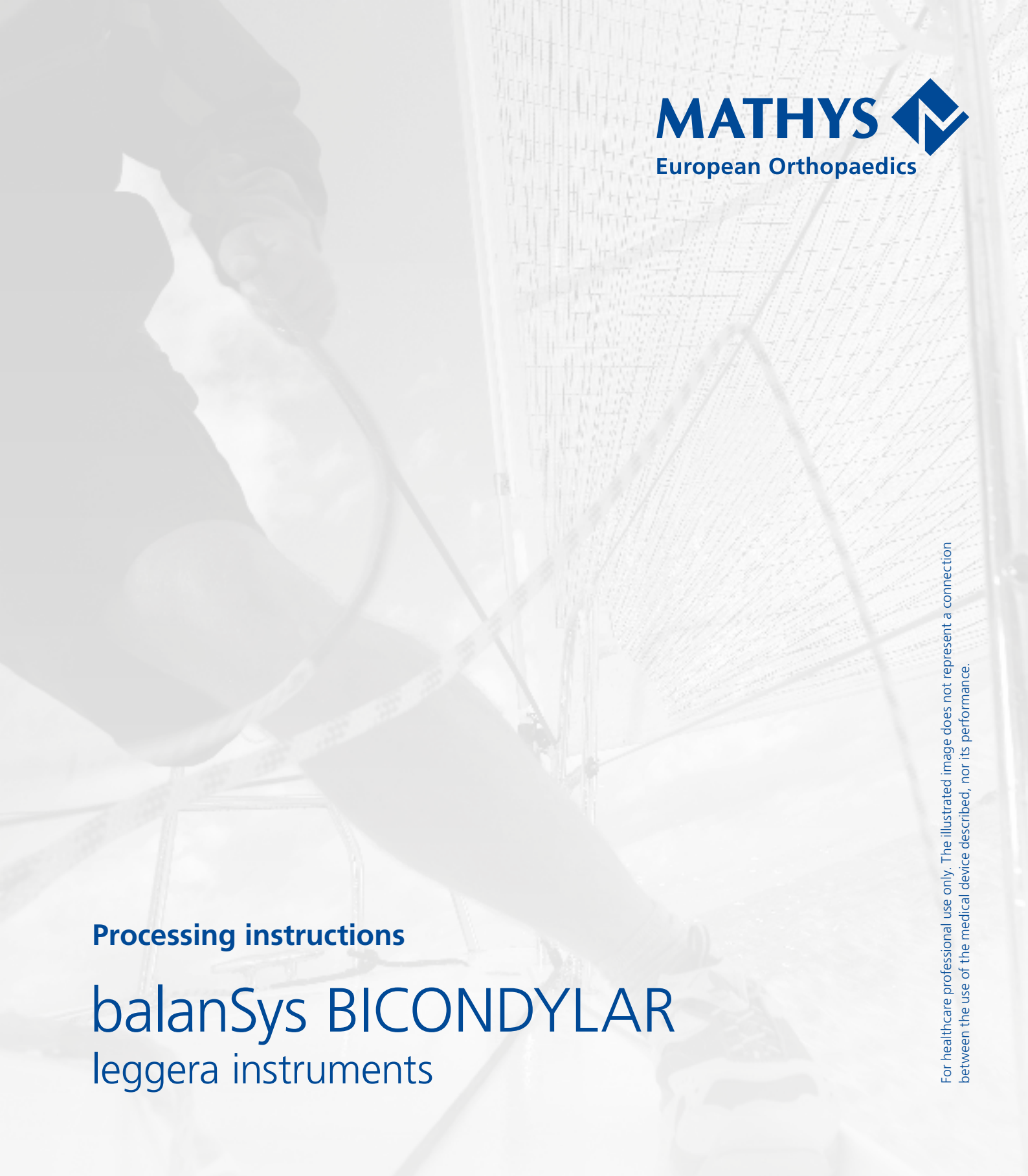
MATHYS
European Orthopaedics



Processing instructions

balanSys BICONDYLAR
leggera instruments

For healthcare professional use only. The illustrated image does not represent a connection between the use of the medical device described, nor its performance.

***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.

Table of contents

1. Objective

These processing instructions represent a recommendation according to the requirements of SN EN ISO 17664 and apply to all balanSys BICONDYLAR leggera instruments in order to achieve cleanliness and sterility for these instruments. Mathys Ltd Bettlach (hereafter referred to as «Mathys») has validated the methods recommended in these instructions based on the normative specifications for reusable surgical instruments and their instrument trays.

The processor is responsible for effective and safe processing with its individual equipment, cleaning chemicals and trained staff. Alternative processing steps may be performed, but must be validated by the processor.

If these processing instructions are in conflict with country-specific applicable cleaning, disinfection and sterilisation requirements, laws or regulations, these requirements, laws or regulations have priority over the recommendations from Mathys.

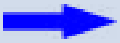
The hospital management and the central sterile services department (CSSD) must be aware of these processing instructions in order to ensure a safe and effective reprocessing. This is important to prevent damage affecting the environment, persons and material, or abuse.

2. Scope

The contents of the processing instructions refer to the transport after use to processing, disassembly, cleaning, disinfection, assembly, maintenance/care, functional check, sterilisation, packaging and storage of the instruments from orthopaedic surgery.

3. Symbols

Symbol	Description
	Non-sterile
	Do not re-use
	Do not resterilize
	CE marking medical devices of Risk Class I
	CE marking medical devices of Risk Class II and III
	Caution – consult the instructions for use for important cautionary information
	Date of manufacture
	Batch code
	Catalogue number

Symbol	Description
	Turn in the direction of the arrow
	Move back and forth
	Move to the right
	Move to the left
	Compress
	Move back and forth
	Move in the direction of the arrow
	Maintenance
	Rinsing

4. Important information for processing/ Recommendations for processing

4.1 Cleaning agent

- A mildly alkaline-enzymatic cleaning solution is recommended (pH 10 – 11).
- 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.
- Low-foam cleaning solutions should be used to ensure visibility of the instruments.
- Mathys advises against the use of drying or neutralising agents.
- Always follow the manufacturer's instructions for preparing and using the solutions.

4.2 Water

- 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.
- 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.
- 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.

4.3 Aids for manual cleaning

- 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.
- Any use of saline solutions is to be avoided, since this leads to corrosion of the instruments.
- Brushes must be decontaminated and sterilised or disposed of after use.

4.4 Safety measures

- 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.
- 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.
- 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.
- 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.
- Furthermore, the instruments may be exposed to body fluids that contain the hepatitis or HI virus («AIDS virus») or other pathogens.
- 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 dry in their specific instrument tray, and additionally stored in a sterilisation container. The sterile container must be closed, sealed and marked 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.
- Brush and clean the instruments below the surface of the cleaning solution to avoid formation of aerosols and thus a risk of infection.

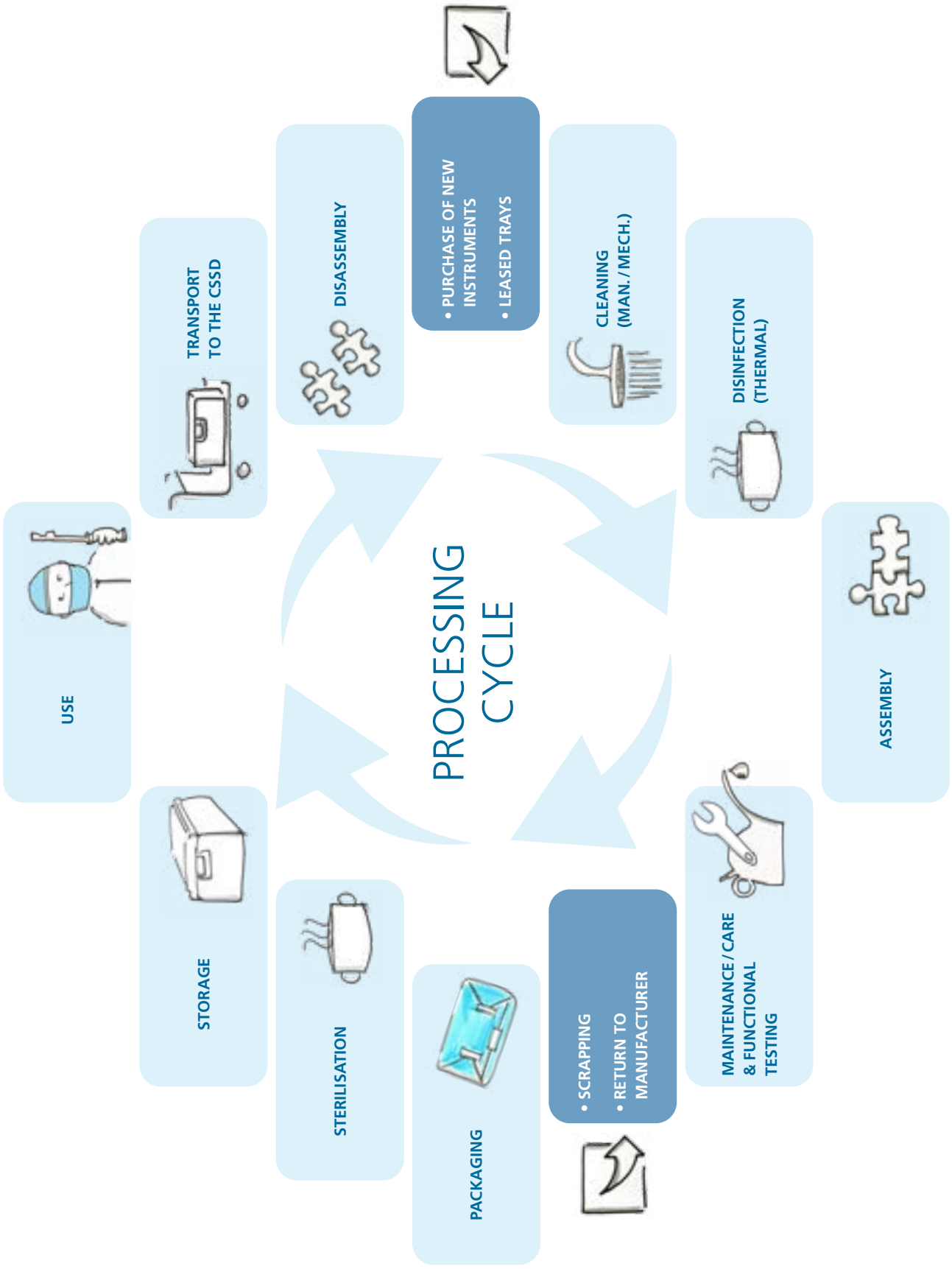
4.5 Restrictions

- 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.
- In the case of aluminium, a protective oxide layer (often also colour-anodized) is created through electrochemical surface treatment, providing good corrosion resistance. Nonetheless, alkaline cleaning solutions (pH ≥ 11), use of DI water and thermal disinfection represent influencing factors that lead to colour changes and degradation of the oxide layer. These cleaning instructions also apply to titanium alloys.

4.6 Notes

- The plastics used by Mathys in the instruments are not suitable for washer-disinfectors that work at temperatures > 141° C (> 285° F). The plastic surfaces of instruments with plastic components could be damaged by this.
- Heavy objects must not be placed on sensitive instruments, as this could impair the function of the instruments.
- The Mathys instrument trays may be loaded only with instruments manufactured and/or marketed by Mathys.
- Instrument trays, inserts and lids must be cleaned separately from the instruments.
- Non-sterile leased instrument trays delivered to the hospital must undergo a complete processing cycle before they may be used. This applies also to the return of leased instrument trays or defective instruments, as well as to repairs.
- New instruments must undergo mechanical cleaning at least three times before use in order to build up the protective oxide layer.
- 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.
- 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.
- 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.

5. Processing cycle



5.1 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.

Table 1: Overview of the reprocessing 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	–
		Mechanical	–
		Ultrasound	+
		Combined manual and mechanical	+
		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)	15
Maintenance	Functional check		Mandatory
	Maintenance	Care product based on paraffin/ white oil (biocompatible, steam-sterilisable and steam-permeable)	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

5.2 Assembly / Disassembly for optimal cleaning

Prior to manual processing in the CSSD, the instruments must be removed from their specific instrument tray. Subsequently, for manual as well as for mechanical cleaning the instruments that consist of several components and are designed for disassembly must be properly dismantled into their individual components (see list below) in order to ensure sufficient and efficient processing. It must be ensured that no small parts are lost. If this should happen anyway, it is extremely important to report this to your Mathys Partner.

5.2.1 Assembly and disassembly of

- balanSys TRS Proximal
- balanSys TRS Distal
- balanSys TRS Ankle Holder
- balanSys TRS Cutting Block

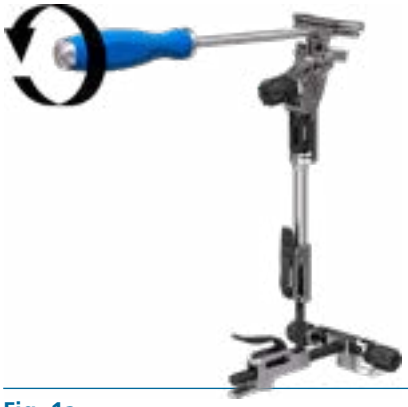


Fig. 1a

Fig. 1b

Fig. 1c

Fig. 1d

Fig. 1e

Fig. 1f

Fig. 1g

5.2.2 Assembly and disassembly of

- balanSys Silicone Handle
- balanSys Intramedullary Rod

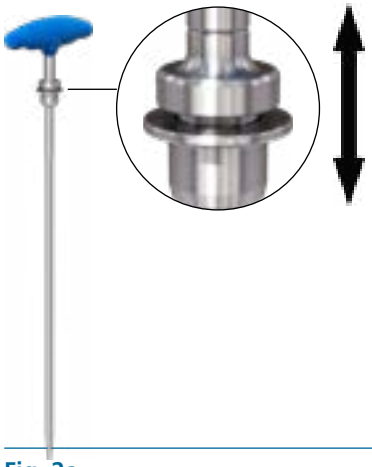


Fig. 2a

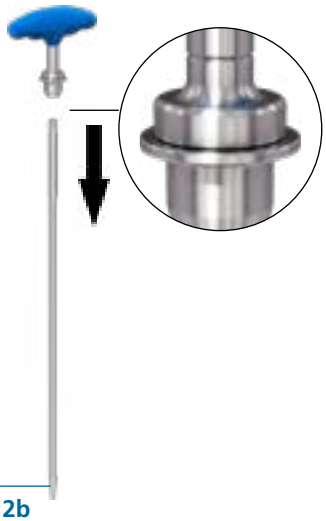


Fig. 2b

5.2.3 Assembly and disassembly of

- balanSys Spacer Block Femur
- balanSys Spacer Block Tibia 8/9 or balanSys Spacer Block Tibia 8/10.5
- balanSys Spacer Block Tibia 10.5/11.5
- balanSys Spacer Block Tibia 13/15.5

Fig. 3a

Fig. 3b

5.2.4 Assembly and disassembly of

- balanSys Spacer Block Femur
- balanSys Spacer Block Tibia 13/15.5
- balanSys Spacer Shift Plate +5

Fig. 3c

Fig. 3d

5.2.5 Assembly and disassembly of balanSys

- Femur Sizing/Rotation Guide with/without AP
- balanSys Handle Femoral Siz./Rotation Guide
- balanSys Femur Rotation Bearing Large and Small
- balanSys Femur Rot. Bearing Short Large and Small
- balanSys Femur Stylus

Fig. 4a

Fig. 4b

Fig. 4c

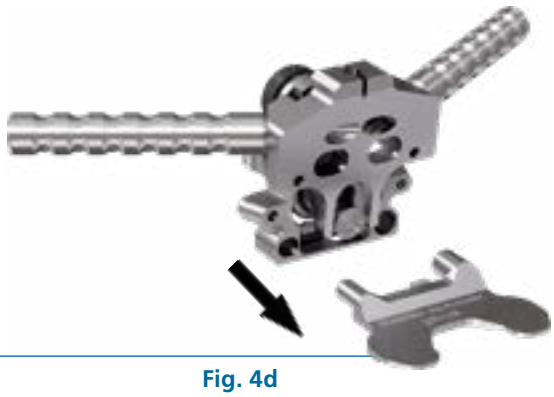


Fig. 4d

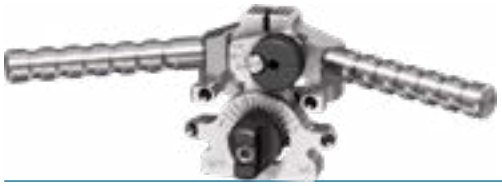


Fig. 4e

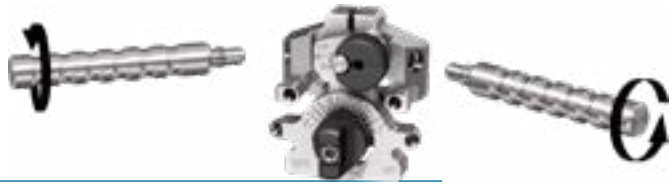


Fig. 4f

5.2.6 Assembly and disassembly of

- balanSys Ligament Tensor
- balanSys Spacer 8G
- balanSys Femoral Feeler 8G
- balanSys Drill Guide 4in1 CuttBlock 8G

Fig. 5a

Fig. 5b

Fig. 5c

Fig. 5d

Fig. 5e

Fig. 5f

5.2.7 Assembly and disassembly of

- balanSys Trial Inlay
- Adapter Trial Inlay

Fig. 6a

Fig. 6b

5.2.8 Assembly and disassembly of

- balanSys TRS Eminentia Shackle
- balanSys TRS Intramedullary Shackle

Fig. 7a

Fig. 7b

5.2.9 Assembly and disassembly of

- balanSys TRS Eminentia Shackle rotating
- balanSys TRS Intramedullary Shackle

Fig. 8a

Fig. 8b

5.3 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.

