MATHYS
European Orthopaedics

Processing instructions

for the Ligamys suturing forceps

***Preservation** in motion*

Building on our heritage
Moving technology forward
Step by step with our clinical partners
Towards a goal of preserving mobility

***Preservation** in motion*

As a Swiss company, Mathys is committed to this guiding principle and pursues a product portfolio with the goal of further developing traditional philosophies with respect to materials or design in order to address existing clinical challenges. This is reflected in our imagery: traditional Swiss activities in conjunction with continuously evolving sporting equipment.

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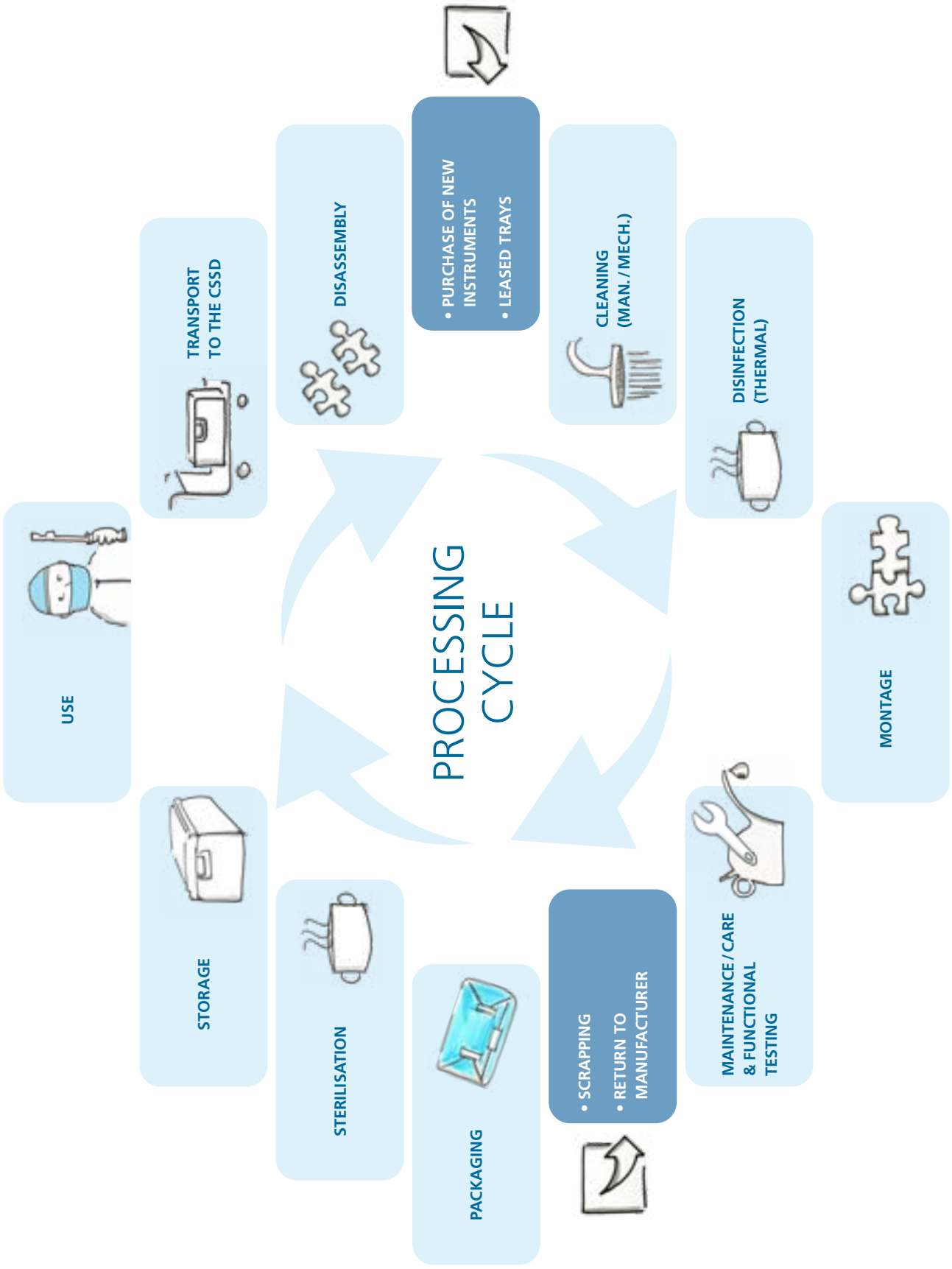
1. Scope

The present processing instructions in accordance with the requirements of SN EN ISO 17664 apply to instruments that are to be reused and therefore need to be reprocessed, as well as to medical devices that are sold non-sterile, but to be used in sterile condition. The Ligamys suturing forceps (re-sterilisable surgical instruments) by Mathys Ltd Bettlach belongs to this group.

