Purpose

Instruments contaminated by use pose a considerable danger potential. This applies both to the medical staff and to the patients. For physicians and staff, the highest risk is from cuts and stab wounds, while patients can suffer cross-infection from incorrectly processed instruments. Thus, processing of instruments is among the essential tasks in medical hygiene.

This document provides everyone involved in the cleaning and sterilisation process with safe handling practices and useful information on the effective processing and maintenance of reusable instruments by Mathys Ltd Bettlach.

The hospital management and the heads of the individual departments must be aware of these instructions and recommendations in order to ensure safe and effective processing by the employees in charge. This is important to prevent damage or abuse affecting the environment, persons and material.

The present processing instructions are intended to support the implementation of the processing of the hospital's own as well as of leased instrument sets. Furthermore, the present processing instructions are intended to aid the hospital management and the management of the central sterilisation department in the development of procedures.
This information is based on validations and examinations by Mathys Ltd Bettlach, as well as on experiences of materials science and generally accepted recommendations of the following organisations:

- World Health Organisation (WHO)
- Robert Koch Institute (RKI)
- Working Group Instrument Preparation (Arbeitskreis Instrumenten-Aufbereitung, AKI)
- Swissmedic
- National Health Service (NHS)
- International Standards Organization (ISO)
- International Association of Healthcare Central Service Material Management (IAHCSMM)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Federation Swiss Medical Technology (FASMED)

Important
The present processing instructions describe and define the necessary processing steps for new as well as for used instruments to ensure their cleanliness and sterility.

3. Scope

The contents of the processing instructions refer to cleaning, disinfection, care/maintenance, functional control, sterilisation, packaging and storage of instruments used in orthopaedic surgery, which must be read carefully. This applies to all reusable medical products as well as to all non-sterile disposable medical products manufactured and/or distributed by Mathys Ltd Bettlach.

Products for single use can be processed as long as they are unused. This includes single-use instruments that were packaged and delivered sterile and subsequently removed from the package and assembled into individual kits.

Unused disposable products contaminated with blood, bone, tissue or body fluids must not be processed or re-sterilised, but discarded.

Products that must not be reused are marked with the following symbol:

	Do not re-use

The information does not apply to disposable products that are sold sterile and cannot be re-sterilised.

Products that must not be re-sterilised are labelled with the following symbol:

	Do not resterilize

These processing instructions refer to functional accessories (reamers, drill bits, etc.), but not to instruments that are operated electronically or pneumatically.

4. Information to be provided by the manufacturer

4.1 Instructions for processing

These processing instructions for invasive surgical instruments are based on a validated manual/automated processing method. A purely manual or purely automated processing method has not been validated by Mathys Ltd Bettlach, and it does not lead to sufficient cleaning success.

4.2 Limitations and restrictions on processing

4.2.1 Notes

The processor should comply with the local laws and regulations where these specify more stringent processing requirements than those set forth in this manual. New and used instruments must be processed in accordance with these processing instructions prior to use.

For new instruments delivered to the hospital, Mathys Ltd Bettlach recommends triple cleaning before use in order to build up the protective oxide layer.

During surgery in the area of the musculoskeletal system, the instruments are contaminated with blood, tissue, bone chips and bone marrow. Furthermore, the instruments may be exposed to body fluids that contain hepatitis or HI virus or other pathogens.

All staff involved must be trained in the necessary and generally accepted precautionary measures. Injury from sharp instruments during and after surgical procedures as well as during processing can be avoided thereby.

In orthopaedic surgery, heavy instruments with multiple components, pivoting or joint mechanisms, removable handles, spare parts made of plastic and a variety of gauges or other measuring devices in different sizes are required. The instruments are supplied as sets of instruments and are distributed over instrument trays and containers.
The processor is responsible for the cleaning, disinfection, maintenance/care, function control, packaging and sterilisation of the instruments of rental instrumentation sets by Mathys Ltd Bettlach. Upon receipt of the leased instrument sets, these must be checked once more for cleanliness and contamination. Only subsequently may the processing be performed to prepare for the following use.

Pursuant to the Swiss Therapeutic Products Act (Heilmittelgesetz, HMG) Chapter I Art. 3, the processor must process leased instruments after use before they are returned, to Mathys Ltd Bettlach. Before the leased instrument sets are sent to the customer again, they are examined for cleanliness, completeness and function control. Complete processing before reuse in the hospital is mandatory.

By following the instructions for manual/automated cleaning, all instruments of Mathys Ltd Bettlach can be safely and effectively processed. All medical instrument sets must be complete and in good condition so that proper use is ensured.