Instruments that have a cleaning position must be set to the same before manual pre-cleaning.

With regard to manual pre-cleaning, the entire instrumentation is divided into three cleaning categories (Tab. 2).

Table 2: Overview of the cleaning categories of the balanSys BICONDYLAR leggera instrumentation

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 mechanical 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.

Optimum cleaning is ensured if the instruments are properly reprocessed within one hour after transport to the CSSD. To do this, the contaminated instruments must be removed from the instrument tray and, after disassembly, cleaned of any residues of body fluids as quickly as possible while being held beneath the water surface (tap water or mildly alkaline-enzymatic cleaning solution) to prevent drying and corrosion. If necessary, specific surface and lumen brushes made of nylon, plastic syringes and water jet guns (no steamers!) can be used for rinsing. Extensive rinsing of the instruments with demineralised water after manual pre-cleaning prevents detergent residues on them.

The pre-cleaned instruments are then placed into a suitable cleaning basket (e. g. mesh screen) for the mechanical cleaning in the washer-disinfector (WD).

If it is not possible to clean the instruments within this specified time, Mathys recommends immersing the instruments into deionised water at room temperature. However, it is also possible to wrap the instruments for up to 6 hours into cloths moistened with deionised water at room temperature.

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

The instruments in this category have no specific design features and do not require manual pre-cleaning.

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

The instruments of this category must be manually pre-cleaned with surface and lumen brushes made of nylon, plastic syringes and a water jet gun until no visible residues are left.

5.3.2.1 balanSys Chisel Centering Guide

Fig. 9a

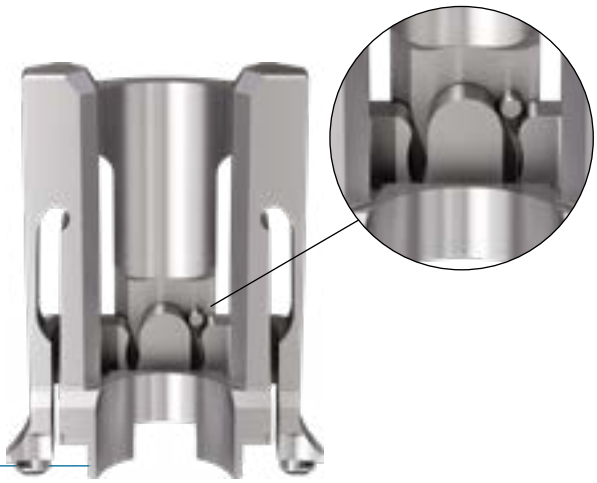


Fig. 9b

Cleaning position: The rotary knob must be in the vertical position.

5.3.2.2 balanSys Positioner for Tibial Plateau

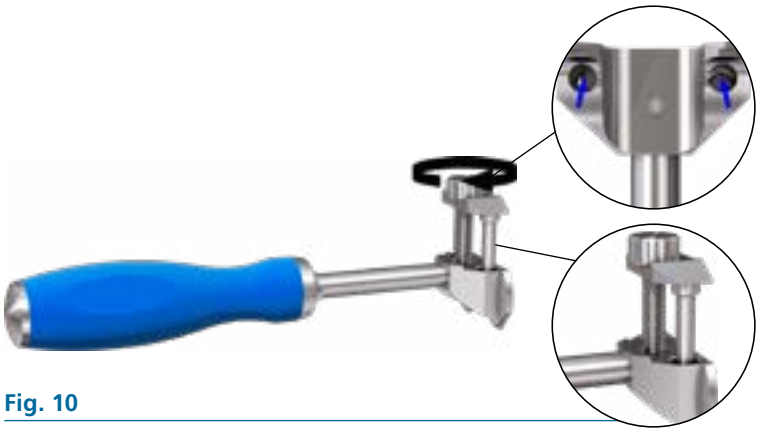


Fig. 10

Cleaning position: By rotating the head of the threaded rod, the two bolt guides on the left and right of the threaded rod must be exposed so that the part that can be screwed out folds backwards easily. Thus, the two guide holes of the bolts can also be rinsed effectively.

5.3.2.3 balanSys TRS Intramedullary Shackle

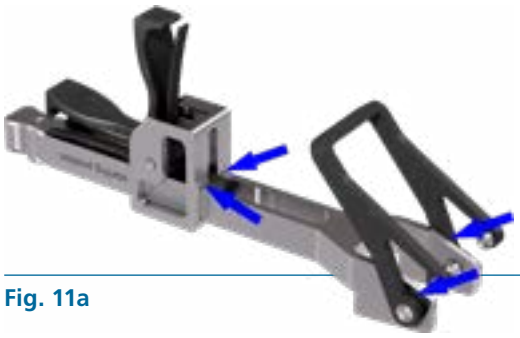


Fig. 11a

Fig. 11b

5.3.2.4 balanSys TRS Eminentia Shackle rotating

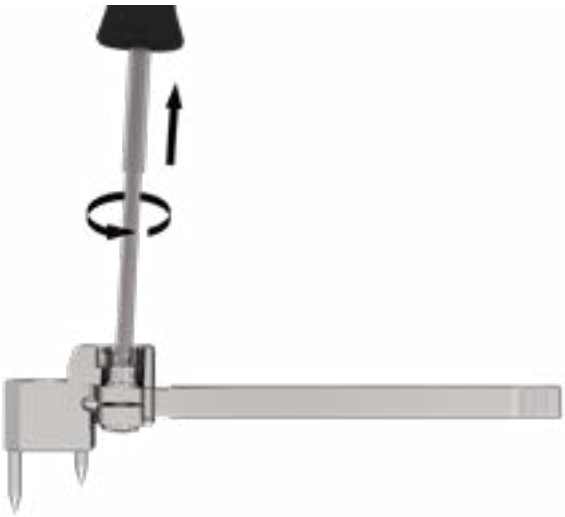


Fig. 12b

Turn the screw with the hexagonal screwdriver to the middle position between the lower and upper stopper.

Fig. 12a

Fig. 12c

Pull the rod out of the head of the instrument until it stops, and turn it by 90°.

Fig. 12d

Cleaning position

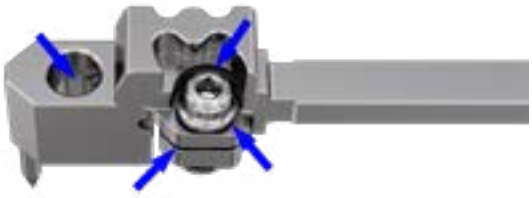


Fig. 12e

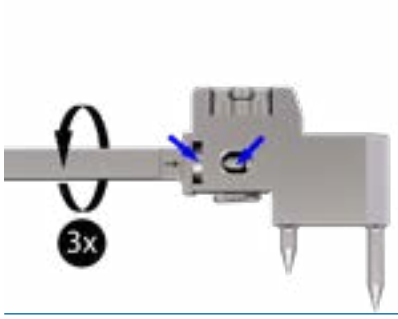


Fig. 12f

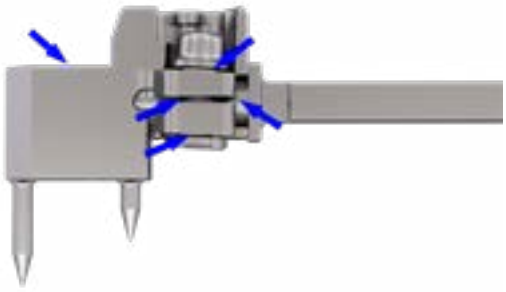


Fig. 12g

5.3.2.5 balanSys Pin Pliers

Fig. 13a

Cleaning position: The Pin Pliers must be cleaned in open state.

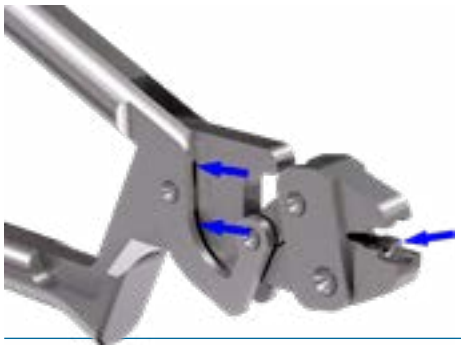


Fig. 13b

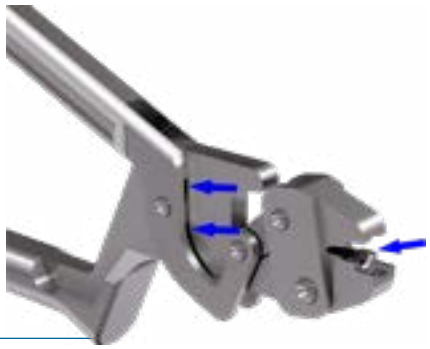


Fig. 13c

Fig. 13d

5.3.2.6 balanSys Femur Stylus, balanSys Tibial Stylus and balanSys Femoral Feeler 8G

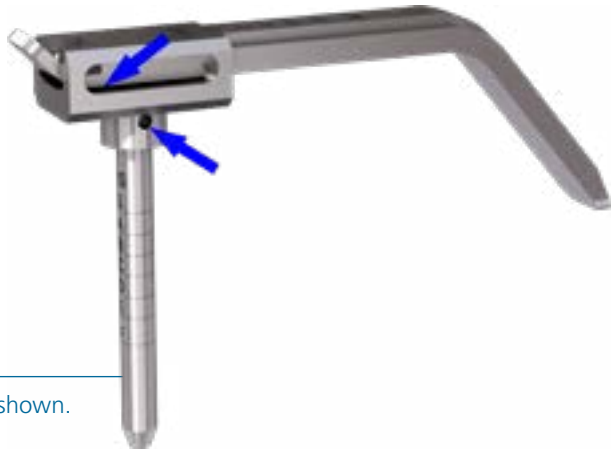


Fig. 14 balanSys Femur Stylus

Cleaning position: Move the stylus to the position shown.

Fig. 15 balanSys Tibial Stylus

Cleaning position: Move the stylus to the position shown.

Fig. 16 balanSys Femoral Feeler 8G

Cleaning position: Move the stylus to the position shown.

5.3.2.7 balanSys Holder Tibial Template

Fig. 17a

Fig. 17b

Compress the balanSys Holder Tibial Template several times during manual rinsing.

Fig. 17c

Fig. 17d

5.3.2.8 balanSys Ligament Tensor

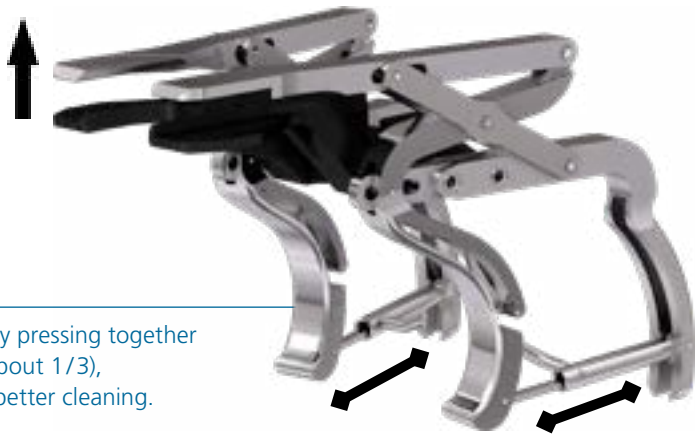


Fig. 18

Cleaning position: By pressing together the two handles (by about 1/3), the claws expand for better cleaning.

5.3.2.9 balanSys Drill Guide 4in1 CuttBlock 8G

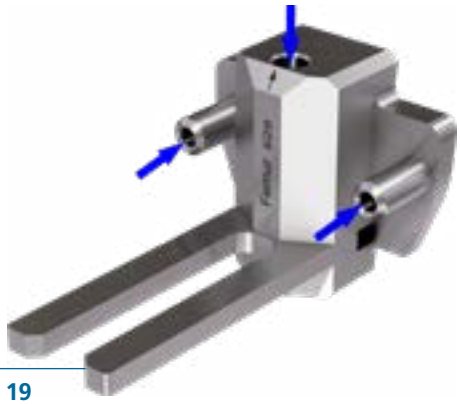


Fig. 19

5.3.2.10 balanSys Spacer 8G

Fig. 20a

Fig. 20b

Cleaning position: With the balanSys Screwdriver, the thread must be unscrewed until it stops.

Fig. 20c

Fig. 20d

5.3.2.11 balanSys Cutting Blocks

Fig. 21: balanSys TRS Cutting Guide

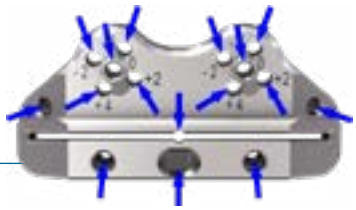


Fig. 22: balanSys Distal Cutting Guide

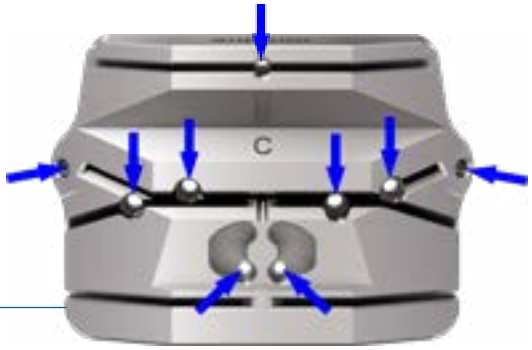


Fig. 23: balanSys Distal Cutting Block 4in1, size XS, S and A–F

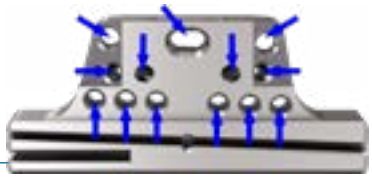


Fig. 24: balanSys Corrective Cutting Guide

5.3.2.12 balanSys Tibial Positioner Tibial Plateau RP

Fig. 25a

Fig. 25b

Cleaning position: The pull rod **(a)** must be completely exposed by turning the screw head **(b)**.