The process chemistry parameters as well as the equipment of the following processing instructions are recommendations resulting from the findings of the validation process for instrument processing of Mathys Ltd Bettlach.

The processor is responsible for ensuring that the processing actually performed achieves the desired results with the individual equipment, process chemicals and staff in the processing facility. It is not mandatory to use the same chemicals, parameters and 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 which is proven to lead to the desired result, there is no need for the user to change the method.

2. Processing cycle



3. Information to be provided by the manufacturer

3.1 Instructions for reprocessing

These processing instructions for the Ligamys suturing forceps are based on a validated manual/automated processing procedure. A purely manual or purely automated processing method has not been validated by Mathys Ltd Bettlach and does not lead to sufficient cleaning success.

3.2 Limitations and restrictions of reprocessing

3.2.1 Warnings and precautions

An alkaline-enzymatic cleaning solution is recommended (pH 10 – 11).

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

Personnel who come into contact with potentially or actually contaminated surgical instruments must be trained with regard to generally accepted hygienic protective measures (protective clothing, mouth and nose protection, goggles, cut-resistant gloves, work shoes, etc.) and be able to use them. When handling instruments with sharp points or edges, special caution is advised.
Personal protective equipment (gown, mask, goggles, visors, gloves, shoes, over-shoes, etc.) are required in order to avoid contact with contaminated or potentially contaminated materials, instruments and products.

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

In the manual cleaning process, low-foam detergents are to be used in order to ensure visibility of the instruments. 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 are avoided that might spread contaminants. To prevent accumulation of detergent residues, the detergents must be completely removed by thorough rinsing of the product surfaces.

Heavy objects should not be placed on sensitive instruments, since this can impair the function of the instruments.

Do not allow contaminated instruments to dry before reprocessing them. This is important because all the steps described below for cleaning and sterilisation are facilitated by preventing blood, body fluids, bones and tissue residues as well as saline or disinfectant from drying on used instruments.

When loading the cleaning trays and baskets, ensure that instruments cannot damage each other, and that they can be easily rinsed all around.

The chloride and iodide ions contained in detergents and disinfectants can cause corrosion. For this reason, contact of the instruments with such agents must be kept as brief as possible. Rinse the instruments thoroughly with tap water and then deionised water (demineralised water) in order to remove all residues. Never leave wet instruments to stand. Rather, dry them immediately. The condensation moisture resulting from sterilisation can be prevented by extension of the drying phase.
Cleaning solutions that are too concentrated, too acidic or alkaline, or that contain aldehydes, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide, may damage the instruments. Such cleaning solutions are to be avoided.
Mathys advises against the use of drying or neutralising agents.

Attention must be paid to the quality of the water used. The deionised water (hereafter DI water) used for rinsing should microbiologically be at least of drinking water quality.
If only water (without the addition of cleaning solution) is used for cleaning, Mathys recommends a water temperature of no more than 45° C (113° F), since otherwise proteins will be fixed on the instrument, making removal difficult.
The last rinse in mechanical cleaning is to be performed with DI water.

For cleaning reusable instruments, Mathys Ltd Bettlach recommends a combined manual/automated cleaning process with a detergent and enzyme solution at an alkaline pH of < 11.
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 be followed.

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 legal manufacturers may not.

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

Before returning any instruments to Mathys, these instruments must undergo a full processing cycle in order to exclude a risk of infection.

If contaminated instruments are sent to external treatment facilities for processing, they must be manually pre-cleaned, visually clean and drey in their specific instrument tray, and additionally stored in a sterilisation container. The sterile container must be closed, sealed and markde with a Biohazard label.

Before being returned to Mathys, contaminated leased instrument trays must undergo a complete processing cycle in order to avoid danger to third parties. This also applies to the return of contaminated individual instruments, and to repairs.

Instruments for single use may be used only once and never reprocessed or resterilised, not even if they are removed from the package but not contaminated or used. The single-use instruments are to be disposed of after use.
This also includes single-use instruments that were packaged and delivered sterile, removed from the package and inserted into individual trays.

The Mathys instrument trays may be loaded only with instruments manufactured and/or marketed by Mathys.

Instrument trays and lids must be cleaned separately from the instruments.

Non-sterile leased instrument trays that are delivered to the hospital must undergo a complete processing cycle. This also applies to the return of leased instrument trays or non-functional instruments, as well as to repairs.

If necessary, after drying in the WD the instruments must be dried with medical compressed air before being serviced. For maintenance/care, the instruments must be completely dry.

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.

Mathys advises against the use of metal brushes or metal sponges, since these could damage the protective oxide layer. This can lead to corrosion.
Use of steamers is not recommended, since the high temperature fixes proteins to the surface.

3.2.2 Limitations

High-risk patients with 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. Furthermore, the instruments may be exposed to body fluids that contain the hepatitis or HI virus («AIDS virus») or other pathogens.

