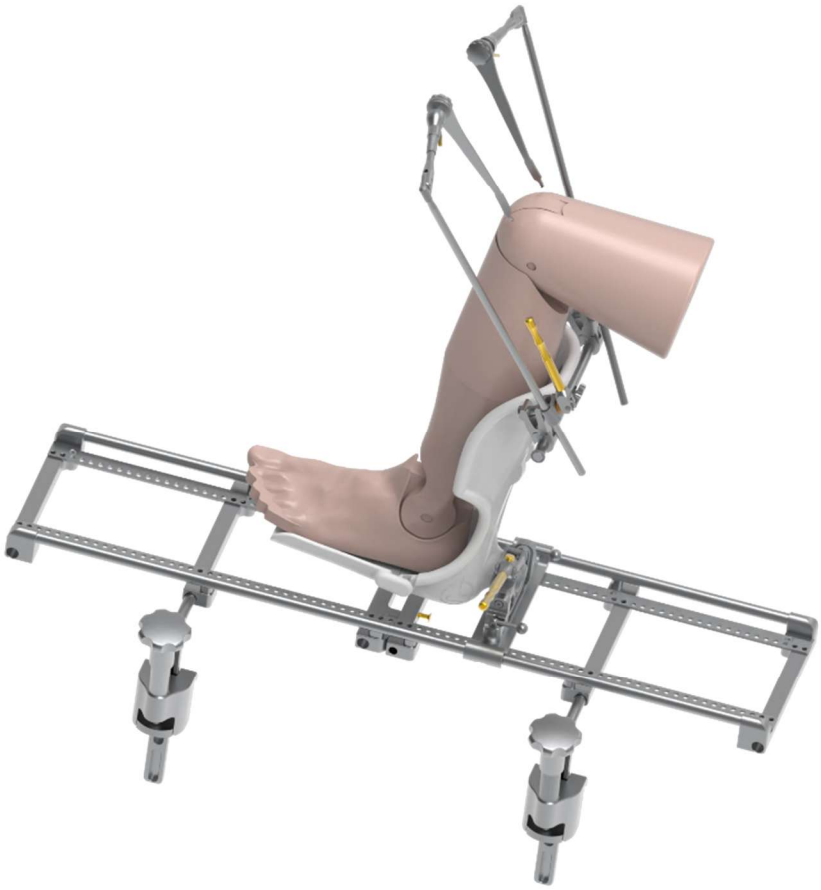
Instruction for Use and Reprocessing

CONDOR® MedTec
EXPAND YOUR POSSIBILITIES

Condor® Knee Positioner



Condor® Knee Positioner TKR

100.035.570 KS

100.035.570 KSB

CE

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Contents

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1. Introduction

1.1 About these instructions for use and reprocessing

This section contains information about the structure of the user manual, as well as explanations of the signs and symbols used.

The Knee Positioner is a medical device and is used and processed exclusively by specialist personnel (specialist physician, OR nursing, Central Sterile Services Department (CSSD) staff with appropriate training, e.g. specialist knowledge 1 course, or country-specific qualification requirements).

These instructions for use contain guidelines on handling the Knee Positioner with regard to operation, hygiene, service, maintenance, and disposal.

These instructions for use encompass all the information relevant to the use of the Condor® Knee Positioner. It may contain inaccuracies or printing errors.

The information provided here is updated periodically, and changes are incorporated in later issues in the course of product modification. Thus, changes or improvements are possible at any time without prior notification. The latest version of these instructions for use can be found on the Condor® website: www.condor-medtec.de.

Should you have further questions, please contact us directly. These instructions for use are to be read and used by all persons who use or operate the Knee Positioner. In addition to the instructions in this manual and any binding regulations for the prevention of accidents in the country and at the location of use, observe accepted rules for safe and professional work.

CE

1.2 Symbols used in the text

The following signal words and/or symbols are used in this instruction to indicate especially important information.

Danger!

This symbol indicates safety instructions war-ning of risks to personal health and safety. It indicates imminent danger of death or serious injury.

Attention!