Fig. 25c

Fig. 25d

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

The instruments of this category must be manually pre-cleaned with surface and lumen brushes made of nylon, plastic syringes and a water jet gun until no visible residues are left. In addition, the instruments must be subjected to ultrasonic bath treatment prior to mechanical cleaning.

5.3.3.1 balanSys TRS Proximal

Fig. 26a

Fig. 26b

Cleaning position:

1. Slope dial must be set to CLEAN.
2. Turning the height adjustment wheel to the left moves the Cutting Block Holder upwards, thus exposing it.

Fig. 26c

Fig. 26d, 26e

Fig. 26f

5.3.3.2 balanSys TRS Ankle Holder

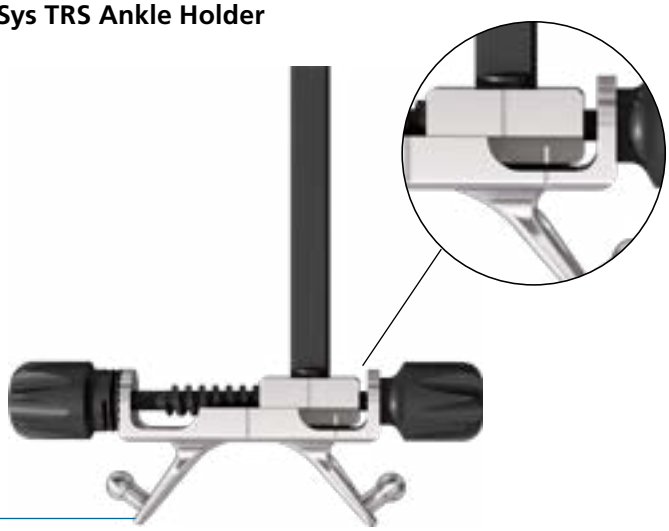


Fig. 27a

Cleaning position: Turn the spindle to adjust the cleaning position.

Fig. 27b

Fig. 27c

5.3.3.3 balanSys Angle Guide

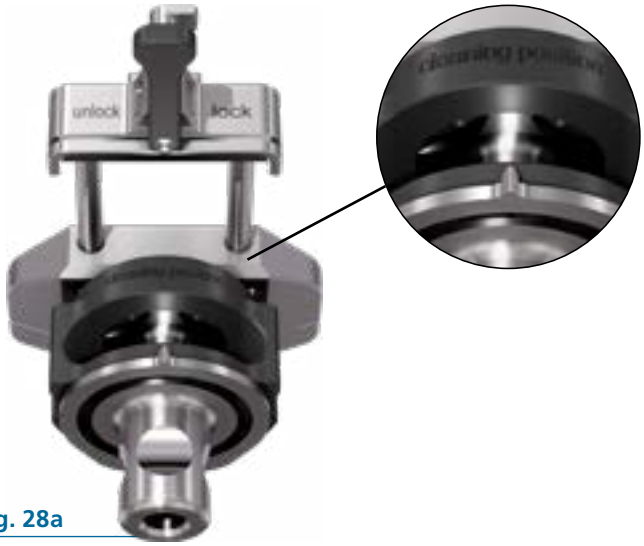


Fig. 28a

Cleaning position: The angle adjustment drum must be brought into the cleaning position shown (opening must face upwards).

Fig. 28b

Fig. 28c

5.3.3.4 balanSys Femur Sizing / Rotation Guide without AP

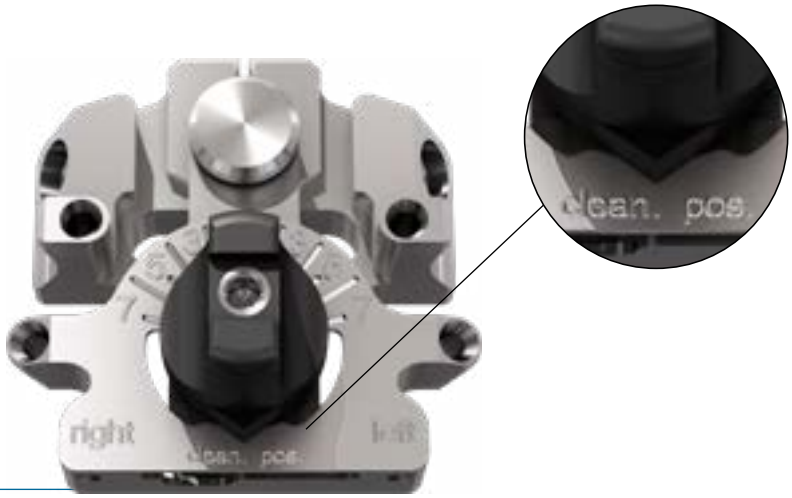


Fig. 29a

Cleaning position: The pointer of the rotary knob must be set to the cleaning position.

Fig. 29b

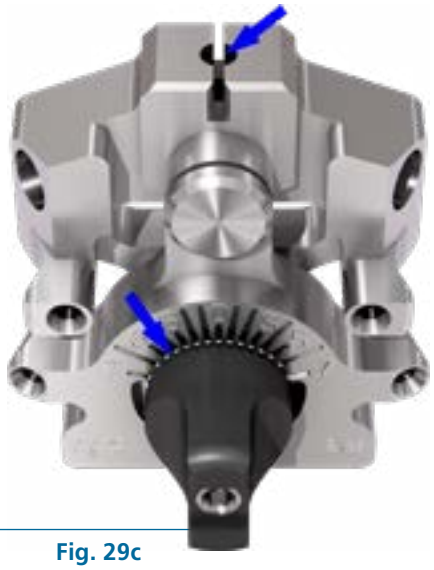


Fig. 29c

5.3.3.5 balanSys Femur Sizing / Rotation Guide with AP

Fig. 30a

Cleaning position: The pointer of the rotary knob must be set to the cleaning position.

Fig. 30b

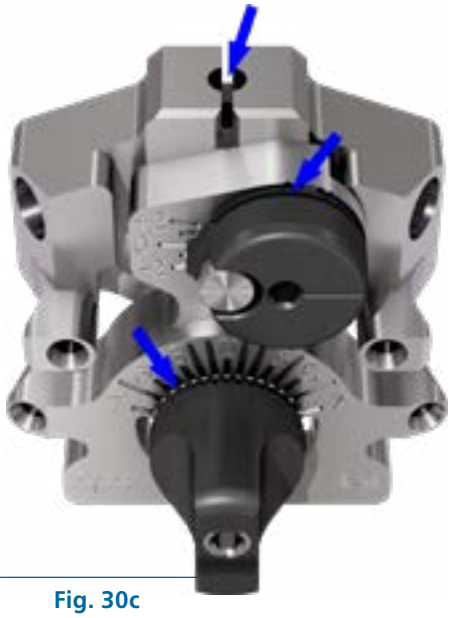


Fig. 30c

5.3.3.6 balanSys Femur Holder

Fig. 31a

Cleaning position: The thread and the locating surfaces must be exposed by rotating until it stops and then back half a turn.

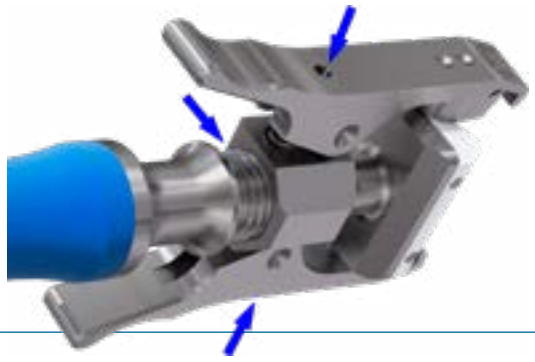


Fig. 31b

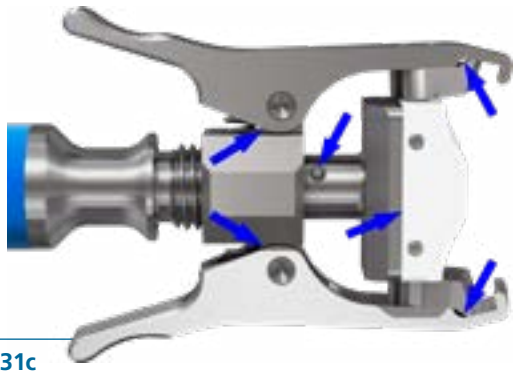


Fig. 31c

5.3.4 Instructions for mechanical cleaning and disinfection (all cleaning categories)

After manual pre-cleaning, mechanical cleaning and disinfection is carried out in the WD.

For this purpose, the pre-cleaned instruments are placed in a suitable cleaning basket (e. g. mesh screen) of the WD and cleaned. Here, the instructions of the WD manufacturer must be followed precisely.

To ensure efficient mechanical cleaning, it must be made sure that the instruments cannot touch each other. Instruments with holes or perforations must, whenever possible, be connected in the WD so that their lumen can be actively flushed.

Mechanical cleaning was validated with a WD (Miele Professional G 7836 CD) and a cleaning program using the mildly alkaline enzymatic cleaning solution neodisher MediClean forte by Dr. Weigert GmbH.

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] Mechanical 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 (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.

5.4 Maintenance / Care and function check

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 yellow arrows in the figures below). To this end, Mathys recommends use of a care product based on paraffin/white oil that is biocompatible, suitable for steam sterilisation, and vapour-permeable. Alternative products must be free of mineral oil and 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.

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, 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 for angles and for determination of implant size, length and/or depth, and orientation indicators such as «left» and «right». If any scales or other markings should not be legible any more, contact your local Mathys Partner promptly for replacement of the instruments.

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 x magnifier. If the cutting instruments are no longer sharp, or visibly or palpably damaged, or if there is feedback from the surgeons that the instrument is no longer fulfilling its cutting, drilling, milling, chiseling or rasping function, your local Mathys partner must be contacted, or the instruments returned to Mathys for scrapping.
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.

5.4.1 balanSys TRS Proximal

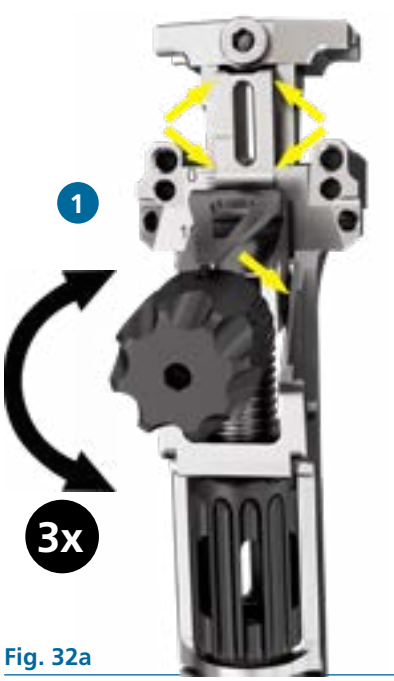


Fig. 32a

Fig. 32b

Fig. 32c

Function test:

1. Slope dial must turn without jamming. Turn the setting wheel to the left and to the right 3x.
2. Height adjustment wheel must be able to rotate without jamming. After maintenance, turn the height adjustment wheel 3x to the right.
3. Clamping support must be mobile. After maintenance on both sides, move the clamp support lever up and down 3x.

Fig. 32d

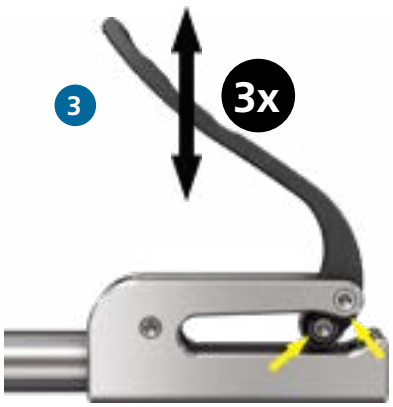


Fig. 32e

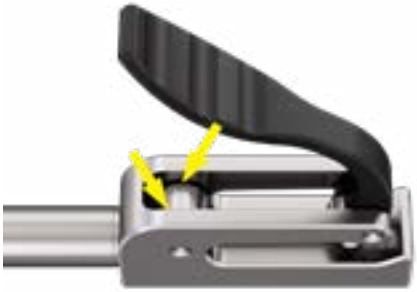


Fig. 32f

5.4.2 balanSys TRS Distal

Fig. 33a

Fig. 33b

Fig. 33c

5.4.3 5.4.3 balanSys TRS Ankle Holder

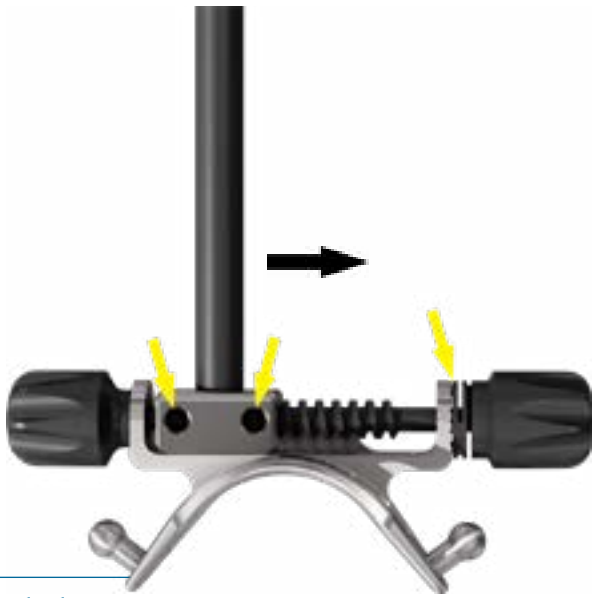


Fig. 34

Function test:
Spindle must turn without jamming. After maintenance, turn the spindle from left to right using the spindle wheel.

5.4.4 balanSys Femur Holder

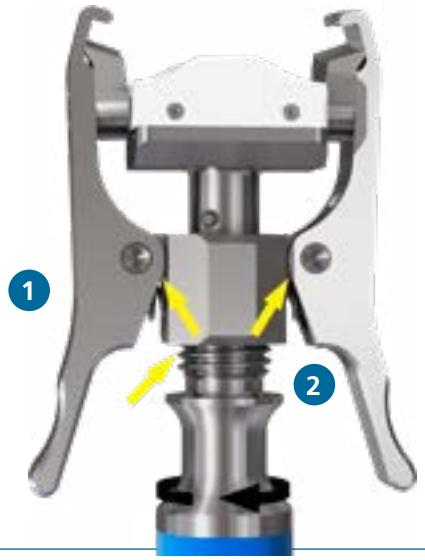


Fig. 35a

Fig. 35b

Function test:
1. Claws must be able to move without jamming. After maintenance, compress the claws on both sides 3x.
2. Thread must be able to turn without tilting or grating. After maintenance, screw the thread into the nut.