It is extremely important to neutralise alkaline cleaners completely and rinse them thoroughly off the instruments.

The suturing forceps must be carefully inspected after cleaning. In doing so, the functionality of the forceps must be checked. It must be ensured that the cannula tip of the suturing forceps is sharp for use and has not been damaged by improper handling during cleaning. Also use a PDS II 2-0 thread or equivalent thread of thickness 2-0 to ensure the suture-guiding needle is completely patent. If this is no longer the case, contact your local Mathys partner.

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

Use of hard water (> 14° dH) is to be avoided. The softer the water used, the better contamination can be removed and visible mineral residues avoided. For the initial rinsing, soft tap water is suitable. Rinse thoroughly with deionised water (demineralised water) to remove any residues. Tap water often contains high concentrations of minerals (e. g. lime or silica), which can be seen on the instrument surface as stains with sharply defined edges.

Tip

Never leave instruments wet, but dry them instantly.

3.2.3 Transport after use to processing (CSSD)

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.

3.3 Preparations at the place of use

3.3.1 Processing during and immediately after use

First, residues of body fluids and tissues must be removed using a specific nylon brush. Saline, blood, body fluids, tissue, bone residues or other organic particles on instruments must be removed before cleaning as soon as possible in order to avoid drying as well as corrosion.

Tip

Immersion of the used instruments into enzyme solutions or into cold deionised water (demineralised water) facilitates cleaning, particularly in the case of instruments featuring complex shapes and areas difficult to access (e. g. cannulated and tubular designs, etc.). The enzyme solutions degrade the protein-containing substances, preventing blood and protein-containing materials from drying on the instruments.

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 the specified time, Mathys Ltd Bettlach recommends immersing the instruments into an enzyme solution or deionised water (demineralised water) of room temperature, or to wrap them for up to 6 hours into cloths wetted with enzyme solution or deionised water (demineralised water).

For prevention of contamination, the used instruments must be transported in closed or covered containers to the CSSD.

3.4 Preparation before cleaning

Excessive concentrations of the cleaning agents, as well as strongly acidic and alkaline detergents, can damage the protective oxide layer and cause pitting. When using such agents, the concentration and exposure time recommended by the manufacturers must be strictly adhered to. Mathys Ltd Bettlach recommends use of alkaline cleaning agents with a pH < 11.
The concentration, temperature and exposure time for the cleaning agents recommended by the manufacturers must be observed under all circumstances in order to achieve optimal cleaning.

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

Strongly contaminated solutions (blood and/or clouding) should be replaced with freshly prepared cleaning solutions.

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 blood contained in contaminations would start to coagulate, leading to strong fixation of proteins on the instrument, which can then be detached only with great effort in the automated cleaning.

The Ligamys suturing forceps must be treated in a two-stage cleaning process, first manually, followed by automated cleaning, in order to achieve the necessary cleaning results.

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

Process			Reusable surgical instruments
Preparation at the place of use	Condition	Wet	• Recommendation Cold deionised water (demineralised water) or enzyme solution (fluid or wetted cloths) • Max. 6 hours
		Dry	• Max. 1 hour
Decontamination	Preparation	• Selection according to the cleaning and disinfection method	
	Cleaning	Manual	–
		Automated	–
		Ultrasound	+
		Combined manual/automated	+
		Mildly alkaline-enzymatic (pH 10–11)	+
		Acidic	–
		Neutral to slightly alkaline (pH 7–9.5)	–
	Rinsing		Final rinse with deionised water (demineralised water)
	Disinfection [1]	Chemically max. 60° C (140° F)	–
		Thermally 90° C (194° F)	+
	Drying	T_{max}/time	115° C (239° F)/15 min
Maintenance	Function check		Mandatory
	Care	Care products based on paraffin/white oil (biocompatible, steam-sterilisable and steam-permeable)	Mandatory
Sterilisation	Moist heat [2]		+
	Ethylene oxide		–
	Formaldehyde		–
	Plasma		–

Legend: + validated method, – non-validated method
[1] Non-automatic disinfection process according to «Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008»
[2] Preferred sterilisation method according to SN EN ISO 17664