Optional medical instruments are available upon request from your local Mathys Partner. For proper care of the surgical instruments, it is important to strictly adhere to the following processing instructions:

- Warnings and Precautions
- Completeness and functionality of the instrument sets
- Restrictions of processing
- Preparation for processing at the point of use
- Preparation for cleaning
  (including disassembling/ assembling, where necessary)
- Cleaning, disinfection and drying
- Maintenance, inspection and treatment with care products
- Packaging
- Sterilisation
- Storage

4.2.2 Warning and precautions

Staff exposed to actually or potentially contaminated surgical instruments must take the generally accepted precautionary measures (personal protective equipment: gown, mask, goggles, face shields, gloves, shoes, shoe covers, etc.). When handling instruments with sharp points or edges, special caution is advised.

Particular care must be taken when handling cutting instruments (reamers, drill bits, rasp, chisels), as they pose a risk of injury to the patients on the one hand and to the staff (operating theatre and CSSD personnel) on the other.

It must be clarified in advance that the patients, as well as the staff (operating theatre and CSSD personnel), do not react with allergic reactions due to material intolerance (various steels and plastic materials) upon direct contact with instruments.

For manual cleaning processes, Mathys Ltd Bettlach advises against steel brushes or mops (damage to surfaces and coatings of the instruments). Plastic brushes with nylon bristles and cleaning wires (e. g. pipe cleaners) that do not damage the surfaces are recommended.

For the manual cleaning process, use low-foam detergents to ensure the instruments remain visible. In manual cleaning with brushes, it is recommended to keep the instruments always below the surface of the cleaning solution. This ensures that no aerosols form and splashes that might pose a risk of infection are avoided.

In order to avoid accumulation of detergent residues, all detergents must be removed completely from the product surfaces by adequate rinsing.

Heavy objects may not be placed onto sensitive instruments.

Do not allow contaminated instruments to dry before reprocessing. This hampers all the steps for cleaning and sterilisation described below.

The chloride and iodide ions contained in some detergents and disinfectants can cause pitting corrosion. For this reason, contact of the instruments with such agents must be kept as brief as possible. Then rinse thoroughly with deionized water (DI water) to remove any residues. Never leave instruments wet after cleaning, but dry them instantly.

Strongly acidic or alkaline detergents or excessive doses can corrode and destroy the protective oxide layer of the instruments or markings. The concentrations and exposure times recommended by the manufacturers must be observed under all circumstances.

For cleaning reusable instruments, Mathys Ltd Bettlach recommends a combined manual/automated cleaning process with a mildly alkaline detergent at a pH of < 11.

It is extremely important to neutralise the alkaline detergent completely and rinse it thoroughly off the instruments. In automated cleaning, the information provided by the manufacturers of the equipment and cleaning detergents must be followed.

Only instruments manufactured and/or distributed by Mathys Ltd Bettlach may be placed into the instrument trays and containers by Mathys Ltd Bettlach. The processing instructions apply only to instrument trays and containers by Mathys Ltd Bettlach.

The condensation moisture resulting from sterilisation can be prevented by extension of the drying phase.

4.2.3 Verification of the Instrument Set upon receipt for content and functionality

Upon receipt of the instrument set at the hospital, the set must be checked for completeness. The completeness of each of the following must be checked:

- Screws
- Screw handles or other removable handles
- Replaceable accessory parts such as blades, right-/left-sided accessories and heads

Most instrument sets have a systematic arrangement of the instruments. This is screen-printed or otherwise printed onto the instrument trays and containers in the form of schematic diagrams, summary tables, catalogue numbers and instrument designations or sizes.

If any instruments should be missing from an instrument set, please contact your local Mathys Partner to add these.

Markings on the instruments must be legible. These include measurement markings, angles, inner or outer diameters, length or depth calibrations, as well as indications for right-/left-hand side. If any scales or other markings should not be legible anymore, notify your local Mathys Partner promptly for assessment or for replacement of the instruments, respectively.

4.2.4 Limitations

Patients to be considered as high-risk patients in respect of prion diseases such as Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob disease (CJD) and its variants (vCJD) must be operated on with disposable instruments whenever possible.

Mathys Ltd Bettlach recommends selecting a cleaning agent with enzymatic additives to remove blood, body fluids and tissues. Please note that some enzyme solutions are intended specifically for decomposing faecal matter or other organic contaminations, and are therefore not suitable for cleaning surgical instruments.

There is a restriction in terms of service life for the acetabular reamers (5439.00.5 to 5472.00.5). These may pass through a maximum of 60 life cycles (processing and application) only. Then the acetabular reamers must be replaced. For replacement, please contact your Mathys partner in good time.

The plastic materials used in the instrument sets by Mathys Ltd Bettlach can be sterilised with steam/moist heat.

Instruments with plastic materials must be replaced if:

- *the surfaces look «chalky»*
- *they show excessive damage (e. g. whitening by micro-cracks, delaminations)*
- *they have excessive shape changes, or they are visibly warped*

For replacement, contact your Mathys Partner.