This symbol is used with safety instructions indicating a risk of damage to the device or other property This symbol is placed in front of additional helpful hints.

Caution!

This symbol indicates potentially danger-ous situations involving a risk of light injury.

This symbol is placed in front of additional helpful hints.

- A dot in front of the text means:
  This task is mandatory. Indented text describes the result of your action.
- A dash in front of the text means:
  This is part of a list.

1.3. General safety instructions

The Condor® Knee Positioner is constructed according to the state of the art and complies with accepted safety rules. However, its use may present risks to the patient or third parties or risk of damage to the device or other property.

Use the Condor® Knee Positioner only when it is in proper working condition, within the scope of the intended use, with consideration of safety and potential hazards, and in compliance with this user manual. Immediately address and repair any defects that could affect safety.

The Knee Positioner may only be used for human medical purposes. The Condor® Knee Positioner should not be used for purposes other than those specified. Always keep this manual readily accessible at the location of use. In addition to this manual, observe all applicable laws and other regulations on accident prevention and environmental protection.

Do not make any changes, extensions, or modifications to the Knee Positioner without the manufacturer's permission. Spare parts must comply with the requirements stipulated by the manufacturer. Original spare parts always comply with these requirements. Observe the prescribed checks! Ensure the safe and environmentally friendly disposal of operating and auxiliary materials, as well as replacement parts.

1.4 Summary of the safety instructions

The Condor® Knee Positioner is built according to the state of the art and recognized safety regulations. Nevertheless, its use may present risks to the patient or third parties or cause damage to the device and other property.

Only use the Knee Positioner if it is in perfect, sterile condition, in accordance with its intended use, in a safety-conscious and hazard-conscious manner and in compliance with the instructions for use! In particular, have any faults that could impair safety rectified immediately!

The Knee Positioner may only be used for human medical purposes. The Condor® Knee Positioner should not be used for purposes other than those specified. Always keep these instructions for use to hand at the place of use! In addition to the instructions for use, observe the generally applicable statutory and other binding regulations on accident prevention and environmental protection!

Do not make any modifications, attachments or conversions without the manufacturer's authorization. Spare parts must fulfil the requirements specified by the manufacturer. This is always guaranteed with original spare parts. Comply with the prescribed inspections! Ensure safe and environmentally friendly disposal of operating and auxiliary materials and replacement parts!

Danger!

Direct skin contact with metal can lead to burns. Please note that there is no direct metal contact between patients and foot storage.

Attention!

If the clamp is too widely opened, inserting the crossbar is not possible. In this case, rotate it back slightly.

Attention!

The Condor® Knee Positioner must not be used concurrently with an MRI (Magnetic Resonance Imaging) as it may cause malfunctions in the MRI.

Only components approved by Condor® MedTec GmbH are permitted for use.

Attention!

Slide the lower cover of the operating table slightly towards the head to avoid possible tension on the sterile cover when the Knee Positioner is being fixed.

Attention!

If the sterile cover on the operating table becomes too short at the caudal end, potentially compromising the sterile zone, please extend it accordingly

Attention!

The PEEK inserts insulate the crossbars and provide additional protection against electrical current.

Condor® Knee Positioner

Attention!

Insufficient drying can lead to corrosion of the instruments! Therefore, ensure that the instruments are completely dry after disinfection.

Attention!

If stored for several days, the product must be disinfected again before sterilization!

Attention!

Improper storage can lead to a loss of sterility – the manufacturer assumes no liability in this regard.

Attention!

For improved usability, the sliding rail has two locking options with the lever lock. In exceptional cases, both lever locks can be used to lock the sliding rail.

Attention!

The foot storage may only be cleaned and sterilized when completely disassembled.

Attention!

Avoid turning the clamping lever of the universal clamp when it is closed.

Damage to the clamp can be caused by turning the clamping lever when the clamp is closed.

Open the lock before turning the clamping lever.

Attention!

Only sterilize the knee positioner when it has been disassembled!

Caution!