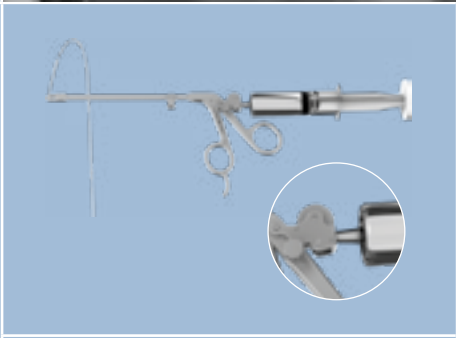
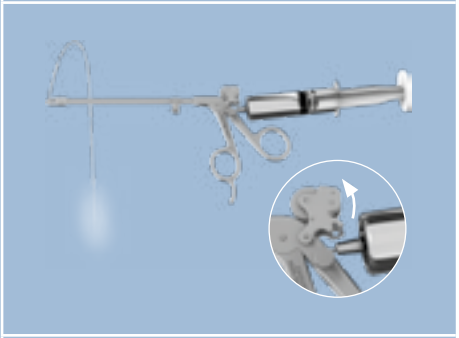
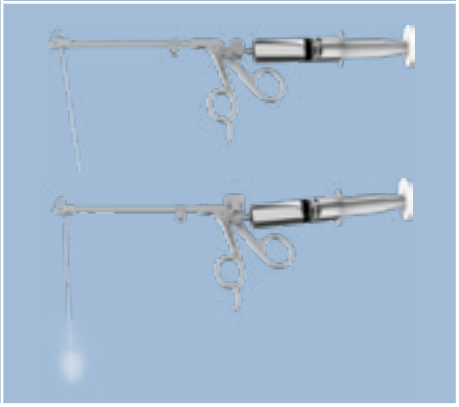
3.5 Cleaning and disinfection

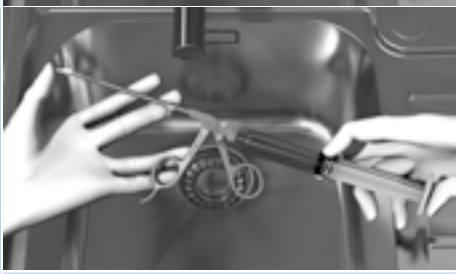
For cleaning the instrumentation, Mathys recommends using a combined manual and mechanical cleaning process with a mildly alkaline-enzymatic cleaning solution (pH from 10 to 11) using DI water (according to SN EN 285) to achieve optimum and thorough cleaning results.

In the case of manual pre-cleaning, all blind holes and boreholes, slits and crevices as well as other visible design features must be rinsed thoroughly with tap water and, if necessary, pre-cleaned with a nylon brush.

3.5.1 Instructions for manual pre-cleaning

According to Mathys's internal process, the Ligamys suturing forceps fall into cleaning category 3 and must be processed as follows:

No.	Step	Material / Medium	Images
1	Manual removal of all visible contaminations using a plastic brush* below the water surface until no visible residues are present any more.	• Nylon brush • Tap water (cold)	
2	Flush the suture-guiding cannula through the roller housing of the suturing forceps with 50 ml of enzyme-containing cleaning solution. Ensure that liquid visibly flows out of the tip of the cannula.	• 50 ml plastic syringe without Luer lock • 1 % deconex® TWIN PH10 and 1 % deconex® TWIN ZYME (v/v) • Deionised water (demineralised water)	
	If the needle is blocked by tissue fragments, the roller housing must be folded up and the cannula flushed by direct application of a syringe. Ensure again that liquid visibly flows out of the tip of the cannula.		
	If upon rinsing of the suture-guiding cannula with enzymatic cleaning solution or deionised water no or only reduced liquid outflow is seen, neither through the roller housing nor with the roller housing folded up, the suturing forceps may not be used and must be replaced.		

No.	Step	Material / Medium	Images
3	The pre-rinsed suturing forceps are treated with ultrasound in the combined cleaning agent/enzyme solution in an ultrasonic bath (35–47 kHz) for 5 minutes. It is to be ensured that the forceps are completely covered with the cleaning agent.	• Ultrasonic bath • 1 % deconex® TWIN PH10 and 1 % deconex® TWIN ZYME (v/v) in DI water	
4	Rinse the suturing forceps well under running tap water.	• Tap water (cold)	
5	Rinse the suture-guiding cannula of the suturing forceps with 50 ml of tap water.	• 50 ml plastic syringe without Luer lock • Tap water (cold)	
6	Rinse the suture-guiding cannula of the suturing forceps with 50 ml of deionised water (demineralised water).	• 50 ml plastic syringe without Luer lock • Deionised water (demineralised water)	
7	The suturing forceps must be checked visually for any residues or damage. If there are still any visible residues, these should be removed using a plastic brush under running water, and the manual cleaning steps 3 to 7 should be repeated.	• Visual control	

* Decontaminate brushes after use and sterilise or dispose of them. Do not use steel brushes.

3.5.2 Instructions for automated cleaning and disinfection

The process was carried out at Mathys Ltd Bettlach using a washer and disinfector (WD) by Miele KG (Miele Professional G7836CD) and a combined manual/automated cleaning process with the detergent and enzyme solution deconex® TWIN PH10 and deconex® TWIN ZYME by Borer Chemie AG.

The cleaning basket of the WD must be equipped with a Luer lock attachment and a quiver nozzle.