All instruments available from Mathys Ltd Bettlach that comprise plastic materials are unsuitable for washing/sterilising machines that operate at temperatures > 141 °C (285 °F) and use steam nozzles as cleaning aids (steamers). The plastic surfaces of the instruments with plastic components can be severely damaged thereby. In addition, due to the high temperature proteins are fixed on the surface and become difficult to remove.

Soaking of instruments with plastic components in disinfectants may be a necessary step for the removal of certain viruses. Their use can lead to discoloration up to corrosion of the instruments. Disinfectants may contain glutaraldehyde or other aldehydes and thus be able to structurally alter proteinaceous contaminants, hardening them and making them difficult to remove. Therefore Mathys Ltd Bettlach advises against immersion of instruments with plastic components into disinfectants.

Instruments with removable plastic covers must be disassembled for sterilisation (e. g. adapters for acetabular reamers).

Automated cleaning alone is insufficient for medical instruments with lumina, cannulas, cavities, precisely matching surfaces and other complex design features. Therefore Mathys Ltd Bettlach recommends performing thorough manual pre-cleaning and a combined manual/automated cleaning procedure.

For manual and/or automated cleaning processes, the instruments must be removed from the instrument trays. Cleaning of the instruments in the instrument trays after use is not allowed. Instrument trays, containers and lids must be cleaned separately. After cleaning, the instruments can be placed back into the instrument trays and packaged for sterilisation and subsequent use.

Because of its low weight, aluminium is used for the instrument trays and containers and for certain instrument parts. By electrochemical surface treatment (standard anodising, Ematal anodising or hard anodising), a protective oxide layer is formed on the aluminium. Surface-treated aluminium has good corrosion resistance. Nevertheless, contact with strongly alkaline detergents and disinfectants as well as with solutions containing iodine or certain metal salts must be avoided. The treated aluminium surface can be chemically corroded under these conditions. In solutions with pH > 11, the oxide layer may even dissolve.

The cleaning instructions for aluminium apply to titanium as well. The protective oxide layer of the titanium alloys can be corroded by treatment with detergents with pH values > 11.
Use of hard water (° dH value > 14) is to be avoided. It has been proven that blood residues can be removed the more easily, the softer the water used is.
Rinse thoroughly with deionized water (DI water) to remove any residues. Tap water often contains high concentrations of minerals (e. g. calcium carbonate), which can be seen on the instrument surface as spots with sharply defined edges.

Only instruments by Mathys Ltd Bettlach may be used for the placement of implants by Mathys Ltd Bettlach (see the respective surgical technique); instruments by other manufacturers may not.

No additional lettering of any kind may be applied to the instruments.

The instruments are packaged separately and delivered in non-sterile condition. The packaging materials must be disposed of in accordance with the local and country-specific regulations.

4.2.5 Water quality

Attention must be paid to the quality of the water to be used. This should at least correspond to potable water quality, especially in microbiological terms. Here, the respective national regulations and recommendations must be complied with. The specifications of the device manufacturers regarding water quality must also be observed.
Use of hard water (> 14 °dH) is to be avoided. The softer the water to be used, the better contamination can be removed and visible mineral residues avoided.
For an optimal and reproducible result of the processing sequence, it is recommended to use fully demineralised water (hereinafter referred to as deionised water, DI water). At least the final rinse in mechanical cleaning must be carried out with deionised water to achieve a residue-free cleaning result.

The quality of the deionised water should at least correspond to the boiler feed water quality described in EN 285, Annex B, Table B1. Deviating from this, however, a conductivity of 15 µS/cm is sufficient. A silicate content below 0.4 mg/L is recommended in order to avoid discolouration and stains caused by silicate deposits.
If only water (without detergent added) is used for cleaning, Mathys recommends a water temperature of no more than 45 °C / 113 °F, since otherwise proteins will become fixated on the instrument, making it difficult to remove them.

4.3 Preparations at the place of use

First, residues of body fluids and tissues must be removed below the water surface using a specific plastic brush made of nylon. If water without detergent additives is used for cleaning, Mathys Ltd Bettlach recommends a water temperature of no more than 45 °C (113 °F), since otherwise the proteins contained in the blood will start to denature and hence proteins are going to be strongly fixed on the instrument, so they will be removed only with major effort in automated cleaning.

Saline, blood, body fluids, tissue, bone residues or other organic particles must be removed before cleaning the instruments as soon as possible in order to prevent drying as well as corrosion.

Tip

Immersion of the used instruments after use into an enzymatic cleaning solution or into cold deionized water (DI water) facilitates cleaning, especially for instruments with complex design and difficult-to-reach areas (e. g. cannulated and tubular designs, etc.).

Saline solutions as well as detergents and disinfectants that contain aldehydes, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and must not be used.

Always follow the manufacturer's instructions for preparation and use of the solutions strictly.