If you do **not** want to use support bar of the the foot storage, do not insert the adapter plate with the screw. The screw does not have sufficient distance to the patient and could injure them

Caution!

Only use the adapter plate, support bar and screw of the foot storage in combination and use all components!

- Ensure that the Condor Knee Positioner is clean and prepared in accordance with the applicable sterilization guidelines before use.
- Do not use the instrument if it is damaged or its sterility is impaired.
- Check the instrument for any damage or defects before use.

1.5 Graphical symbols used

Graphical symbol	Identification
	Identification in agreement with ISO 15223-1 standard. Symbol for 'product number'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'serial number'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'name and address of the manufacturer '
	Identification in agreement with ISO 15223-1 standard. Symbol for „date of manufacture "
	Identification in agreement with ISO 15223-1 standard. Symbol for 'observe instructions for use '
	Identification in agreement with ISO 15223-1 standard. Symbol for 'product not sterile'

Graphical symbol	Identification
	Labelling of medical devices. Symbol for "Medical Device"
	Identification for a data carrier which contains the Unique Device Identifier contains. Symbol for "Unique Device Identifier".
	Labelling of products developed and marketed in accordance with relevant European legal provisions.
	Labeling of products that are marketed in Switzerland. Symbol for "Swiss AR Symbol"
	<u>Alternative:</u> Labeling of products that are marketed in Switzerland. Symbol for "Swiss AR Symbol"

2. Basic requirements

2.1 Intended use

The Condor® Knee Positioner is a Class I medical device intended for intraoperative use. It is exclusively designed for human medical purposes and must only be used in conjunction with an operating table.

The Knee Positioner must be used in a sterile condition and should not come into contact with the patient's skin, therefore it must be adequately padded.

The Knee Positioner is used for intraoperative positioning of the leg. It maintains the leg's position, optimizing precise surgical work. Its adjustable settings allow for an intra-operative stability test.

2.2 General information on product use

The Knee Positioner may only be operated by persons who have familiarized themselves with the product on the basis of the instructions for use and who are qualified medical personnel. It may only be used in full compliance with the relevant instructions for use. We cannot accept any liability for any damage to the product or personal injury caused by third-party accessories or if the intended purpose of the product is mutually violated.

The specified use is the intended purpose. For the operator or user, it is completely clear from the labeling and the respective instructions for use.

Intended use also includes observing the instructions for use and complying with the inspection and maintenance conditions.

- The Condor Knee Positioner may only be used by medically trained personnel.
- Check the intact condition of the product before each use

2.3 Device description

The main features of the Knee Positioner are as follows:

- High stability
- Electrical safety
- Long product life cycle, thanks to the recommended regular maintenance
- Freedom of movement in the operating field
- Simple, quick assembly and operation
- Easy cleaning, disinfection and sterilization