For correct machine cleaning, the Ligamys suturing forceps must be positioned with the front end in the quiver nozzle of the WD to actively clean the suture-guiding cannula. Furthermore, the Ligamys suturing forceps must concomitantly be connected to the Luer lock connection of the WD for optimal cleaning of the suturing forceps (Fig. 1).

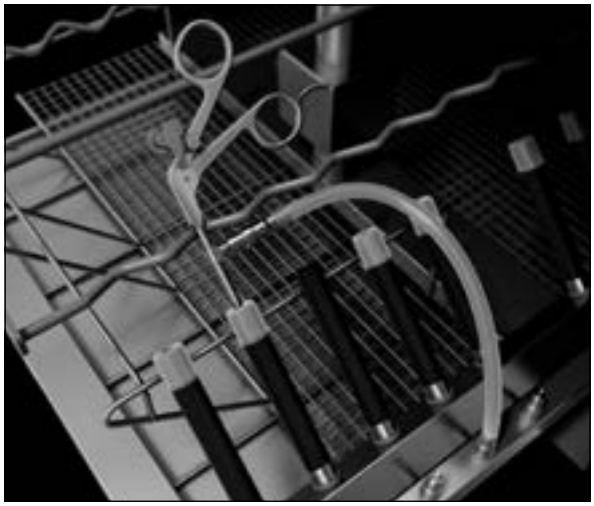


Fig. 1 Mechanical cleaning via Luer lock adapter and introduction of the front end of the Ligamys suturing forceps into a quiver nozzle

No.	Step		Equipment / Medium
1	The Ligamys suturing forceps is positioned with the front end in a quiver nozzle of the WD and additionally attached, with the roller housing folded up, to the cleaning basket via Luer lock adapter (see Fig. 1). Make sure the Ligamys suturing forceps is not damaged during rotation or by the rotor.		• Cleaning basket with quiver nozzle and Luer lock attachment
2	**Pre-rinse**	**Duration:** 2 minutes	• Tap water (cold)
3	**Cleaning process** [1]	**Dosage / Temperature:** 0.5 % deconex® TWIN PH10 at 35° C (95° F) 0.2 % deconex® TWIN ZYME at 40° C (104° F) **Duration / Temperature:** 10 minutes at 55° C (131° F)	• Enzymatic cleaner 0.5 % deconex® TWIN PH10 [2] and 0.2 % deconex® TWIN ZYME [2], (v/v) in deionised water (demineralised water) [3, 4]
4	**Rinse I**	**Duration:** 2 minutes **Temperature:** Max. 50° C (122° F)	• Tap water (cold)
5	**Rinse II**	**Duration:** 2 minutes **Temperature:** Max. 40° C (104° F)	• Deionised water (demineralised water) [3, 4]
6	**Thermal disinfection** [5]	**Duration:** 5 minutes **Temperature:** 90° C (194° F)	• Deionised water (demineralised water) [3, 4]
7	**Drying**	**Duration:** 15 minutes **Temperature:** 115° C (239° F)	• Hot air
8	The suturing forceps must be checked visually for any residues or damage. If any residues are visible, the entire manual and automated process must be repeated.		• Visual control

[1] Mechanical cleaning must be carried out in a WD in accordance with the DIN EN ISO 15883 series of standards
[2] Recommendation for exposure time, concentration, temperature and pH according to the manufacturer's product information sheet (Dr. Weigert GmbH)
[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 (Dr. Weigert GmbH)
[5] If necessary, after drying in the WD the instruments must be completely dried with medical compressed air

3.6 Control and maintenance

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 mechanical cleaning and disinfection process must be repeated immediately.

Once the instrument is visually clean, it must undergo maintenance (see arrows in figure 2). 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. Alternative products must be oil-free, free of silicone oil-containing care products, 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.

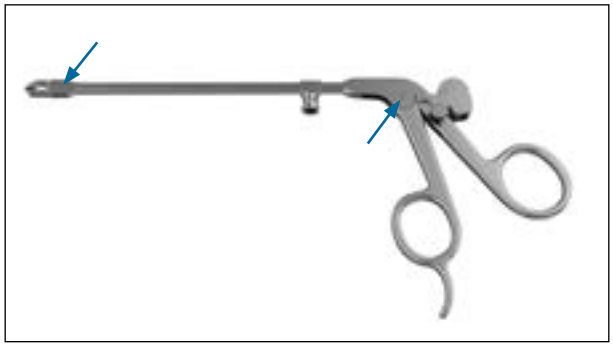


Fig. 2 Hinge mechanisms to be treated

3.7 Function testing

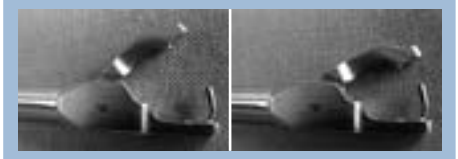
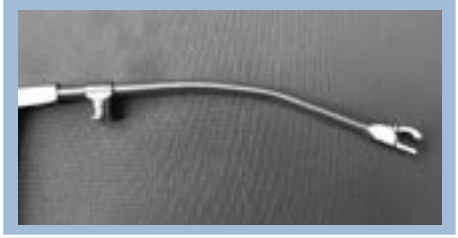
The suturing forceps must be checked for damage. In particular, the tip of the cannula must be sharp, and the forceps must be able to be closed and opened without any resistance.