5.4.5 balanSys Tibial Stylus, balanSys Femur Stylus and balanSys Femoral Feeler 8G

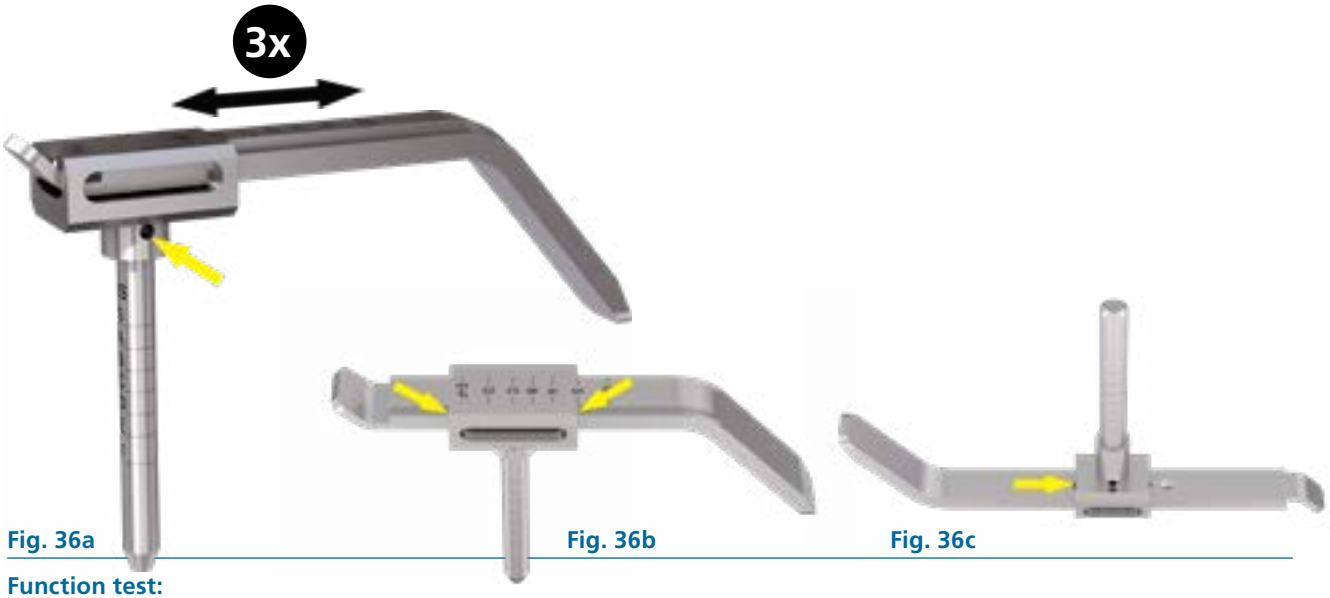


Fig. 36a **Fig. 36b** **Fig. 36c**

Function test:
The sliding parts must be able to move back and forth without jamming.
After maintenance of all the positions shown to require care, the sliding parts must be moved back and forth 3x.

Fig. 36d **Fig. 36e** **Fig. 36f**

Function test:
The sliding parts must be able to move back and forth without jamming.
After maintenance of all the positions shown to require care, the sliding parts must be moved back and forth 3x.

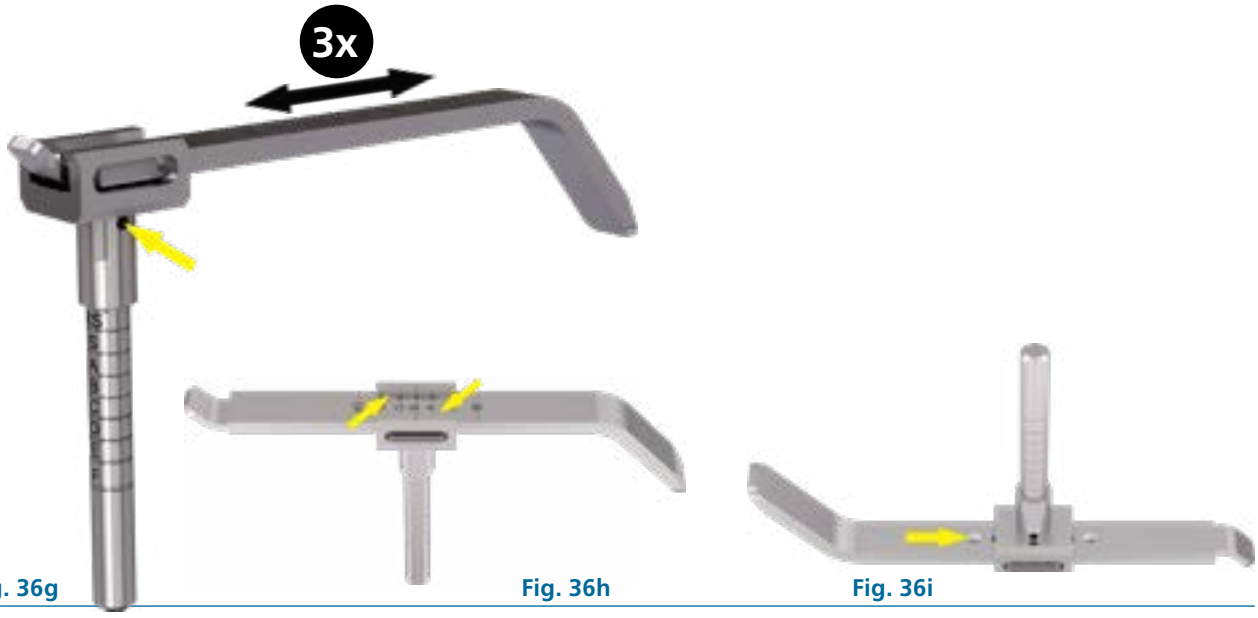


Fig. 36g **Fig. 36h** **Fig. 36i**

Function test:
The sliding parts must be able to move back and forth without jamming.
After maintenance of all the positions shown to require care, the sliding parts must be moved back and forth 3x.

5.4.6 balanSys Silicone Handle

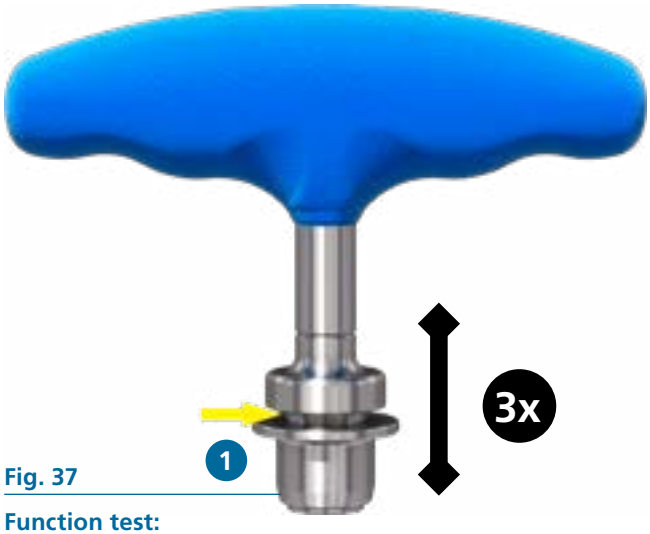


Fig. 37

Function test:
1. The coupling must be able to be compressed properly. After maintenance, compress 3x.
2. The intramedullary rod must engage neatly **(see also Fig. 2a and 2b)**.

5.4.7 balanSys Pin Pliers

Fig. 38a

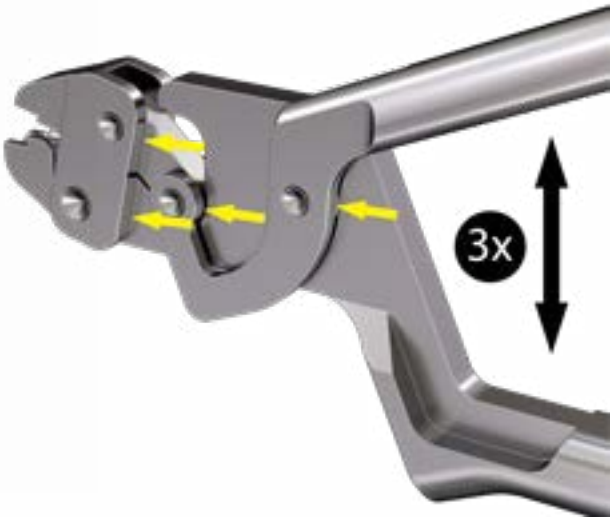


Fig. 38b

Function test:
The Pin Pliers must open and close properly. After maintenance on both sides, open and close the pliers 3x.

5.4.8 balanSys Holder Tibial Template

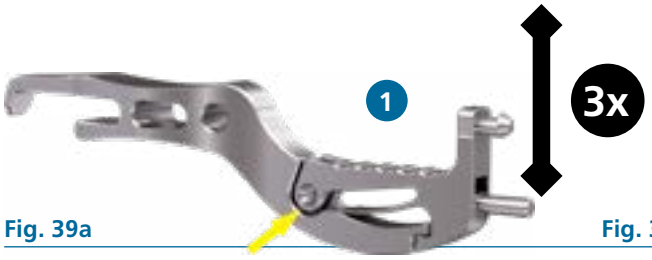


Fig. 39a

Fig. 39b

Function test:

1. The joint must be able to move without jamming. After maintenance, move the joint 3x by pressing the front section.
2. The balanSys Tibial Templates must be easy to plug in and remove.

5.4.9 balanSys Chisel Centering Guide

Fig. 40a

Fig. 40b

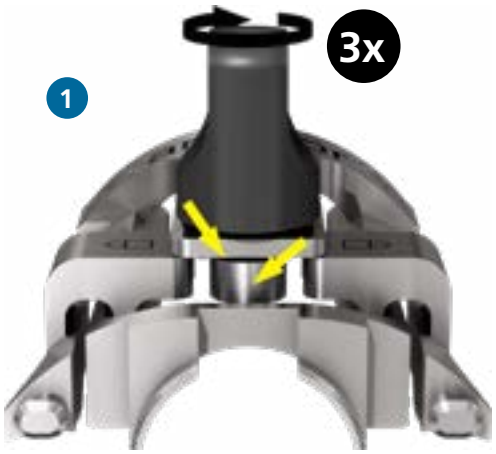


Fig. 40c

Function test:

1. The rotary knob must turn without jamming. After maintenance, turn the rotary knob 3x.

5.4.10 balanSys Angle Guide

Fig. 41a

Fig. 41b

Function test:

1. Clamp support on the height guide for the balanSys Distal Cutting Block must be able to move without tilting. After maintenance, move it back and forth 3x.
2. The angle adjustment drum must rotate without jamming and grating. After maintenance, the angle drum must be turned 3x.

Fig. 41c

Fig. 41d

Fig. 41e

Function test:

3. The balanSys Distal Cutting Block must be easy to install and remove with the clamp support on the height guide on the balanSys Angle Guide.

5.4.11 balanSys Femur Sizing / Rotation Guide with and without AP

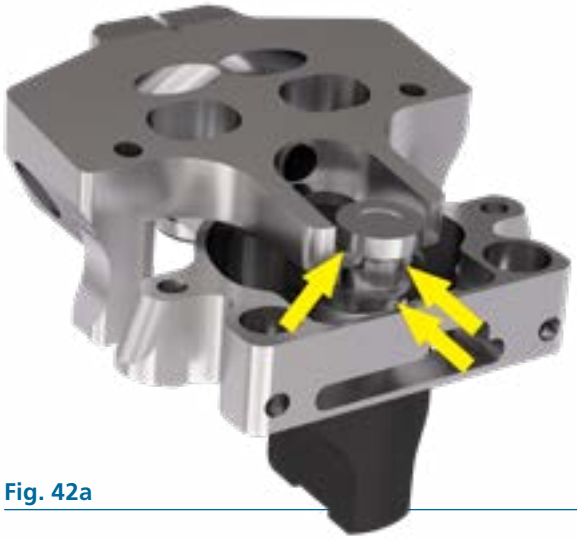


Fig. 42a

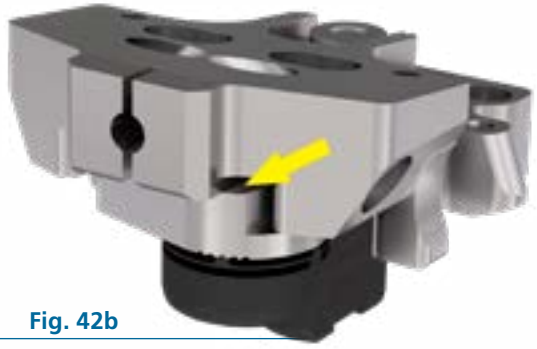


Fig. 42b

Fig. 42c

Fig. 42d

Fig. 42e

Function test:

1. The angle selection knob must turn without jamming. After maintenance, turn the angle selection knob 3x.

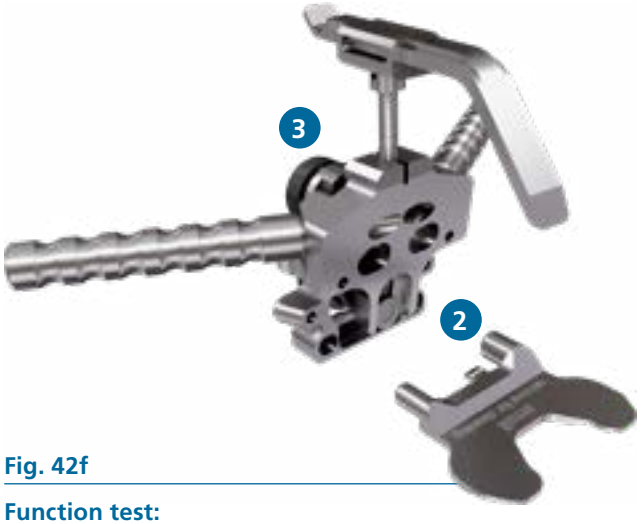


Fig. 42f

Function test:

2. The two balanSys Femur Rotation Bearings large and small must be easy to plug in, snap in and remove again.
3. balanSys Femur Stylus must be easy to insert and remove.

5.4.12 balanSys Positioner for Tibial Plateau

Fig. 43a

Function test:
The threaded rod must be able to turn without jamming, and the bolt guide on the right and left of the threaded rod must follow without jamming. After maintenance, screw the bolt guide in and remove it again 1x.

Fig. 43b

5.4.13 balanSys TRS Intramedullary Shackle

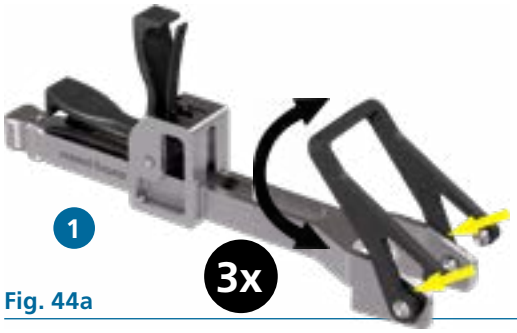


Fig. 44a

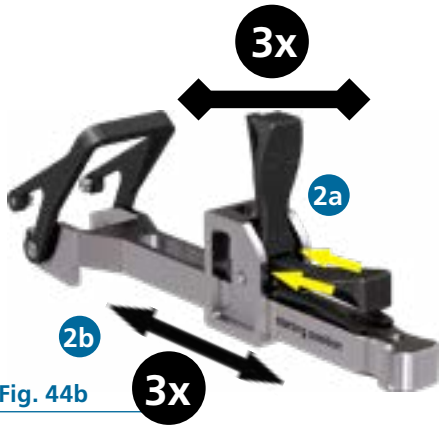


Fig. 44b

Function test:

1. The shackle must be able to move without jamming. After maintenance, move the shackle 3x.
2. The locking lever **(2a)** and the carriage **(2b)** must move without jamming. After maintenance, compress the locking lever 3x and move the carriage back and forth 3x.

Fig. 44c

Function test:

3. The bracket of the balanSys TRS Intramedullary Shackle must clamp effortlessly but firmly into the indentation in the height guide of the balanSys TRS Proximal.