Condor® Knee Positioner

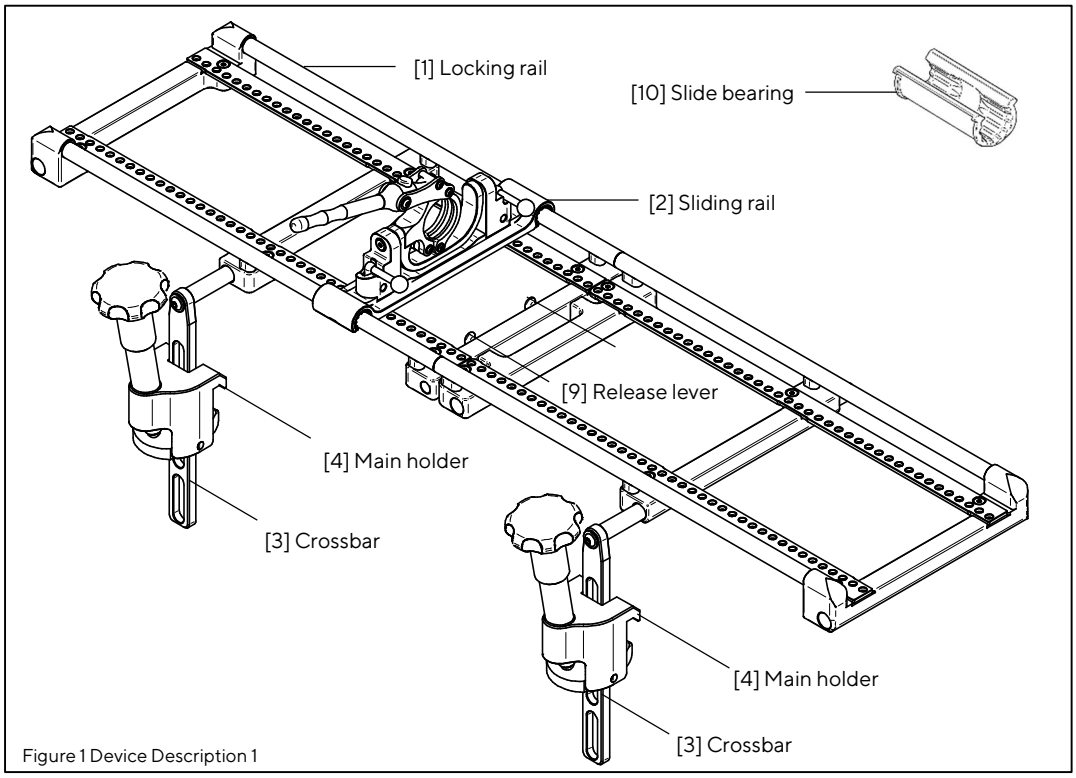


Figure 1 Device Description 1

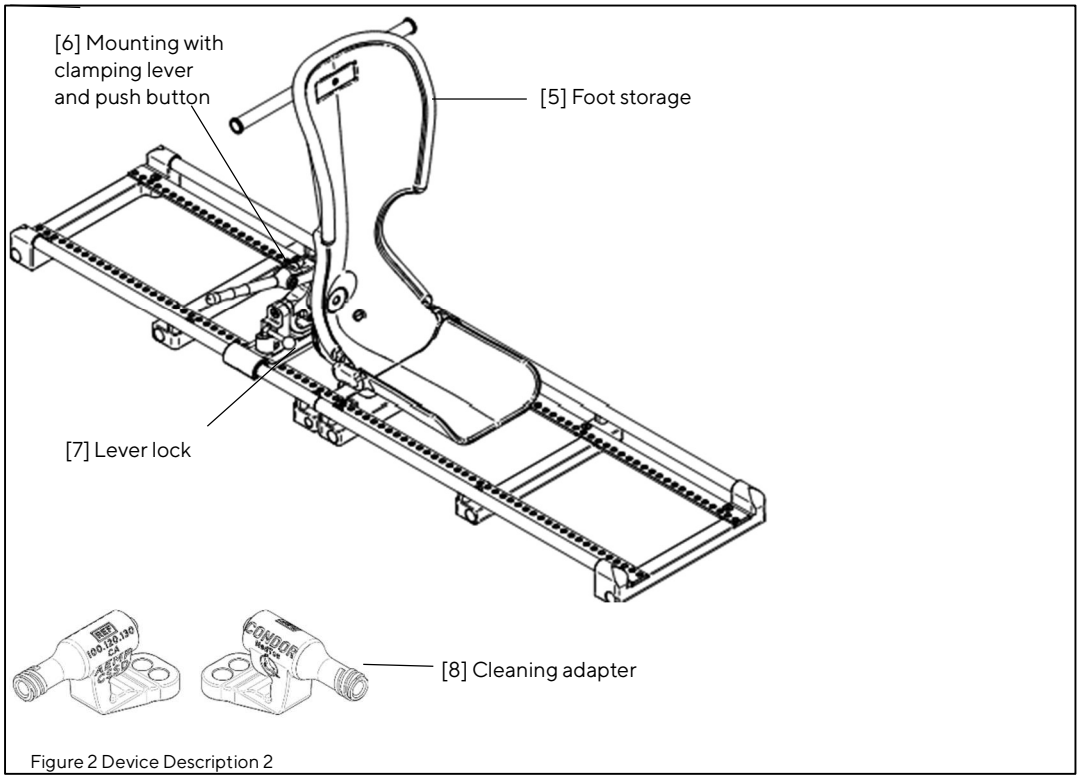


Figure 2 Device Description 2

3. Storage

The Condor® may only be used in a sterile state. Observe the instructions for use and preparation when storing, preparing, and sterile system.