Rotation of the wheel on the roller housing must work properly in both directions.

Also use a PDS II 2-0 thread or equivalent thread of thickness 2-0 to ensure the suture-guiding needle is completely patent. If this is no longer the case, please contact your local Mathys partner.

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 and/or exchange of the instruments.

Defects and their causes, as well as correct troubleshooting in case of damage, are shown in the table below.

Defect	Cause	Examination and measure
Bent or broken cannula tips 	• Improper handling • Overpacked trays	**Can be successfully bent back** • Continued use **Not possible to bend back or broken** • Do not use instrument any longer and discard
Complete opening of the jaws not possible  Correct Incorrect	• Improper handling • Overload during use • Overpacked trays	• Do not use instrument any longer and discard
Complete closing of the jaws not possible  Correct Incorrect	• Improper handling • Overload during use • Overpacked trays	• Do not use instrument any longer and discard
Tube bent 	• Improper handling • Overload during use • Overpacked trays	**Can be successfully bent back** • Continued use **Not possible to bend back or broken** • Do not use instrument any longer and discard
Knurled knob blocked 	• Improper handling • Tissue residues in the roller housing	**Successful removal of tissue residues with positive functional check** • Continued use **Functional check negative** • Do not use instrument any longer and discard

Defect	Cause	Examination and measure
Luer connection damaged 	• Improper handling • Overpacked trays • Damage due to being dropped	**Connection can no longer be attached** • Do not use instrument any longer and discard
Labelling no longer legible 	• Worn off due to use • Fading due to the cleaning process, cleaning agents and sterilisation procedure	**Article number, lot and CE marking can still be read** • Continued use **Article number, batch or CE marking can no longer be read** • Do not use instrument any longer and discard
Corrosion 	• Unsuitable cleaning agents • Excessive time spent in cleaning agents and disinfectants • Improper processing	• Do not use instrument any longer and discard
Organic residues 	• Unsuitable cleaning agents and disinfectants • Residues allowed to dry for too long prior to processing • Insufficient brushing, rinsing during manual pre-cleaning	• Repeat the processing **If repeat processing is not successful** • Do not use instrument any longer and discard
Water spots (lime or silicate deposits) 	• Poor water quality • Rinsing with distilled water not performed • Penetration of cleaning agents containing silicate	• Repeat the processing

Instruments must be replaced if:
1. the surfaces look «chalky».
2. they show any signs of damage (e. g. (hairline) cracks, flaking, 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 trays.
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 and 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 – 12 × 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.

3.8 Packaging

Mathys recommends double packaging of the instrument trays.
For sterilisation, the instruments by Mathys must be placed in their specific instrument trays. Before the start of sterilisation, ensure that the contents are sorted in properly, and that the instrument tray is not tilted.
Instruments that cannot be placed into any specific instrument tray may be neither stacked on top of each other nor come into contact with each other; they must be arranged such that the steam can reach every part of the instrument surface.
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 must form a sterile barrier system. In addition, the packaging provides protection during transport and storage.

If sterilisation fleece is used, this must be free of any cleaning solution residues. Mathys discourages use of recyclable fleece.

3.9 Sterilisation

For optimum sterilisation, the instrumentation must be properly prepared and packaged into the instrument trays provided for this purpose. Only in this way can the spread and penetration of steam reach all surfaces. In case of steam sterilisation, it must be ensured that the product is completely dry after sterilisation.

The steam (DI water according to SN EN 285) used for sterilisation must be free of impurities (according to SN EN 285) and may neither interfere with the sterilisation process nor cause damage to the steriliser or the material to be sterilised.

For the sterilisation of the packaged instrument trays, Mathys recommends steam sterilisation with a fractionated pre-vacuum cycle.

Ethylene oxide, formaldehyde, gas plasma, and dry heat are not recommended as sterilisation methods for reusable instruments.

The plastic materials used in the instrument trays by Mathys can be sterilised with steam.

Instructions by the manufacturer of the sterilisation device and national recommendations and guidelines must always be followed. If several instrument trays are sterilised in one sterilisation cycle, the maximum loading of the device in accordance with the manufacturer's instructions must not be exceeded.

Below are the minimum sterilisation parameters which were conducted by Mathys with a sterilisation device (Sterimed FAV6767100S) and validated through microbiological examinations to achieve a SAL (sterility assurance level) of 10^{-6}.