5.4.14 balanSys Eminentia Shackle rotating

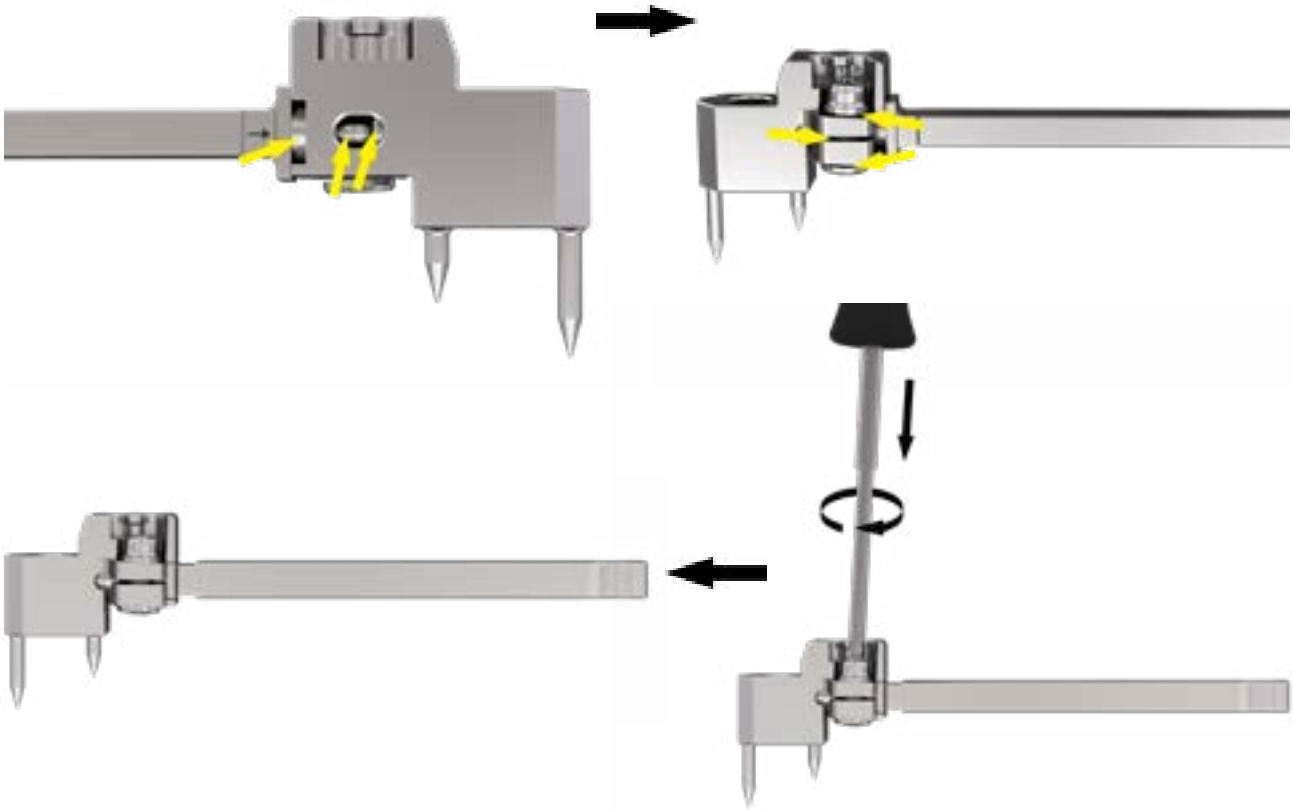


Fig. 45

Function test:
Apply care product to the screw at the yellow arrows and then screw the screw back in using the hexagonal screwdriver.

5.4.15 balanSys Ligament Tensor

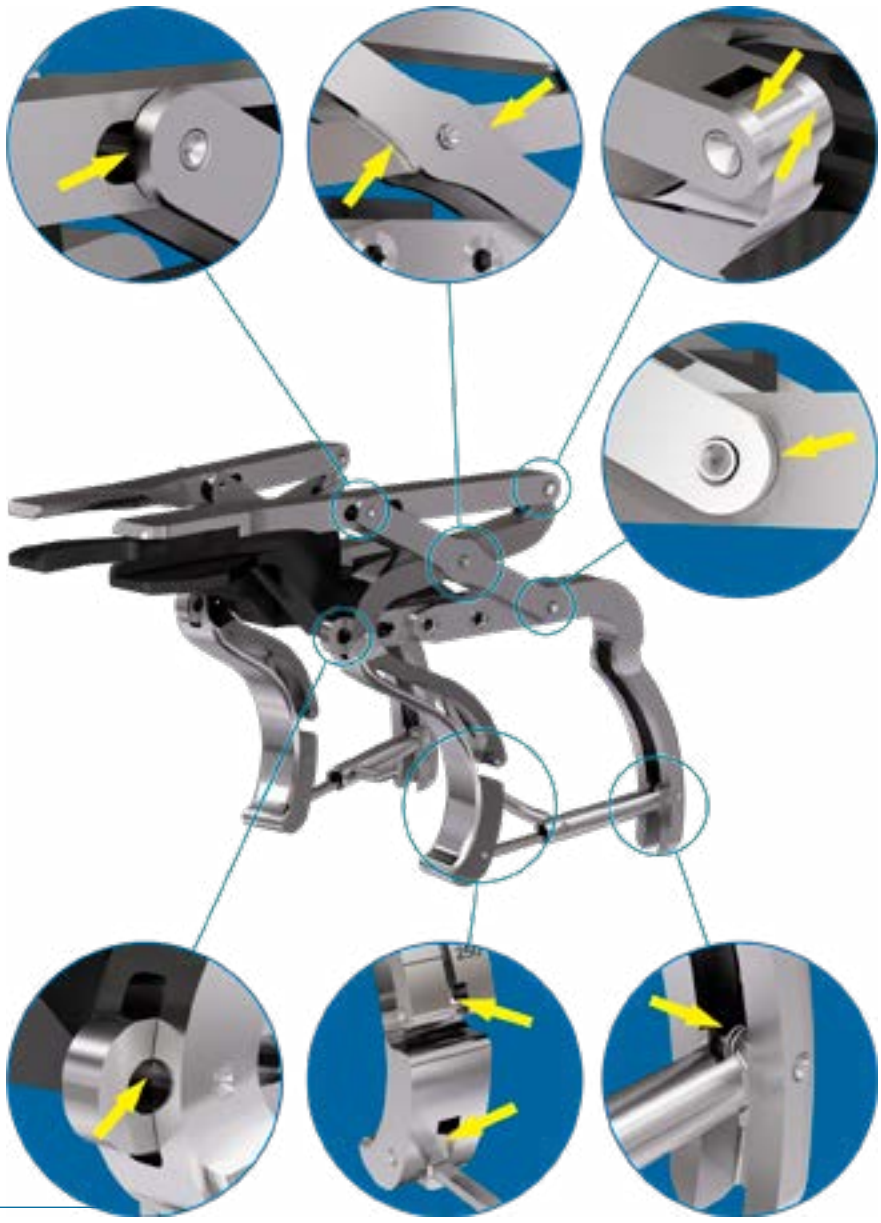


Fig. 46

Function test:
Never move the balanSys Ligament Tensor when it is dry, but always maintain it first. The two handles of the balanSys Ligament Tensor must be able to be pressed together without jamming. The claws must move apart **(see also Fig. 18)**.

5.4.16 balanSys Spacer 8G

Fig. 47

Function test:
The thread of the balanSys Spacer 8G must be able to be effortlessly screwed in and out using the balanSys Screwdriver **(see Fig. 20a and 20b)**.

5.4.17 balanSys Positioner Tibial Plateau RP

Fig. 48a

Fig. 48b

Function test:
The pull rod a) of the balanSys Positioner Tibial Plateau RP must be able to be screwed in and out effortlessly by rotation of the screw head (a), whereby the pull rod can also be extended and retracted effortlessly **(see Fig. 48d)**.

Fig. 48c

Fig. 48d

5.4.18 balanSys Drill Guide 4in1 8G

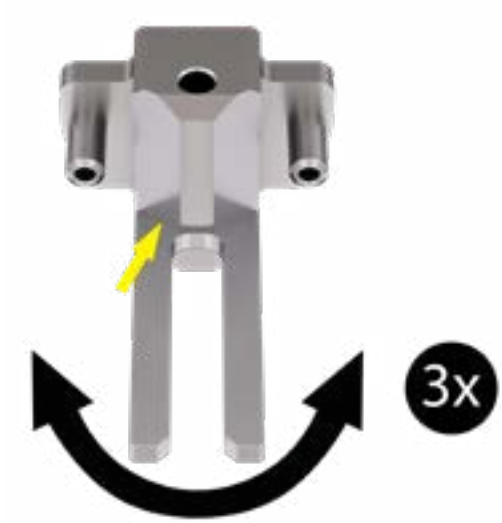


Fig. 49a

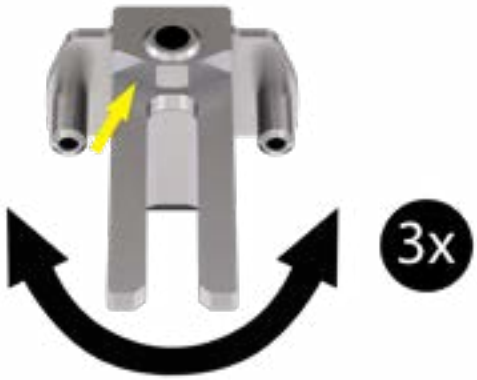


Fig. 49b

Function test:
After maintenance, move the ankle holder back and forth 3x.

After mechanical cleaning, maintenance/care and function control, the instruments must be properly placed back into the instrument trays for efficient sterilisation. To allow finding the correct position of the instrument in the instrument tray, the balanSys BICONDYLAR leggera instrument trays feature a systematic arrangement of the instruments. This is printed onto the tray by means of a screen printing process (silkscreen).

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

Defect	Cause	Test	Measure
Bur formation at the drill guide of the test femur 	• Improper handling • Canting of the drill bit • Drill 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	• Continue use
		Material protrusion (bur) on tread	Return to Mathys Ltd Bettlach or disposal, depending on contractual relationship

5.5 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.

5.6 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 (Euro-Selectomat, MMM GmbH) and validated through microbiological examinations to achieve a SAL (sterility assurance level) of 10^{-6}.

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	≥ 3042
Fractionated pre-vacuum [4]	134/273	5	30	≥ 3042
Fractionated pre-vacuum [5, 6]	134/273	3	30	≥ 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] Maximum pressure during the sterilisation phase at 137°C (279°F) must be ≥ 3318.5 mbar according to DIN ISO/TS 17665-2.

5.7 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 authorised 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 (ISO 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.

6. 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 4.6 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.

7. Customer service information

Instructions for use and brochures about surgical procedures and/or methods can be obtained from Mathys as further sources of information to illustrate certain complex instruments.

Mathys Ltd Bettlach
Robert Mathys Strasse 5
P. O. Box
2544 Bettlach
Switzerland

Phone +41 32 644 1 644
Fax +41 32 644 1 161
info@mathysmedical.com

8. Annex – Quick starter

8.1 Manual pre-cleaning

8.1.1 Cleaning category 1 No manual pre-cleaning necessary. Instruments may be placed directly into the WD.
8.1.2 Cleaning category 2 Instruments must be manually pre-cleaned with nylon brushes, plastic syringes and water jet guns before they may be placed into the WD.
8.1.3 Cleaning category 3 Instruments must be manually pre-cleaned with nylon brushes, plastic syringes and water jet guns and subsequently be treated for 5 minutes at 35–47 kHz in the ultrasonic bath with 0.5 % neodisher MediClean forte before they may be placed into the WD.

8.2 Mechanical 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

8.3 Steam sterilisation with fractionated pre-vacuum

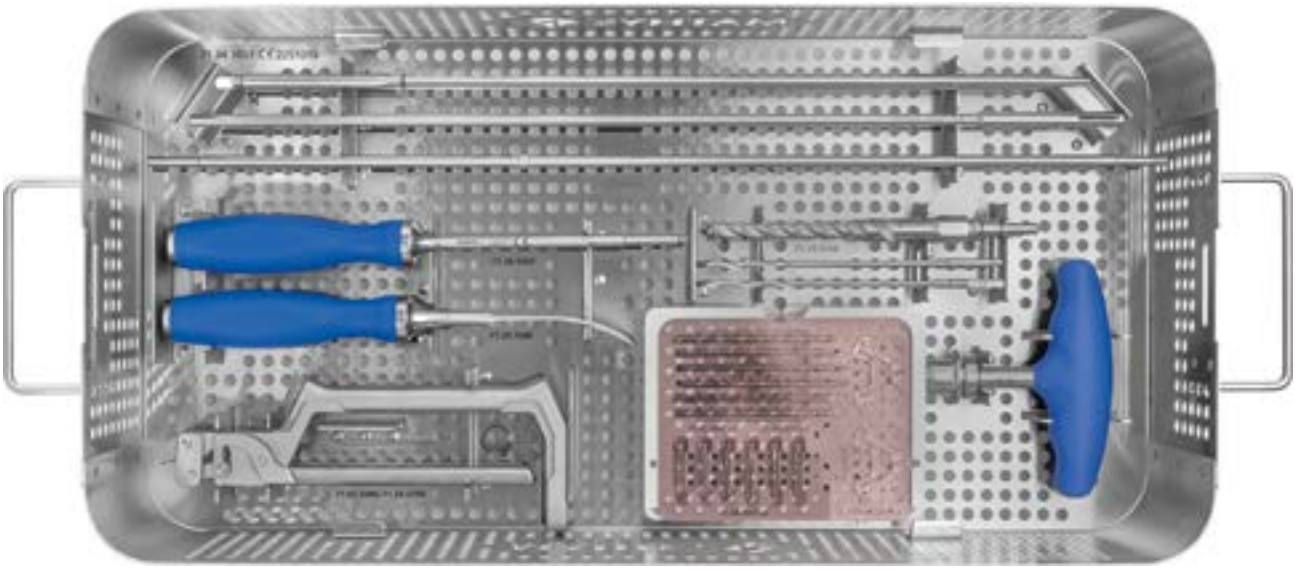
Type of cycle	Minimum temperature in °C/°F	Minimum sterilisation time in minutes	Minimum drying time in minutes	Minimum pressure in mbar
Fractionated pre-vacuum [1]	134/273	18	30	≥ 3042
Fractionated pre-vacuum [2]	134/273	3	30	≥ 3042

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

9. Overview of the balanSys BICONDYLAR leggera instruments

9.1 leggera Basic Set

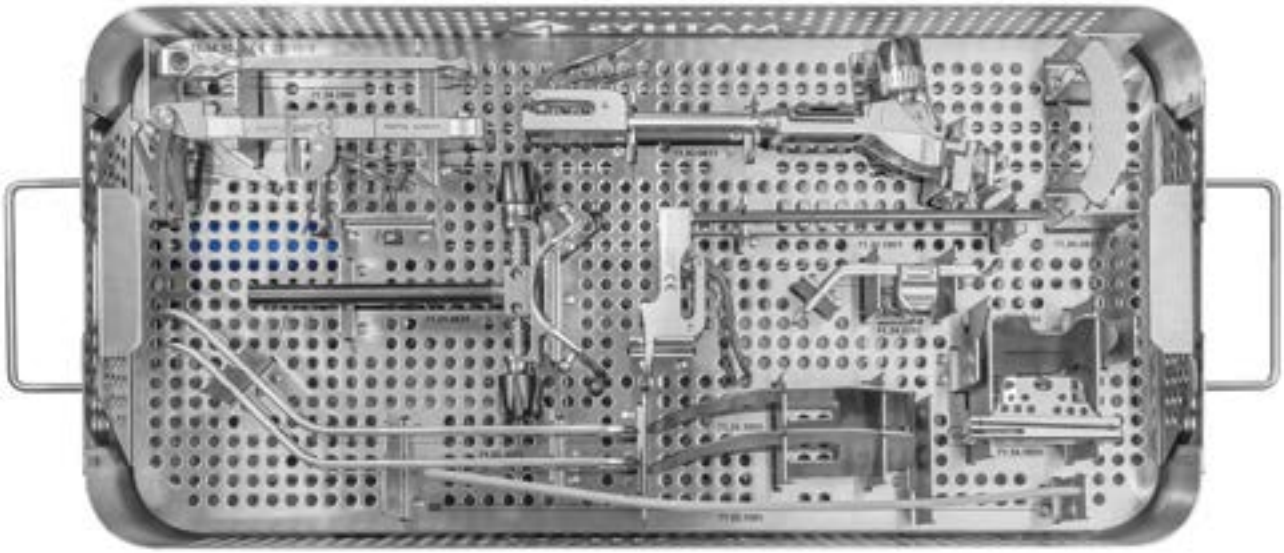
9.1.1 Tray



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	Silicone Handle	10.935-RAL5010	2	**Fig. 2**	–	**Fig. 37**
1	balanSys Intramedullary Rod	71.34.0793	1		–	–
1	balanSys Alignment Rod Long	71.34.1009	1	–	–	–
1	balanSys Alignment Rod Short	71.34.1008	2	–	–	–
1	balanSys Pin Pliers	71.34.0798	2	–	**Fig. 13**	**Fig. 38**
2	AO Drill bit 3.2	315.310	2	–	–	–
1	balanSys drill bit 8.5/11 mm	71.34.0100	2	–	–	–
1	balanSys Osteophyte Chisel, curved	71.34.1048	2	–	–	–
1	balanSys Screwdriver	71.34.1049	2	–	–	–
Caddy						
4–6	balanSys pin 3.2/80	71.02.3054	1	–	–	–
4–6	Drill Pin 3.2/89/2.25	71.34.0647 [1]	1	–	–	–
4–6	balanSys Pin with Head 3.2/30	71.34.1047	1	–	–	–
1	Quick Coupling Square 2.25	71.34.0787 [1]	1	–	–	–
2	balanSys Adapter Trial Inlay	71.34.1055	1	**Fig. 6**	–	–