Optimal cleaning is ensured if the instruments are properly cleaned within one hour after use in the CSSD to minimise the risk of drying of substances and materials. If it is not possible to clean the instruments within this specified time, Mathys Ltd Bettlach recommends immersing the instruments into an enzymatic cleaning solution or deionized water (DI water) of room temperature, or to wrap them for up to 6 hours into cloths wetted with an enzymatic cleaning solution or deionized water (DI water).

After the use of the instruments, they must be transported in a specific instrument tray by Mathys in order to avoid defects due to transport. This instrument tray in turn must be transported in a closed container to the CSSD in order to protect the personnel and the environment from risks of contamination and infection.

4.4 Preparation before cleaning

Excessive concentrations of non-protein-fixing cleaning agents and strongly acidic and alkaline detergents can corrode the protective oxide layer and lead to pitting corrosion. When using such agents, the concentrations and exposure times recommended by the manufacturers must be strictly adhered to.
It is extremely important to neutralise the alkaline cleaner completely and rinse it thoroughly off the instruments.

In automated cleaning, the information provided by the manufacturers of the equipment and cleaning agents must always be followed.

When using dry detergents in powder form, it must be made sure that these are completely dissolved before use in order to avoid discolouration or corrosion of the instruments.

Heavily contaminated solutions (blood and/or hazes) must be replaced with freshly prepared cleaning solutions.

Instruments that consist of several components and are designed to be disassembled must be disassembled into their component parts beforehand for thorough cleaning. Care is required to ensure that neither small screws nor other small components are lost. If this happens for any reason, it is extremely important to report this to your Mathys Partner when returning the instrument sets.

Manuals and brochures about surgical procedures and/or methods may serve as further sources of information to illustrate certain complexly structured instruments by Mathys Ltd Bettlach.

Table 1: Overview of the processing according to SN EN ISO 17664:

Procedure			Reusable surgical instruments
Initial treatment at the place of use	Condition	Dry	• Recommendation: Immediate reprocessing after use • Up to max. 1 hour
		Wet/moist	• Immerse into cold deionised water (Liquid or wetted cloths) • Up to max. 6 hours
Decontamination	Preparation		
	Cleaning	Manual	–
		Automated	–
		Ultrasound	+
		Combined manual and automated	+
		Strongly alkaline (pH > 11)	–
		Mildly alkaline-enzymatic (pH 10 – 11)	+
		Neutral	–
		Acidic	–
	Rinsing	Final rinse with deionised water	
	Disinfection [1]	Thermal 90 °C (194 °F)	+
	Drying	T_{max} (Time)	115 °C (239 °F) (15 minutes)
Maintenance	Functional check		Mandatory
	Maintenance	Care product based on paraffin/ white oil (biocompatible, steam-sterilisable and steam-permeable, e. g. Aesculap® Sterilit-I JG 598)	Mandatory
Sterilisation	Moist heat (steam) [2]		+
	Ethylene oxide, formaldehyde, plasma		–

+ Validated method
– Non-validated method

[1] Thermal disinfection according to DIN EN ISO 15883
[2] Preferred sterilisation method according to SN EN ISO 17664

4.5 Cleaning and disinfection

In order to achieve optimum and thorough cleaning results, for the cleaning of reusable instruments Mathys Ltd Bettlach recommends a combined manual/automated cleaning process with a cleaning agent at an alkaline pH of < 11.

With regard to manual pre-cleaning, the instruments are classified into three cleaning categories (Table 2).

Table 2: Overview of manual pre-cleaning by cleaning category

Cleaning categories		Description	Cleaning steps	Medium
1	These instruments have no design features that are challenging for the cleaning process (open design).	These instruments do not need to be prepared manually and can be fed directly into the automated cleaning (WD).	No manual pre-cleaning necessary. The instruments may be placed directly into the WD.	–
2	These instruments have blind holes and/or boreholes, slits, crevices, contacting areas and/or rinsing shadows, i. e. areas not cleaned due to surface coverage during the treatment process.	Instruments that have a cleaning position must be set to the same before manual pre-cleaning. These instruments must be cleaned of visible organic residues by means of surface and/or lumen brushes made of nylon beneath the water surface. Plastic syringes and water jet guns (no steamers!) must also be used.	Clean instruments of organic residues immediately after use in the CSSD with **surface and/or lumen brushes** [1] made of nylon under the water surface.	• Surface and/or lumen brushes made of nylon • Tap water (cold)
			If necessary, **plastic syringes** and **water jet guns** must be used for rinsing.	• Plastic syringes • Water jet guns
			Please open instruments with hinges to expose the surfaces as much as possible, and brush the insides of any cavities along their entire length while simultaneously filling and emptying them with running tap water.	–
			Poorly accessible areas or precisely matching surfaces can be rinsed more thoroughly with a **plastic syringe** or a **water jet gun** (do not use steamers); alternatively, contaminations can be removed using a nylon brush [1].	• Tap water (cold) • Plastic syringes • Water jet gun