Sterilisation process with saturated steam

Type of cycle	Minimum Temperature in °C[5] (°F)	Minimum sterilisation time in minutes	Minimum drying time in minutes	Minimum pressure in mbar[6, 7]
Pre-vacuum – pulsating vacuum[1]	**134 (273)**	18	20	≥3042
Pre-vacuum – pulsating vacuum (D)[2]	**134 (273)**	5	20	≥3042
Pre-vacuum – pulsating vacuum (GB)[3, 4]	**134 (273)**	3	20	≥3042

[1] Recommendation of the World Health Organisation (WHO) for steam sterilisation of instruments with potential TSE/CJD contamination
[2] Hygiene requirements on the reprocessing of medical devices, Federal Institute for Drugs and Medical Devices, 2012
[3] 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
[4] Validation in the original instruments case
[5] Maximum temperature 137°C according to SN EN 285
[6] Pressure during the sterilisation phase at 134°C according to DIN ISO/TS 17665-2
[7] Pressure during the sterilisation phase at 137°C must be ≥3318.5 mbar according to DIN ISO/TS 17665-2

3.10 Storage

The sterile material must be stored dry at room temperature (18–25° C) (65–77° F), protected from dust, pests and direct sunlight, and may not be stored directly on the floor or in the vicinity of chemicals which emit corrosive vapours, such as active chlorine. The storage room may be accessible only to au-thorised personnel.
The sterile material must be inspected meticulously prior to opening to ensure that the packaging is intact.
Each user must determine how long the sterile-packed sterile material may be stored prior to next use (DIN 58953-9/DIN EN 868).

If the packaging or a sterile fleece is visibly damaged or has become damp, the instrument tray must be repackaged and resterilised. In case of signs of open or damaged lid gaskets, seals, or filters on the sterilisation container, the instrument tray must likewise be resterilised and the sterile filter replaced. For reusable filters, a careful visual inspection must be carried out.

3.11 Efficacy of the treatment process

The processing method recommended in the present processing instructions has been validated. The results meet the requirements with regard to both the limit value and to the guidance value in terms of protein residues in accordance with the guideline by DGKH, DGSV and AKI for mechanical cleaning and thermal disinfection processes for medical devices (D 2596 F).

3.12 Number of processing cycles

Medical instruments generally have a long service life when used and reprocessed properly, including maintenance and functional checks (instrument is functional, no corrosion, no cracks, no bending, no flaking, no defects) performed according to chapter 3.7 of these reprocessing instructions. The service life of surgical instruments is usually defined by wear and tear, improper use or maintenance – and not by the reprocessing process. If the reprocessing is carried out according to these reprocessing instructions, neither damage nor a limitation of service life of the relevant medical device is to be expected. In addition, Mathys Ltd Bettlach carried out tests comprising 250 reprocessing cycles and was able to demonstrate that 250 reprocessing cycles have no damaging effect on the instruments. During and after each use of medical instruments, the functionality of these instruments should routinely be checked by qualified staff. Instruments that are no longer functional are to be replaced.
The processor is responsible for checking optimal functionality (e. g. cutting ability) – including use of a care product based on paraffin/white oil that is biocompatible, steam-sterilisable and steam-permeable –, cleanliness, and absence of any defects (e. g. corrosion) before each use.
The user must always ensure that hte latest version of these processing instructions is used.