The instrument should always be:

- stored in a clean, cool, and dry place.
- protected against mechanical damage.
- protected against falling and handled carefully.

The generally valid directives and recommendations apply, for example:

- DIN EN ISO 17664-1:2021-11
- KI recommendations
- AKI – Correct instrument preparation for storage of a re-sterilizable instruments

4. Construction and operation

Please read the operating instructions carefully before you start using the Condor Knee Positioner!

The Knee Positioner can be attached to all operating tables that are fitted with a sliding or standard rail.

Assembling the foot storage:

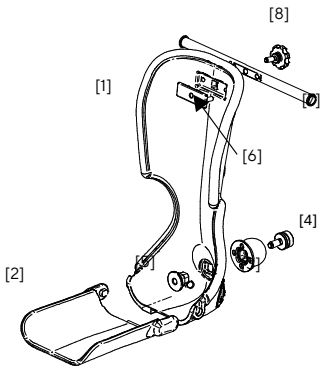
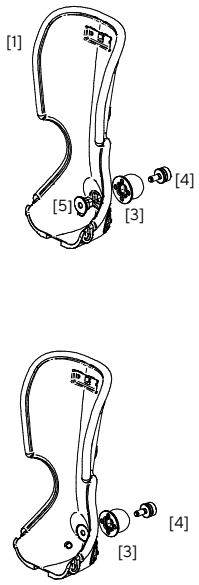


Figure 3 Construction 5

Structure of the foot storage for the Knee Positioner:
[1]: Foot storate part 1
[2]: Foot storage part 2
[3]: Ball
[4]: Connecting screw with washer
[5]:Lock nut
[6]: Adapter plate
[7]: Support bar
[8]: Star grip screw

Please fit the foot storage first before assembling the rail system.

Attention!
The foot storage may only be cleaned and sterilized when completely disassembled.



Firgure 4 Construction 5.1

Mounting the ball :

Place the foot shell part 1 [1] upright and insert the lock nut [5] from the inside through the corresponding opening in the heel area of the foot shell.

Place the ball [3] against the lock nut from the rear and make sure that the four recesses fit exactly on the prefabricated fixing bumps.

Hold the ball firmly and screw the connecting screw [4] by hand as far as possible into the thread provided on the ball

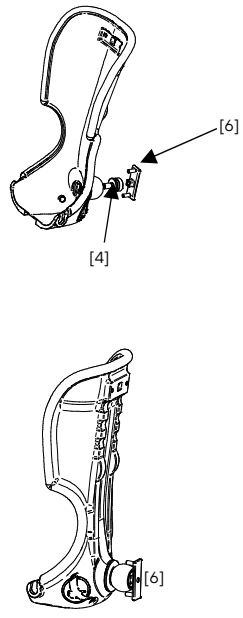
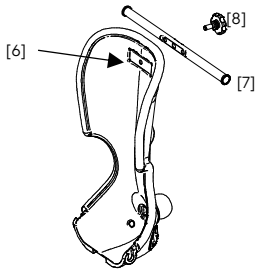
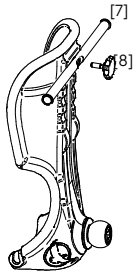


Figure 5 Construction 5.2

Tighten the screw using the integrated tool

You do not need any other tools to fully tighten the connecting screw [4]. Take the enclosed adapter plate [6], insert the square part of the plate into the recess of the connecting screw [4] and use it like an Allen key to finally tighten the screw.





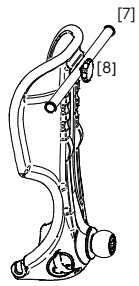


Figure 6 Construction 5.3

Mounting the support bar

Take the adapter plate [6] previously used as a screwing aid and place it from the inside into the prefabricated recesses at the upper end of the foot storage.