Cleaning categories		Description	Cleaning steps	Medium
3	These instruments have, in addition to the characteristics of category 2, several components interacting in a complex manner.	Instruments that have a cleaning position must be set to the same before manual pre-cleaning. In addition to the manual pre-cleaning of category 2, ultrasonic cleaning must be performed.	In addition to the cleaning steps of category 2, instruments must be treated with a mildly alkaline cleaning solution at room temperature for 5 minutes [2] and a frequency of 35 to 47 kHz in an **ultrasonic bath**. The temperature of 45 °C (113 °F) must not be exceeded in the ultrasonic bath.	• Mildly alkaline-enzymatic cleaner 0.5 % neodisher MediClean forte [2] (v/v) in DI water [3] (≤ 45 °C (113 °F) • Ultrasonic bath (Sonorex RK1028H, Bandelin)
			After the ultrasonic bath, the instruments must be thoroughly rinsed. The final rinse must be carried out with deionised water.	• DI water [3]
			If there are any traces of blood or other contamination on the instrument or in the rinse water, all manual processing steps must be repeated.	–

[1] Nylon brushes must be decontaminated and sterilised or disposed of after use. Do not use steel brushes.
[2] Recommendation of exposure time, concentration, temperature and pH according to the product data sheet of the detergent manufacturer (Dr. Weigert GmbH).
[3] Water quality according to SN EN 285.

4.5.1 Instructions for manual pre-cleaning of cleaning category 1 instruments

The instruments in this category show no specific design features and are accessible all over for cleaning solution and the rinsing water; hence they do not need to be pre-cleaned manually.

4.5.2 Instructions for manual pre-cleaning of cleaning category 2 instruments

The instruments of this category comprise slots, crevices, surfaces superimposed on each other, simple instruments with polymer handles, blind and cannulated holes with and without thread and rinsing shadows, and they must be manually pre-cleaned with plastic and lumen brushes made of nylon, plastic syringes and, if necessary, with a water jet gun until no visible residues are left.

4.5.3 Instructions for manual pre-cleaning of cleaning category 3 instruments

In addition to the design features of cleaning category 2, the instruments in this category feature undercuts, ball bearings, hard-to-reach areas and complex interacting instruments, and they must be manually pre-cleaned with nylon brushes, plastic syringes and water jet guns. The instruments must then be treated with 0.5 % neo-disher MediClean forte for 5 minutes at 35 – 47 kHz in an ultrasonic bath.

4.5.4 Instructions for automated cleaning and disinfection (all cleaning categories)

After the manual pre-cleaning as specified in table 2, the automated cleaning and disinfection in the washer/disinfector is performed (table 3).

To this end, the instruments are placed in a suitable cleaning basket of the washer/disinfector (WD) and subjected to a standard instrument cycle of the WD.

The instructions of the manufacturer of the WD must be strictly observed.

At Mathys Ltd Bettlach, the reprocessing procedure was carried out using a WD by Miele AG (Miele Professional G7836CD) and a combined cleaning process using the mildly alkaline enzyme detergent neodisher MediClean forte by Chemische Fabrik Dr. Weigert GmbH & Co. KG.

Table 3: Overview of the automated cleaning process

No.	Step		Medium
1	Pre-rinse	**Duration:** 2 minutes	• Tap water (cold, < 45 °C (113 °F))
2	Cleaning [1]	**Duration / temperature:** 10 minutes at 55 °C (131 °F) [2]	• 0.5 % mildly alkaline-enzymatic cleaning solution [2] (v/v) in DI water [3]
3	Interim rinse	**Duration:** 2 minutes	• DI water (cold) [3, 4]
4	Thermal disinfection [1]	Taking into account the A0 value of the national regulations, e. g. an A_0 value of at least 3000 at 90 °C (194 °F) for 5 minutes.	• DI water [3]
5	Drying [5]	**Duration:** 15 minutes **Temperature:** 115 °C (239 °F)	• Hot air
6	Make sure that no visible residues are present any longer.		

[1] Automated cleaning must be carried out in a WD in accordance with the ISO 15883 series of standards.
[2] Recommendation for exposure time, concentration, temperature and pH according to the manufacturer's product information sheet.
[3] Water quality according to SN EN 285.
[4] Limit value for chemical residues taking into account the information provided by the manufacturer of the cleaning solution.
[5] If necessary, after drying in the WD the instruments must be completely dried with medical compressed air.

4.6 Maintenance / care and function control

After cleaning, the instruments must be completely dry and free of visible and noticeable residues. Critical areas such as handle structures, long and/or thin boreholes or blind holes, joints and complex structures must be treated with special care. To ensure that all contamination has been removed, it is of crucial importance to inspect each instrument carefully and check it for cleanliness as well as water spots (for example, lime or silicate). If any contamination should be discovered adhering to instruments, the complete manual as well as automated cleaning and disinfection process must be repeated immediately.