4. Symbols

4.1 Symbols as used by Mathys Ltd Bettlach


Manufacturer


Caution

Medical device

5. Customer information

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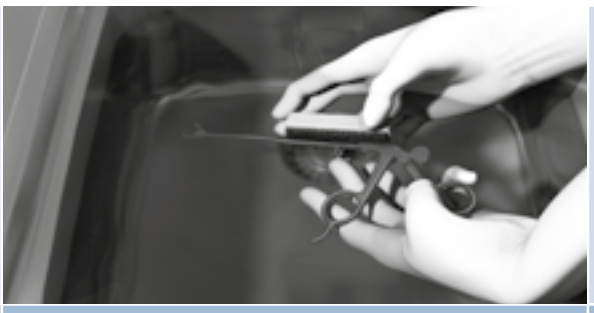
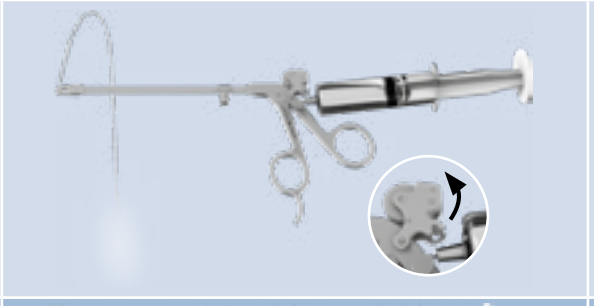
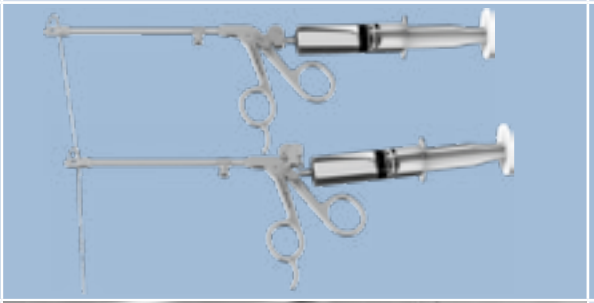
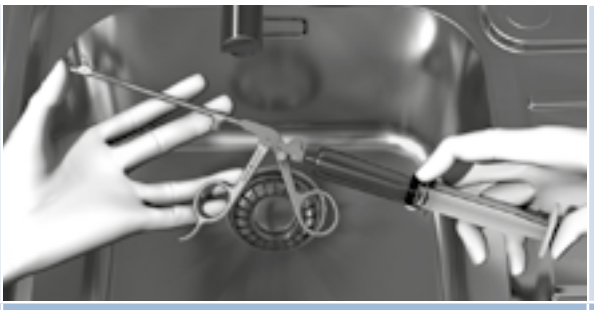
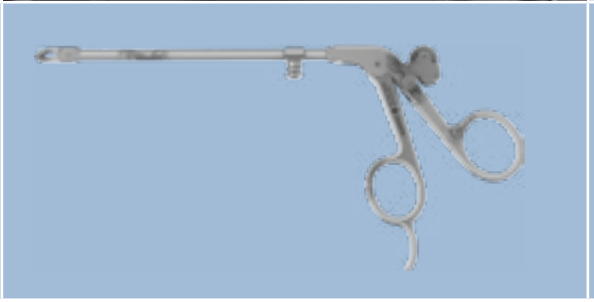
6. Appendix – quick overview

6.1 Manual pre-cleaning

1		Remove visible contaminants using a nylon brush below the water surface until no visible residues are present any longer.
2		Flush the suture-guiding cannula with 50 ml of enzyme-containing cleaning solution. Ensure that liquid visibly flows out of the tip of the cannula.
3		If the needle is blocked by tissue fragments, the roller housing must be folded up and the cannula flushed by direct application of a syringe. Ensure again that liquid visibly flows out of the tip of the cannula.
4		If during flushing no liquid should flow out of the front end of suture-guiding cannula, the Ligamys suturing forceps may not be used and must be replaced.
5		Insert instruments for at least 5 minutes into an ultrasonic cleaning device (35–47 kHz). Max. temperature 40° C (104° F).
6		Rinse the suturing forceps well under running tap water.

7		Rinse the suture-guiding cannula of the suturing forceps first with 50 ml of tap water. Then rinse with 50 ml of DI water.
8		Check suturing forceps visually for any residues or damage. If there are still any visible residues, • remove them using a nylon brush under running tap water and • repeat the entire manual pre-cleaning.

6.2 Machine cleaning

The Ligamys suturing forceps is positioned with the front end in a quiver nozzle of the WD and additionally attached, with the roller housing folded up, to the cleaning basket via Luer lock adapter (see Fig. 1). Make sure the Ligamys suturing forceps is not damaged during rotation or by the rotor.	• Cleaning basket with quiver nozzle and Luer lock attachment

Pre-rinse	**Duration:** 2 minutes	• Tap water (cold)
Cleaning process	**Duration:** 10 minutes **Temperature:** At 55 °C (131 °F)	• Enzymatic cleaner 0.5 % deconex® TWIN PH10 and 0.2 % deconex® TWIN ZYME, (v/v) in deionised water (demineralised water)
Rinse I	**Duration:** 2 minutes **Temperature:** Max. 50 °C (122 °F)	• Tap water
Rinse II	**Duration:** 2 minutes **Temperature:** Max. 40 °C (104 °F)	• Deionised water (demineralised water)
Thermal disinfection	**Duration:** 5 minutes **Temperature:** 90 °C (194 °F)	• Deionised water (demineralised water)
Drying	**Duration:** 15 minutes **Temperature:** 115 °C (239 °F)	• Hot air

The suturing forceps must be checked visually for any residues or damage. If any residues are visible, the entire manual and automated process must be repeated.	• Visual control

6.3 Sterilisation process with saturated steam

Type of cycle	Minimum Temperature in °C (°F)	Minimum sterilisation time in minutes	Minimum drying time in minutes	Minimum pressure in mbar
Pre-vacuum – pulsating vacuum [1]	**134 (273)**	18	20	≥3042
Pre-vacuum – pulsating vacuum (D)	**134 (273)**	5	20	≥3042
Pre-vacuum – pulsating vacuum (GB) [2]	**134 (273)**	3	20	≥3042

[1] Recommended sterilisation process, [2] validated sterilisation process

Notes

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