[1] Optional instruments

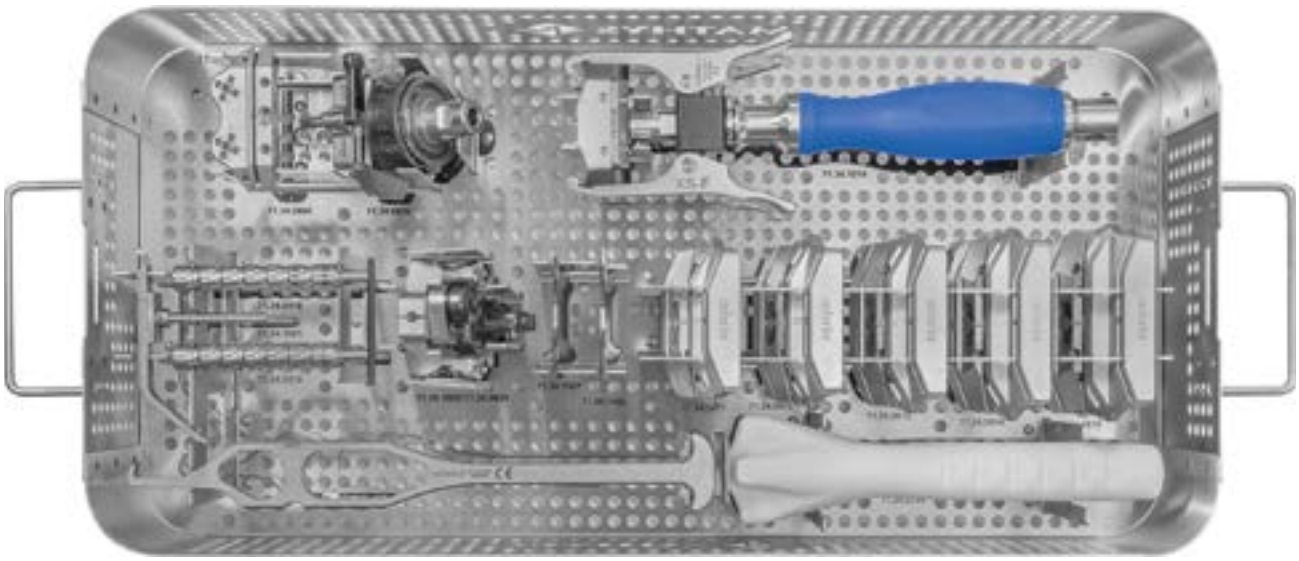
9.1.2 Tray insert



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys TRS Intramedullary Shakle	71.34.1000	2	Fig. 7 & 8	Fig. 11	Fig. 44
1	balanSys TRS Eminentia Shakle	71.34.0999 [1]	2		–	–
	or					
1	balanSys TRS Eminentia Shakle rotating	71.34.1077 [1]	2		Fig. 12	
1	balanSys TRS Ankle Holder	71.34.0835	3	Fig. 1	Fig. 27	Fig. 34
1	balanSys TRS Proximal	71.34.0833	3		Fig. 26	Fig. 32
1	balanSys TRS Distal	71.34.1001	2		–	–
1	balanSys TRS Cutting Guide	71.34.0834	2		Fig. 21	–
2	balanSys bone retractor	71.02.3005	1	–	–	–
1	balanSys Tibial Stylus	71.34.0792	2		Fig. 15	Fig. 36a–36c
2	balanSys reference plate	71.34.1050	1	–	–	–
1	balanSys Trs. rubber band 3 x 25 x 300	71.02.1005	1	–	–	–
1	balanSys Paddle Corrective Cutting Guide	71.34.1054 [1]	1	–	–	–
1	balanSys Corrective Cutting Guide	71.34.0836 [1]	2	–	Fig. 24	–

[1] Optional instruments

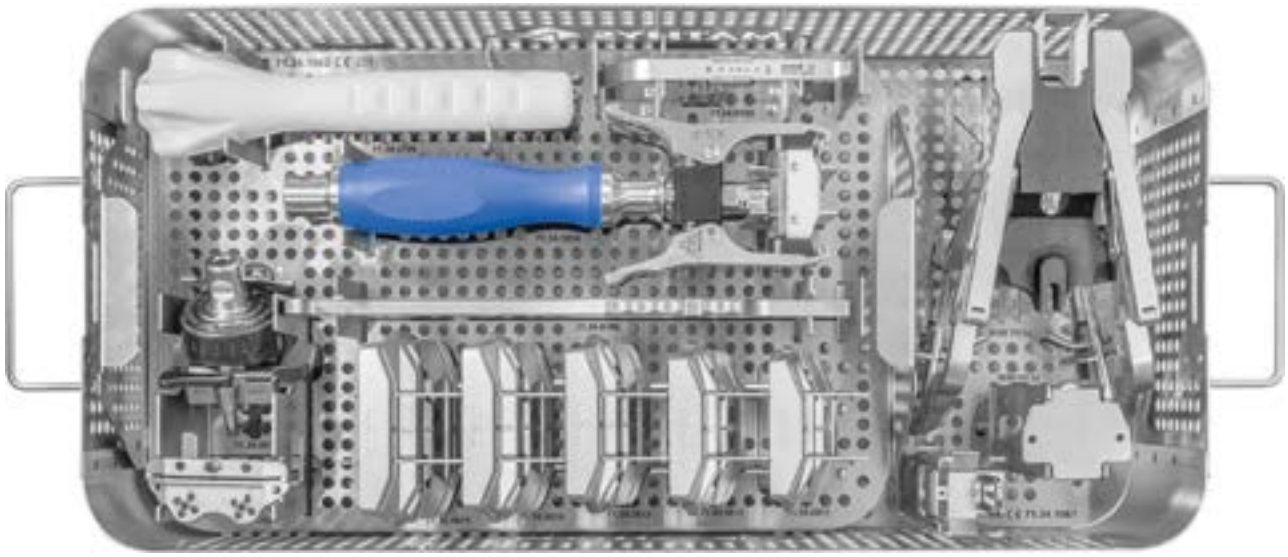
9.2 leggera Femur Set Bone Oriented



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys Distal Cutting Guide	71.34.0804	2	–	**Fig. 22**	–
1	balanSys Angle Guide	71.34.0830	3	–	**Fig. 28**	**Fig. 41**
1	balanSys Femur Holder	71.34.1014	3	–	**Fig. 31**	**Fig. 35**
1	balanSys Femur Stylus	71.34.1005	2	**Fig. 4**	**Fig. 14**	**Fig. 36d–36f**
2	balanSys Handle Femoral Siz./Rot. Guide	71.34.0118	2		–	–
1	balanSys Femur Sizing/Rotation Guide	71.34.0839	3		**Fig. 29**	**Fig. 42**
or						
1	balanSys Femur Sizing/Rotation Guide AP	71.34.1003 [1]	3		**Fig. 30**	
1	balanSys Femur Rotation Bearing Large	71.34.1006	2		–	–
and						
1	balanSys Femur Rotation Bearing Small **or**	71.34.1007	2			
1	balanSys Femur Rot. Bearing Short Large	71.34.1078 [1]	1		–	–
and						
1	balanSys Femur Rot. Bearing Short Small	71.34.1079 [1]	1			
1	balanSys 4in1 Cutting Guide A	71.34.0811	2	–	**Fig. 23**	–
1	balanSys 4in1 Cutting Guide B	71.34.0812	2	–		–
1	balanSys 4in1 Cutting Guide C	71.34.0813	2	–		–
1	balanSys 4in1 Cutting Guide D	71.34.0814	2	–		–
1	balanSys 4in1 Cutting Guide E	71.34.0815	2	–		–
1	balanSys Femur Extractor	71.34.0788	1	–	–	–
1	balanSys Femoral Impactor	71.34.0799	1	–	–	–

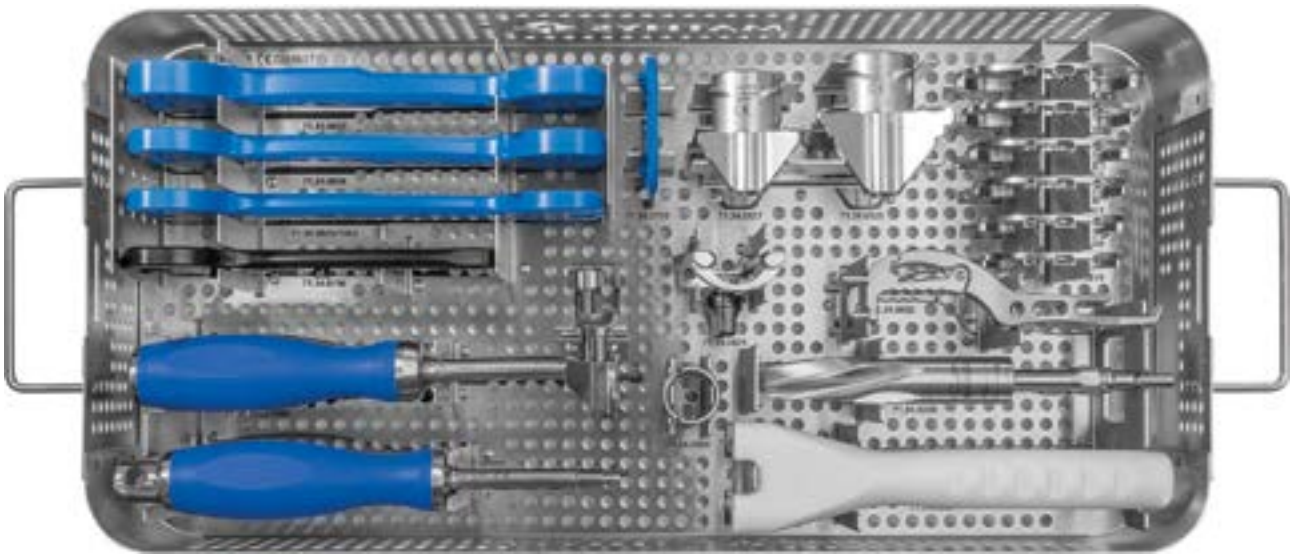
[1] Optional instruments

9.3 leggera Femur Set Combination



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys Femur Extractor	71.34.0788	1	–	–	–
1	balanSys Femoral Impactor	71.34.0799	1	–	–	–
1	balanSys Femur Holder	71.34.1014	3	–	**Fig. 31**	**Fig. 35**
1	balanSys Angle Guide	71.34.0830	3	–	**Fig. 28**	**Fig. 41**
1	balanSys Distal Cutting Guide	71.34.0804	2	–	**Fig. 22**	–
1	balanSys 4in1 Cutting Guide A	71.34.0811	2	–	**Fig. 23**	–
1	balanSys 4in1 Cutting Guide B	71.34.0812	2	–		–
1	balanSys 4in1 Cutting Guide C	71.34.0813	2	–		–
1	balanSys 4in1 Cutting Guide D	71.34.0814	2	–		–
1	balanSys 4in1 Cutting Guide E	71.34.0815	2	–		–
1	balanSys Spacer 8G	71.34.0168	2	**Fig. 5**	**Fig. 20**	**Fig. 47**
1	balanSys Drill Guide 4in1 CuttBlock 8G	71.34.0606	2		**Fig. 19**	**Fig. 49**
1	balanSys ligament tensor	71.02.3018	3		**Fig. 18**	**Fig. 46**
1	balanSys Femoral feeler 8G	71.34.0143	2		**Fig. 16**	**Fig. 36g–36i**

9.4 leggera Tibia Set

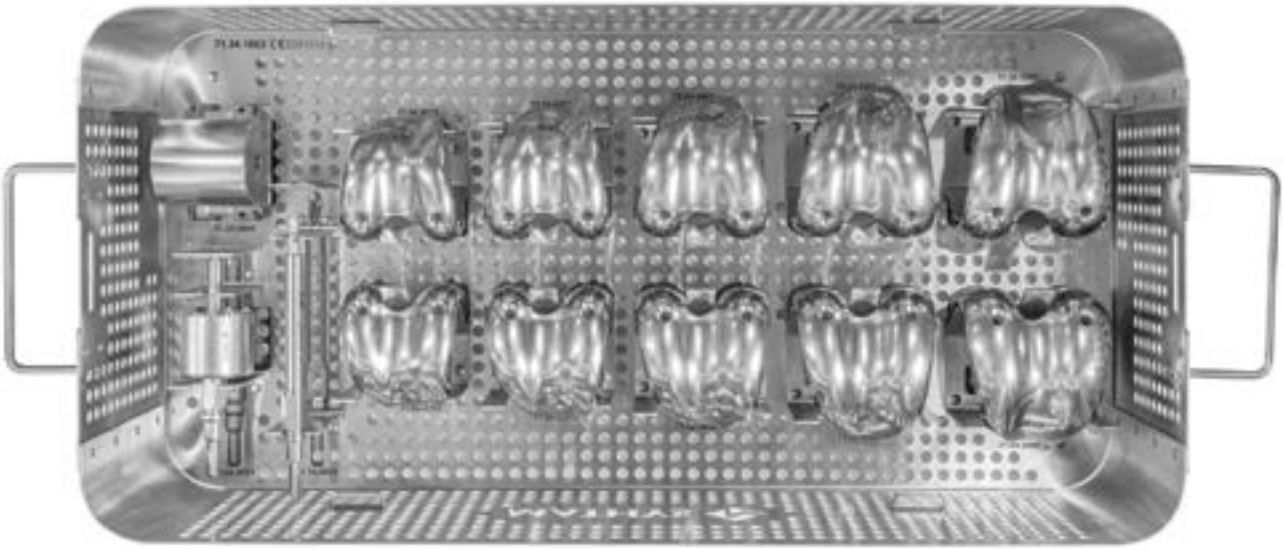


No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys Spacer Block Tibia 13/15.5	71.34.0807	2	Fig. 3	–	–
1	balanSys Spacer Block Tibia 10.5/11.5	71.34.0806	2		–	–
1	balanSys Spacer Block Tibia 8/9	71.34.0805	2		–	–
	or					
1	balanSys Spacer Block Tibia 8/10.5	71.34.1053 [1]	2		–	–
1	balanSys Spacer Block Femur	71.34.0796	2		–	–
1	balanSys Spacer Shift Plate +5	71.34.0795	2		–	–
1	balanSys Tibial Impactor	71.34.0800	1	–	–	–
1	balanSys Reamer	71.34.0200	2	–	–	–
1	balanSys Holder Tibial Template	71.34.0802	2	–	**Fig. 17**	**Fig. 39**
1	balanSys Tibial Template 64	71.34.0819	2	–	–	–
1	balanSys Tibial Template 67	71.34.0820	2	–	–	–
1	balanSys Tibial Template 70	71.34.0821	2	–	–	–
1	balanSys Tibial Template 75	71.34.0822	2	–	–	–
1	balanSys Tibial Template 80	71.34.0823	2	–	–	–
1	balanSys Tibial Template 85	71.34.0824	2	–	–	–
1	balanSys Fin Chisel 59–70	71.34.0827	2	–	–	–
1	balanSys Fin Chisel 59–85	71.34.0828	2	–	–	–
1	balanSys Chisel Centering Guide	71.34.0825	2	–	**Fig. 9**	**Fig. 40**
1	balanSys Attachment Milling Guide	71.34.0826	2	–	–	–
1	balanSys Chisel Handle	71.34.0829	2	–	–	–
1	balanSys Positioner for Tibial Plateau	71.34.1052	2	–	**Fig. 10**	**Fig. 43**
	or					
1	balanSys Positioner Tibial Plateau RP	71.34.0886	2	–	**Fig. 25**	**Fig. 48**