Once the instrument is visually clean, it must undergo maintenance. For this purpose, Mathys recommends use of a care product based on paraffin/white oil that is biocompatible, suitable for steam sterilisation, and steam-permeable e. g. Aesculap® Sterilit-I JG 598. Alternative products must be free of silicone oil, suitable for steam sterilisation and biocompatible (see the «Red Brochure» by the AKI).

For maintenance, the instruments must be cooled to room temperature since otherwise there would be a risk of metal abrasion. The care product must be manually applied specifically, carefully, and drop by drop to hinged or ball bearings of a snap-fit, rotating or joint mechanism and/or sliding surfaces and then distributed evenly by moving the hinges, joints, snap-fit mechanisms, or sliding surfaces. Excess care product must be removed with a lint-free cloth (the manufacturer's instructions must be observed). «Overspraying» the instruments or immersion baths is not recommended by Mathys. Plastic surfaces must not be treated with care products. Observe the expiry date indicated by the manufacturer of the care products.

Instruments with plastic materials must be replaced if:

1. the surfaces look «chalky».
2. they show any signs of damage (e. g. (hairline) cracks, flaking, bur formation, deformation, blistering).
3. they have excessive shape changes and/or are visibly warped.
4. the lettering, such as item no. or LOT no., is no longer legible. This likewise applies to surgical instruments that do not comprise any plastic materials and are made of steel only.

For replacement, contact your Mathys Partner.

If stains on the medical devices should be recognisable, their cause must first be ascertained. Thus, coloured spots indicate incompatibility with a process chemical or exceedance of an exposure time. White spots are often residues of lime, process chemicals or salts. Corrosion marks should not be underestimated, and affected instruments should be immediately separated from unaffected ones («flash rust» or «rust bloom»).

As damaged instruments can no longer function properly, all reprocessible instruments must be checked for proper functioning after maintenance/care but before sterilisation (see the «Red Brochure» by the AKI).

Markings on the instruments must be legible. This includes scales indicating angles, for determining implant size, of length and/or depth, and of directions such as «left» and «right». If any scales or other markings should not be legible any more, notify your local Mathys Partner promptly for assessment or for replacement of the instruments, respectively.

Please pay particular attention to the following:

1. The instrumentation must be checked for completeness.
2. The instruments in the tray must be checked for correct arrangement.
3. The instruments must be checked for damage (e. g. (hairline) cracks, deformations, changing gaps between metal and plastics, fractures, corrosion or signs of wear) and damaged surfaces. Damage or wear that might impair the function of the instrument must be reported to your local Mathys Partner. The same will decide on repair or exchange of the instruments or entire instrument sets.
4. The functionality of mobile components (e. g. hinge joints, sliding parts, moving parts, etc.) must be checked in order to ensure that the intended movement sequence can be performed correctly.
5. Long and narrow instruments must be checked for bending.
6. Instruments that consist of several individual components and have to be assembled for function must be checked for correct assembly and functionality after assembly.
7. Drill bits, reamers, rasps and other cutting instruments must be carefully examined for their cutting edges. It must be ensured that the cutting edges are sharp for use, and that no visible or palpable damage is present. This can be done easily using a 10 – 12x magnifier.
8. Instruments that are no longer functional must be returned to Mathys for repair or scarping. Before, the instruments must undergo an entire processing cycle in order to eliminate the risk of infection.

4.6.1 Bur formation of test femora

Table 4: Defects and their causes, as well as correct troubleshooting in case of damage

Defect	Cause	Test	Measure
Bur formation at the drill guide or the sawing slot of the test femur  	• Improper handling • Canting of the drill bit/ saw blade • Drill/saw started too early or turned off too late	• No material protrusion (no bur) on tread, e. g. only scratches at the transition to the drill guide/sawing slot	• Continue use
		Material protrusion (bur) on tread	Return to Mathys Ltd Bettlach or disposal, depending on contractual relationship

4.7 Packaging

The packaging for the sterilisation must be suitable for the sterilisation procedure with moist heat, i. e., the permeability of the packaging for the steam must be ensured. Moreover, the packaging provides protection during transport and storage.

Mathys Ltd Bettlach therefore recommends double packaging of the instrument tray container.

In the case of sterile barrier systems (e. g. sterile containers and sterilisation wrap) and their requirements, the procedure must be carried out in accordance with DIN EN ISO 11607-1 on the one hand and in accordance with the manufacturer's specifications of the sterile barrier systems on the other.

When using sterilisation wrap, this must be free of detergent residues. Mathys Ltd Bettlach discourages use of recyclable wrap.

For sterilisation, the instruments of Mathys Ltd Bettlach must be placed in their specific instrument trays and containers.

To instruments that cannot be placed into any such specific instrument trays and containers, the following conditions apply:

- The instruments must neither be stacked on top of each other nor come into contact with each other, and they must be arranged so that the steam can reach every area of the instrument surface.
- Before the start of sterilisation, ensure that the contents are sorted in properly, and the instrument container is not tilted. For prevention of slipping of the instruments, silicone mats specified for this purpose may be used.

Only instruments manufactured and/or distributed by Mathys Ltd Bettlach may be placed into the specific instrument trays and containers by Mathys Ltd Bettlach. These processing instructions do not apply to instrument trays and containers of Mathys Ltd Bettlach that are equipped with instruments neither manufactured nor distributed by Mathys Ltd Bettlach.

4.8 Sterilisation

The processor of the instruments shall be responsible for performing a procedure validation of all the above steps in order to ensure a successful sterilisation.
Furthermore, the user must take protective measures for sharp or potentially dangerous instruments.
Instructions by the manufacturer of the sterilisation device must always be followed.
If several sets of instruments are sterilised in one sterilisation cycle, the maximum loading of the device in accordance with the manufacturer’s instructions must not be exceeded.

For optimum sterilisation, the instrument sets must be duly prepared and packaged into the appropriate trays and containers. Only in this way can the steam reach all surfaces. In case of steam sterilisation, it must be ensured that the product is completely dry after sterilisation.

Steam or moist heat is the recommended sterilisation method for instruments by Mathys Ltd Bettlach (SN EN ISO 17664). Ethylene oxide, gas plasma and dry heat are not recommended as sterilisation methods for the sterilisation of reusable instruments.

For sterilisation of the instruments, in any case the national recommendations/guidelines are to be complied with.

Below, the minimum sterilisation parameters used by Mathys Ltd Bettlach with a sterilisation device (Euro-Selectomat, MMM GmbH) and verified by microbiological examinations to reach a SAL (sterility assurance level) of 10^{-6} are indicated.

Table 5: Steam sterilisation using saturated steam [1, 2]

Type of cycle	Minimum temperature in °C/°F [7]	Minimum sterilisation time in minutes	Minimum drying time in minutes	Minimum pressure in mbar [8, 9]
Fractionated pre-vacuum [3]	134/273	18	30 [10]	≥ 3042
Fractionated pre-vacuum [4]	134/273	5	30 [10]	≥ 3042
Fractionated pre-vacuum [5, 6]	134/273	3	30 [10]	≥ 3042

[1] Water quality according to SN EN 285.
[2] Sterilisation must be carried out in accordance with the ISO 17665 series of standards.
[3] Ordinance on the prevention of Creutzfeldt-Jakob disease during surgical and medical interventions (CJKV), SR 818.101.21, 2002.
[4] Hygiene requirements for the processing of medical devices, Federal Institute for Drugs and Medical Devices, 2012.
[5] Validated sterilisation process with a minimum sterilisation time of 3 minutes at 134 °C (273 °F) to achieve a Sterility Assurance Level (SAL) of 10^{-6} in accordance with SN EN ISO 17665-1.
[6] Validation in the original instrument tray with double packaging system.
[7] Maximum temperature 137 °C (279 °F) according to SN EN 285.
[8] Pressure during the sterilisation phase at 134 °C (274 °F) according to DIN ISO/TS 17665-2.
[9] Minimum pressure during the sterilisation phase at 137 °C (279 °F) must be ≥ 3318.5 mbar according to DIN ISO/TS 17665-2.
[10] Clean plastic sieves must be dried for at least 50 minutes.

4.9 Storage

The packaged, sterile instruments must be stored protected from dust, insects, vermin and direct sunlight in a dry and cool room. This may be accessible only to responsible staff. The equipment for storage and transportation must be designed so as to prevent any disorder, overloading or falling off. Sterile medical devices must never be stored directly on the floor.
The instruments must not be stored near chemicals such as active chlorine that release corrosive vapours.
The instruments are to be used in the sequence of the receipt of the goods, and the sterile packaging of the instruments must be inspected meticulously for package integrity before opening.

Each user must, adapted to its validated sterilisation process, specify how long the sterile-packaged instruments may be stored before the next use (DIN 58953-8).

If the packaging or a sterile wrap is torn, punctured, visibly damaged or has become moist, the instrument set must be repackaged and sterilised. In case of signs of open or damaged lid seals or filters on the sterilisation container, the instrument set must likewise be re-sterilised and the sterile filter replaced. For reusable filters, careful visual inspection must be carried out.

4.10 Efficacy of the processing

The processing method recommended in the present processing instructions has been validated. The results meet the requirements with regard to the limit values in terms of protein residues in accordance with the guideline by DGKH (Deutsche Gesellschaft für Krankenhaushygiene e. V.), DGSV (Deutsche Gesellschaft für Sterilgutversorgung e. V.) and AKI (Arbeitskreis Instrumentenaufbereitung – Working Group Instrument Reprocessing) for automated cleaning and thermal disinfection processes for medical devices (D 2596 F).