[1] Optional instruments

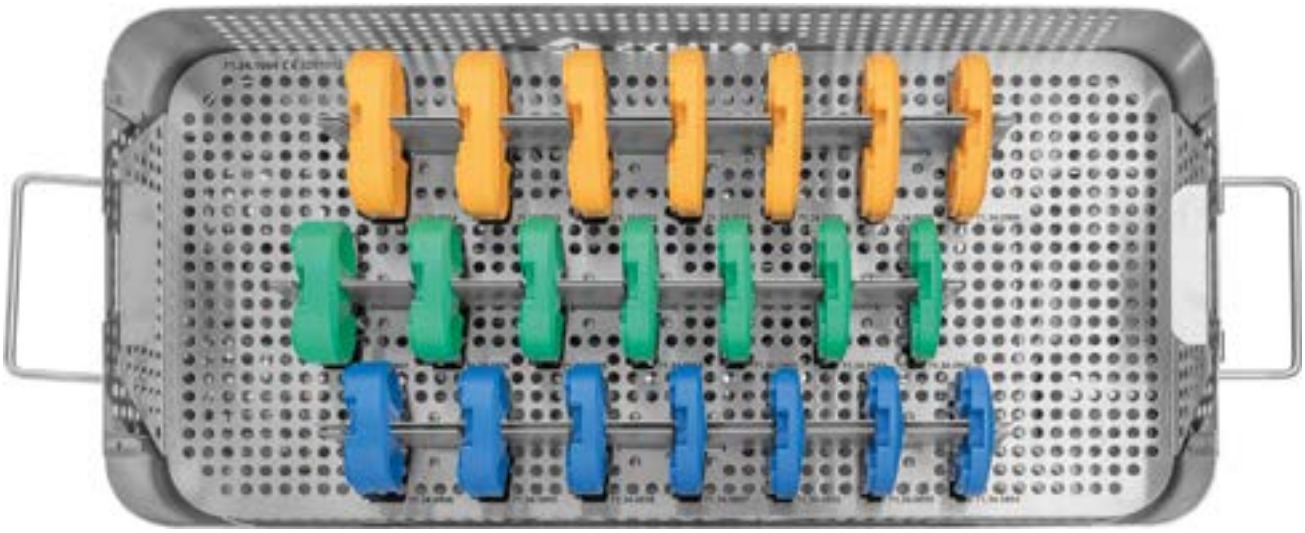
9.5 leggera Trial Set CR / UC

9.5.1 Tray



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys Trochlea Bushing	71.34.0840	2	–	–	–
1	balanSys trochlea reamer	71.02.3023	2	–	–	–
1	balanSys Drill Bit with stop 6	71.34.0023	2	–	–	–
1	balanSys trial femur A left	71.02.4001	2	–	–	–
1	balanSys trial femur A right	71.02.4002	2	–	–	–
1	balanSys trial femur B left	71.02.4301	2	–	–	–
1	balanSys trial femur B right	71.02.4302	2	–	–	–
1	balanSys trial femur C left	71.02.4601	2	–	–	–
1	balanSys trial femur C right	71.02.4602	2	–	–	–
1	balanSys trial femur D left	71.02.4901	2	–	–	–
1	balanSys trial femur D right	71.02.4902	2	–	–	–
1	balanSys trial femur E left	71.02.5201	2	–	–	–
1	balanSys trial femur E right	71.02.5202	2	–	–	–

9.5.2 Tray insert

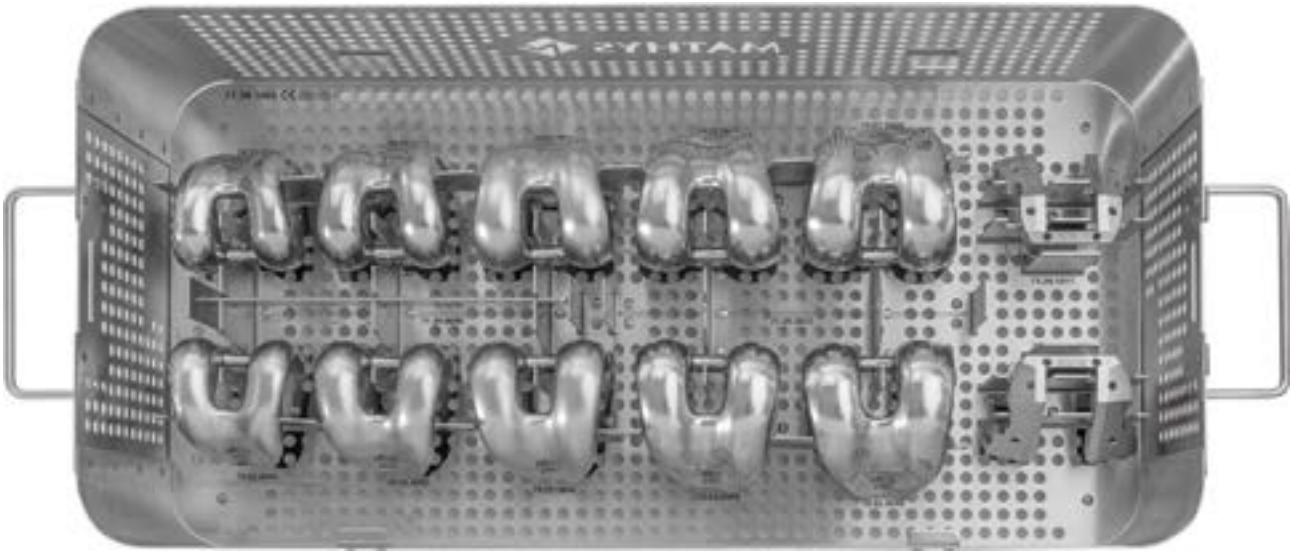


No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys CR/UC Trial Inlay 64–67/8	71.34.0894	2		–	–
1	balanSys CR/UC Trial Inlay 64–67/9	71.34.0895	2		–	–
1	balanSys CR/UC Trial Inlay 64–67/10.5	71.34.0896	2		–	–
1	balanSys CR/UC Trial Inlay 64–67/11.5	71.34.0897	2		–	–
1	balanSys CR/UC Trial Inlay 64–67/13	71.34.0898	2		–	–
1	balanSys CR/UC Trial Inlay 64–67/15.5	71.34.0899	2		–	–
1	balanSys CR/UC Trial Inlay 64–67/18	71.34.0900 [1]	2		–	–
1	balanSys CR/UC Trial Inlay 70–75/8	71.34.0901	2		–	–
1	balanSys CR/UC Trial Inlay 70–75/9	71.34.0902	2		–	–
1	balanSys CR/UC Trial Inlay 70–75/10.5	71.34.0903	2		–	–
1	balanSys CR/UC Trial Inlay 70–75/11.5	71.34.0904	2	**Fig. 6**	–	–
1	balanSys CR/UC Trial Inlay 70–75/13	71.34.0905	2		–	–
1	balanSys CR/UC Trial Inlay 70–75/15.5	71.34.0906	2		–	–
1	balanSys CR/UC Trial Inlay 70–75/18	71.34.0907 [1]	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/8	71.34.0908	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/9	71.34.0909	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/10.5	71.34.0910	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/11.5	71.34.0911	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/13	71.34.0912	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/15.5	71.34.0913	2		–	–
1	balanSys CR/UC Trial Inlay 80–85/18	71.34.0914 [1]	2		–	–

[1] Optional instruments

9.6 leggera Trial Set PS

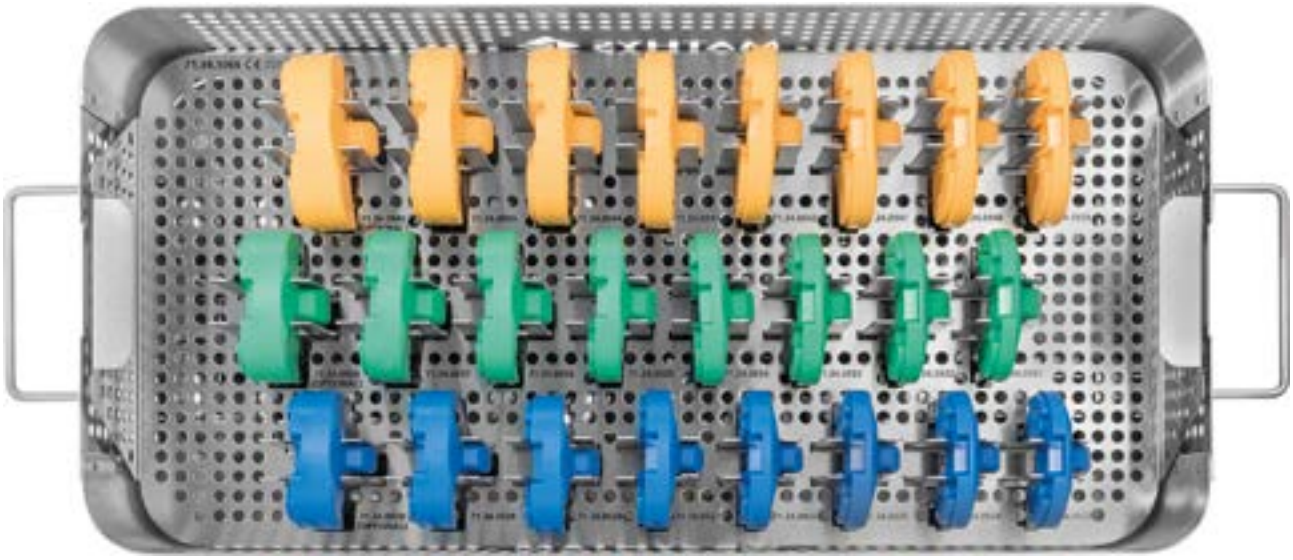
9.6.1 Tray



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys PS trial femur A right	79.02.0040	2	–	–	–
1	balanSys PS trial femur A left	79.02.0041	2	–	–	–
1	balanSys PS trial femur B right	79.02.0042	2	–	–	–
1	balanSys PS trial femur B left	79.02.0043	2	–	–	–
1	balanSys PS trial femur C right	79.02.0044	2	–	–	–
1	balanSys PS trial femur C left	79.02.0045	2	–	–	–
1	balanSys PS trial femur D right	79.02.0046	2	–	–	–
1	balanSys PS trial femur D left	79.02.0047	2	–	–	–
1	balanSys PS trial femur E right	79.02.0048	2	–	–	–
1	balanSys PS trial femur E left	79.02.0049	2	–	–	–
1	balanSys Femur Box Cutting Guide A/B/C	71.34.1011	2	–	–	–
1	balanSys Femur Box Cutting Guide D/E	71.34.1012	2	–	–	–
1	balanSys Chisel 25 mm A–F	71.34.0691	1	–	–	–
1	balanSys Chisel 22 mm XS/S	71.34.0690 [1]	1	–	–	–

[1] Optional instruments

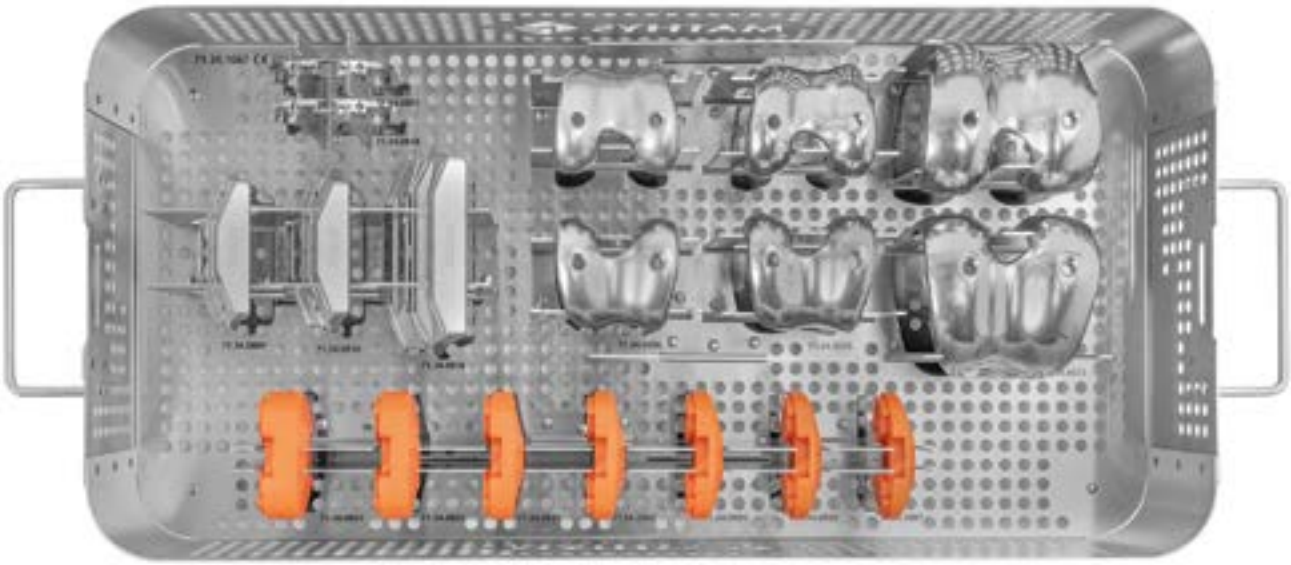
9.6.2 Tray insert



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys PS Trial Inlay 64–67/8	71.34.0923	2	Fig. 6	–	–
1	balanSys PS Trial Inlay 64–67/9	71.34.0924	2		–	–
1	balanSys PS Trial Inlay 64–67/10.5	71.34.0925	2		–	–
1	balanSys PS Trial Inlay 64–67/11.5	71.34.0926	2		–	–
1	balanSys PS Trial Inlay 64–67/13	71.34.0927	2		–	–
1	balanSys PS Trial Inlay 64–67/15.5	71.34.0928	2		–	–
1	balanSys PS Trial Inlay 64–67/18	71.34.0929	2		–	–
1	balanSys PS Trial Inlay 64–67/20.5	71.34.0930 [1]	2		–	–
1	balanSys PS Trial Inlay 70–75/8	71.34.0931	2		–	–
1	balanSys PS Trial Inlay 70–75/9	71.34.0932	2		–	–
1	balanSys PS Trial Inlay 70–75/10.5	71.34.0933	2		–	–
1	balanSys PS Trial Inlay 70–75/11.5	71.34.0934	2		–	–
1	balanSys PS Trial Inlay 70–75/13	71.34.0935	2		–	–
1	balanSys PS Trial Inlay 70–75/15.5	71.34.0936	2		–	–
1	balanSys PS Trial Inlay 70–75/18	71.34.0937	2		–	–
1	balanSys PS Trial Inlay 70–75/20.5	71.34.0938 [1]	2		–	–
1	balanSys PS Trial Inlay 80–85/8	71.34.0939	2		–	–
1	balanSys PS Trial Inlay 80–85/9	71.34.0940	2		–	–
1	balanSys PS Trial Inlay 80–85/10.5	71.34.0941	2		–	–
1	balanSys PS Trial Inlay 80–85/11.5	71.34.0942	2		–	–
1	balanSys PS Trial Inlay 80–85/13	71.34.0943	2		–	–
1	balanSys PS Trial Inlay 80–85/15.5	71.34.0944	2		–	–
1	balanSys PS Trial Inlay 80–85/18	71.34.0945	2		–	–
1	balanSys PS Trial Inlay 80–85/20.5	71.34.0946 [1]	2		–	–