4.11 Responsibilities of the hospital for leased instruments from Mathys Ltd Bettlach

Medical instruments usually have a long service life if properly used and cared for appropriately. Instruments that no longer function properly due to wear, improper use or improper maintenance, are to be returned to Mathys Ltd Bettlach for disposal. Report any instrument problems immediately to your local Mathys Partner.

Leased instrument sets must undergo cleaning, disinfection, inspection and final sterilisation before being returned. Upon return, a certificate of the decontamination must be attached.

To enable the next hospital to work with a complete and fully functional instrument set, any missing or damaged instruments in the leased instrument sets must be reported to the local Mathys Partner by the respectively responsible person from the theatre or the CSSD.

Responsibility for implementation of the present processing instruction shall rest with the hospital. It shall be responsible for ensuring that equipment and materials appropriate for the processing are used, and the personnel involved is trained accordingly. This can be achieved only by validation and routine monitoring of equipment and processes. In case of any deviation from the procedure described herein, this must be tested for efficacy in order to exclude possible adverse consequences.

4.12 Number of processing cycles

Medical instruments generally have a long service life if they are used and processed properly, including maintenance and functional checks (functional instrument, no corrosion, no breakage, no cracks, no bending, no flaking, no defects) in accordance with Chapter 4.6 of these processing instructions. This service life of surgical instruments is normally defined by wear, tear and improper use and care, and not by processing. If processing is carried out in accordance with these processing instructions, no damage to or limitation of the service life of the medical device is to be expected. Moreover, Mathys Ltd Bettlach tested 250 processing cycles and showed that 250 cycles of processing have no detrimental effect on the instruments. Whenever medical instruments are to be used, as well as after each use, their functionality is regularly checked by the specialists involved. Instruments that are no longer functional are to be replaced.

The processor is responsible for checking optimal functionality (e. g. cutting capability), including use of a paraffin / white oil-based care product that is biocompatible, steam-sterilisable and steam-permeable (e. g. Aesculap® Sterilit-I JG 598), cleanliness and defects (e. g. corrosion) before each use.

The user must always ensure that the current version of these processing instructions is used.

5. Symbols

Symbol	Description
	Sterilized using steam
	Non-sterile
	Do not re-use
	Do not resterilize
CE	CE marking for medical devices of Risk Class I
CE 0123	CE marking for medical devices of Risk Class Ir, Is, Im, II and III
	Caution
EC REP	Authorized representative in the European Community/European Union

Symbol	Description
	Use-by date
	Date of manufacture
Mat.	Material
LOT	Batch code
REF	Catalogue number
	Caution
MD	Medical Device
	Importer

6. Customer information

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7. Annex – Quick starter

7.1 Instructions for manual pre-cleaning

7.1.1 Cleaning category 1
No manual pre-cleaning necessary. Instruments can be placed directly in the WD.

7.1.2 Cleaning category 2
Instruments must be completely cleaned of organic residues using plastic brushes/lumen brushes made of nylon for 3 minutes under the water surface. Subsequently, the instruments must be rinsed for 1 minute with a water jet gun and for 2 minutes under running tap water. Only then may the instruments be placed in the WD.

7.1.3 Cleaning category 3
After the manual pre-cleaning, as described in Chapter 7.1.2, the instruments must be treated with 0.5 % neodisher MediClean forte for 5 minutes at 35–47 kHz in an ultrasonic bath. After the ultrasonic bath, the instruments must be rinsed for 3 minutes with a water jet gun. Only then may the instruments be placed in the WD.

7.2 Automated cleaning (in the WD)

Pre-rinse	**Duration:** 2 minutes	• Tap water (cold, < 45 °C (113 °F))
Cleaning	**Duration:** 10 minutes **Temperature:** 55 °C (131 °F)	• 0.5 % mildly alkaline-enzymatic cleaning solution neodisher MediClean forte in DI water
Rinse	**Duration:** 2 minutes	• DI water (cold)
Thermal disinfection	Taking into account the A_0 value according to the national regulations, e. g. an A_0 value of at least 3000 at 90 °C (194° F) for 5 minutes.	• DI water
Drying	**Duration:** 15 minutes **Temperature**: 115 °C (239° F)	• Hot air

7.3 Steam sterilisation with fractionated pre-vacuum

Type of cycle	Minimum temperature in °C/ °F	Minimum sterilisation time in minutes	Minimum drying time in minutes	Minimum pressure in mbar
Fractionated pre-vacuum [1]	134/273	18	30	≥ 3042
Fractionated pre-vacuum [2]	134/273	3	30	≥ 3042

[1] Recommended sterilisation process
[2] Validated sterilisation process

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Item no. 336.040.028 05-0822-DV 2022-08

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