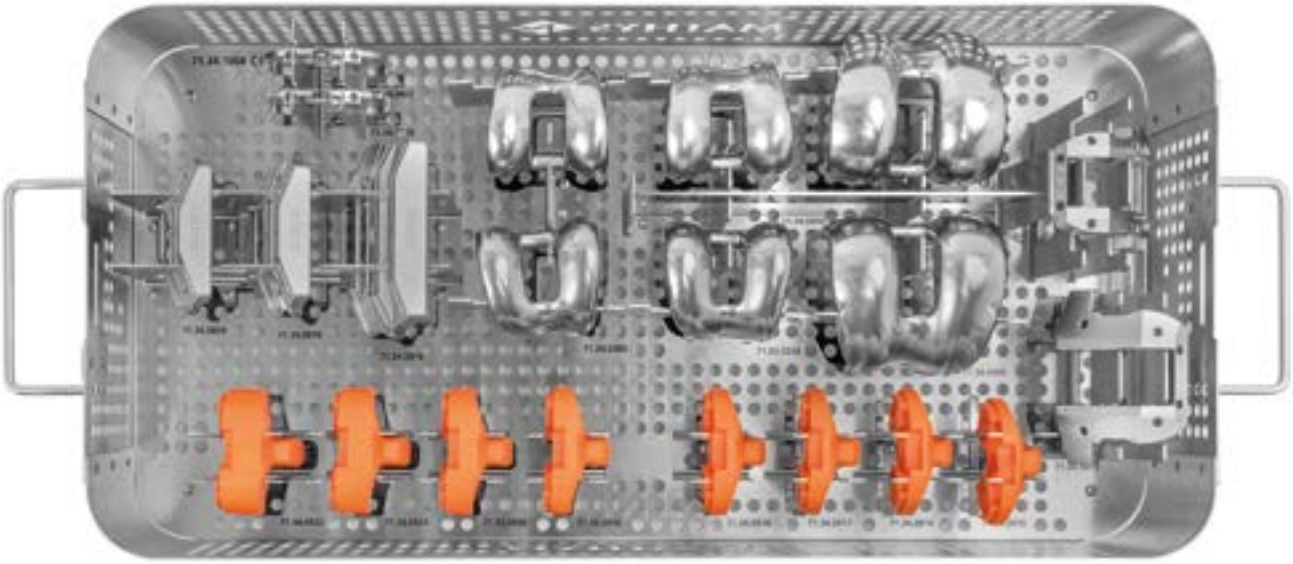
[1] Optional instruments

9.7 leggera Trial Set CR / UC Add. Sizes



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys 4in1 Cutting Guide XS	71.34.0809	2	–	Fig. 23	–
1	balanSys 4in1 Cutting Guide S	71.34.0810	2	–		–
1	balanSys 4in1 Cutting Guide F	71.34.0816	2	–	–	–
1	balanSys Tibial Template 59	71.34.0818	2	–	–	–
1	balanSys Tibial Template 62	71.34.0801	2	–	–	–
1	balanSys trial femur XS left	71.34.0355	2	–	–	–
1	balanSys trial femur XS right	71.34.0356	2	–	–	–
1	balanSys trial femur S left	71.34.0504	2	–	–	–
1	balanSys trial femur S right	71.34.0505	2	–	–	–
1	balanSys trial femur F left	71.34.0371	2	–	–	–
1	balanSys trial femur F right	71.34.0372	2	–	–	–
1	balanSys CR/UC Trial Inlay 59–62/8	71.34.0887	2	Fig. 6	–	–
1	balanSys CR/UC Trial Inlay 59–62/9	71.34.0888	2		–	–
1	balanSys CR/UC Trial Inlay 59–62/10.5	71.34.0889	2		–	–
1	balanSys CR/UC Trial Inlay 59–62/11.5	71.34.0890	2		–	–
1	balanSys CR/UC Trial Inlay 59–62/13	71.34.0891	2		–	–
1	balanSys CR/UC Trial Inlay 59–62/15.5	71.34.0892	2		–	–
1	balanSys CR/UC Trial Inlay 59–62/18	71.34.0893	2		–	–

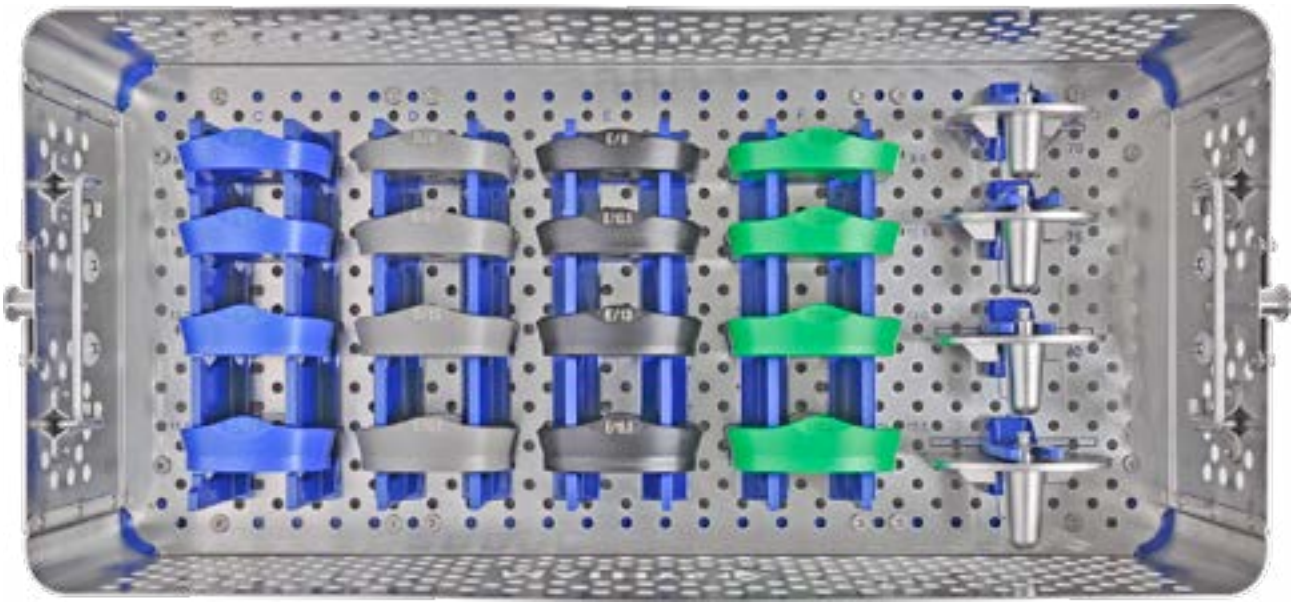
9.8 leggera Trial Set PS Add. Sizes



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys Femur Box Cutting Guide XS/S	71.34.1010	2	–	–	–
1	balanSys Femur Box Cutting Guide F	71.34.1013	2	–	–	–
1	balanSys Chisel 22 mm XS/S	71.34.0690	1	–	–	–
1	balanSys PS Trial femur XS left	71.34.0382	2	–	–	–
1	balanSys PS Trial femur XS right	71.34.0383	2	–	–	–
1	balanSys PS Trial femur S left	71.34.0247	2	–	–	–
1	balanSys PS Trial femur S right	71.34.0248	2	–	–	–
1	balanSys PS Trial femur F left	71.34.0399	2	–	–	–
1	balanSys PS Trial femur F right	71.34.0400	2	–	–	–
1	balanSys PS Trial Inlay 59–62/8	71.34.0915	2	Fig. 6	–	–
1	balanSys PS Trial Inlay 59–62/9	71.34.0916	2		–	–
1	balanSys PS Trial Inlay 59–62/10.5	71.34.0917	2		–	–
1	balanSys PS Trial Inlay 59–62/11.5	71.34.0918	2		–	–
1	balanSys PS Trial Inlay 59–62/13	71.34.0919	2		–	–
1	balanSys PS Trial Inlay 59–62/15.5	71.34.0920	2		–	–
1	balanSys PS Trial Inlay 59–62/18	71.34.0921	2		–	–
1	balanSys PS Trial Inlay 59–62/20.5	71.34.0922	2		–	–
1	balanSys 4in1 Cutting Guide XS	71.34.0809	2	–	Fig. 23	–
1	balanSys 4in1 Cutting Guide S	71.34.0810	2	–		–
1	balanSys 4in1 Cutting Guide F	71.34.0816	2	–		–
1	balanSys Tibial Template 59	71.34.0818	2	–	–	–
1	balanSys Tibial Template 62	71.34.0801	2	–	–	–

9.9 balanSys Trial Set RP [1]

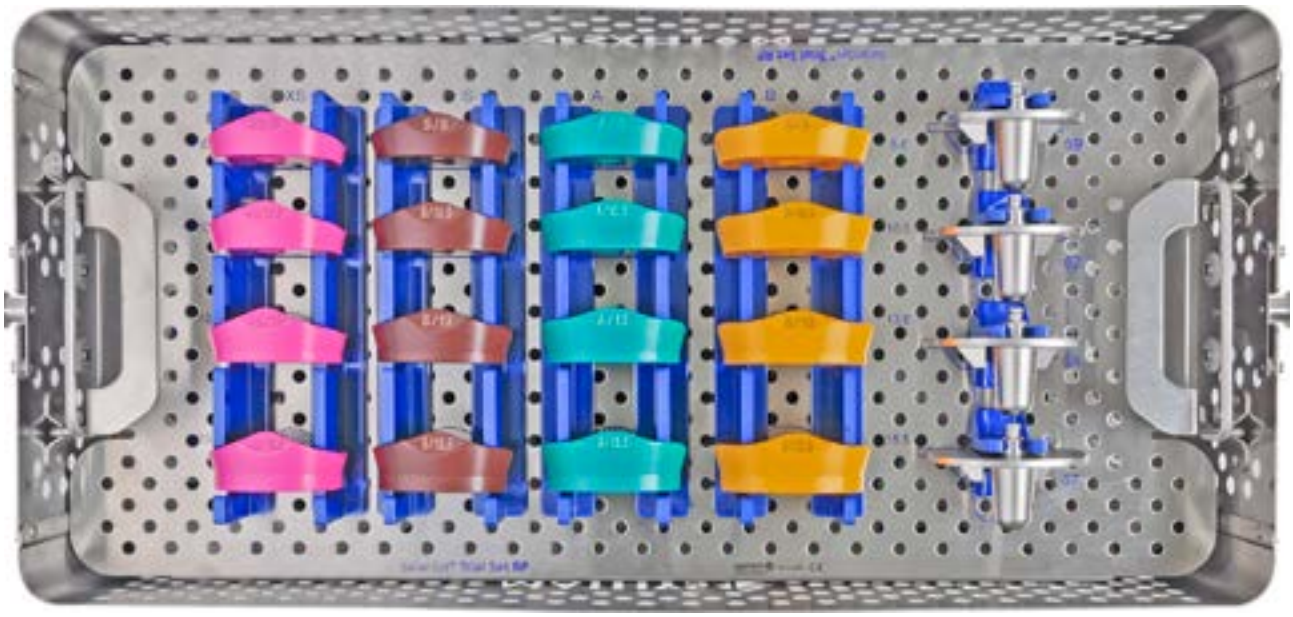
9.9.1 Tray [1]



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Mainte-nance / care
1	balanSys RP PE Trial Inlay C/8	71.34.0574	2	–	–	–
1	balanSys RP PE Trial Inlay C/10.5	71.34.0575	2	–	–	–
1	balanSys RP PE Trial Inlay C/13	71.34.0576	2	–	–	–
1	balanSys RP PE Trial Inlay C/15.5	71.34.0577	2	–	–	–
1	balanSys RP PE Trial Inlay D/8	71.34.0580	2	–	–	–
1	balanSys RP PE Trial Inlay D/10.5	71.34.0581	2	–	–	–
1	balanSys RP PE Trial Inlay D/13	71.34.0582	2	–	–	–
1	balanSys RP PE Trial Inlay D/15.5	71.34.0583	2	–	–	–
1	balanSys RP PE Trial Inlay E/8	71.34.0586	2	–	–	–
1	balanSys RP PE Trial Inlay E/10.5	71.34.0587	2	–	–	–
1	balanSys RP PE Trial Inlay E/13	71.34.0588	2	–	–	–
1	balanSys RP PE Trial Inlay E/15.5	71.34.0589	2	–	–	–
1	balanSys RP PE Trial Inlay F/8	71.34.0429	2	–	–	–
1	balanSys RP PE Trial Inlay F/10.5	71.34.0430	2	–	–	–
1	balanSys RP PE Trial Inlay F/13	71.34.0431	2	–	–	–
1	balanSys RP PE Trial Inlay F/15.5	71.34.0432	2	–	–	–
1	balanSys RP Trial Tibial Plateau 70	71.34.0297	1	–	–	–
1	balanSys RP Trial Tibial Plateau 75	71.34.0298	1	–	–	–
1	balanSys RP Trial Tibial Plateau 80	71.34.0299	1	–	–	–
1	balanSys RP Trial Tibial Plateau 85	71.34.0300	1	–	–	–

[1] Instrument tray is optional

9.9.2 Tray insert [1]



No.	Item	Item no.	Clng. catg.	Assembly / disassembly	Cleaning	Maintenance / care
1	balanSys RP PE Trial Inlay XS/8	71.34.0413	1	1	–	–
1	balanSys RP PE Trial Inlay XS/10.5	71.34.0414	1	1	–	–
1	balanSys RP PE Trial Inlay XS/13	71.34.0415	1	1	–	–
1	balanSys RP PE Trial Inlay XS/15.5	71.34.0416	1	1	–	–
1	balanSys RP PE Trial Inlay S/8	71.34.0301	1	–	–	–
1	balanSys RP PE Trial Inlay S/10.5	71.34.0302	1	1	–	–
1	balanSys RP PE Trial Inlay S/13	71.34.0303	1	1	–	–
1	balanSys RP PE Trial Inlay S/15.5	71.34.0304	1	1	–	–
1	balanSys RP PE Trial Inlay A/8	71.34.0562	1	1	–	–
1	balanSys RP PE Trial Inlay A/10.5	71.34.0563	1	1	–	–
1	balanSys RP PE Trial Inlay A/13	71.34.0564	1	1	–	–
1	balanSys RP PE Trial Inlay A/15.5	71.34.0565	1	1	–	–
1	balanSys RP PE Trial Inlay B/8	71.34.0568	1	1	–	–
1	balanSys RP PE Trial Inlay B/10.5	71.34.0569	1	1	–	–
1	balanSys RP PE Trial Inlay B/13	71.34.0570	1	1	–	–
1	balanSys RP PE Trial Inlay B/15.5	71.34.0571	1	1	–	–
1	balanSys RP Trial Tibial Plateau 59	71.34.0418	1	1	–	–
1	balanSys RP Trial Tibial Plateau 62	71.34.0294	1	1	–	–
1	balanSys RP Trial Tibial Plateau 64	71.34.0295	1	1	–	–
1	balanSys RP Trial Tibial Plateau 67	71.34.0296	1	1	–	–

[1] Instrument tray is optional

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