Place the support bar [7] from behind with the two openings on the metal pins of the adapter plate [6] and screw the adapter plate, the foot storage and the support bar together using the star grip screw [8].

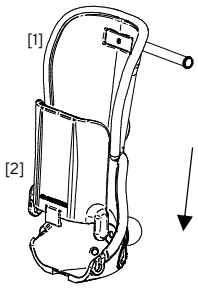
Make sure to hold the support bar firmly in position during this process to prevent it from shifting.

Caution!

If you do **not** want to use the support bar, do not insert the adapter plate with the screw. The screw does not have sufficient distance to the patient and could injure them!

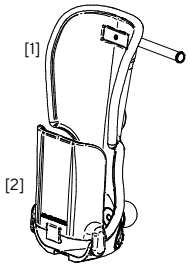
Caution!

Only use the adapter plate, support bar and screw in combination and use all components!

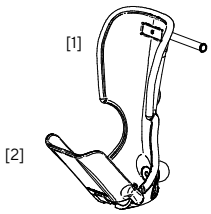


Fitting the foot storage extension (foot storage part 2)

To fit the second part of the foot storage [2], the extension, hold part 1 of the foot shell [1] upright and insert part 2 of the foot storage vertically from above into the two grooves on the lower side of foot storage 1.



Press part 2 of the foot storage firmly vertically downwards into the recesses.



As soon as part 1 and part 2 are connected, fold part 2 down. The two parts are now locked in place.

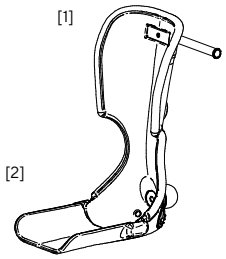


Figure 7 Construction 5.4

Assembling the rail system:

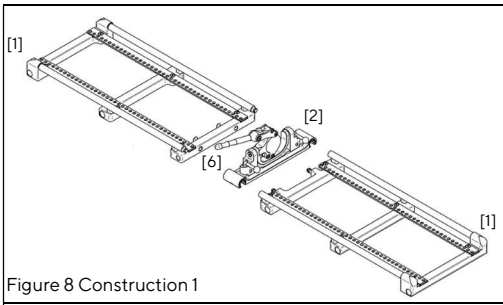


Figure 8 Construction 1

Start the assembly with the two locking rail [1].

Slide the sliding rail [2] onto one part of the locking rail [1].

Ensure that the golden clamping lever [6] is facing outward when the rail is positioned on the operating table. Make sure that the lever locks [7] of the sliding rail [2] are open.

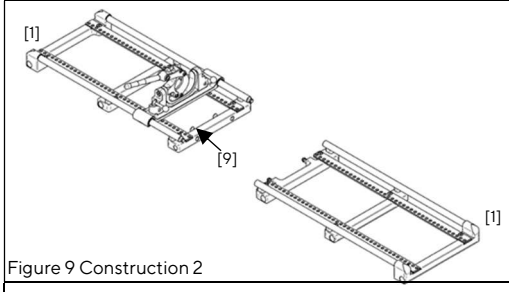
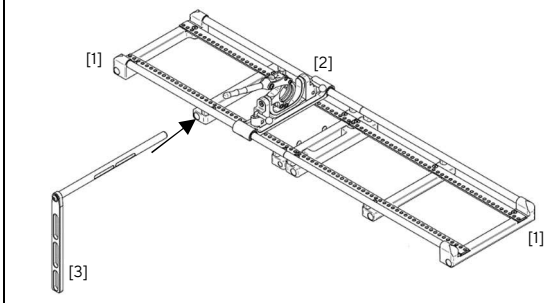


Figure 9 Construction 2

- Now, slide the two parts of the locking rail [1] together.
- Ensure proper fixation.
- The locking rail [1] will automatically secure itself.

To release the locking rail [1]:

- Press the two release levers [9] together and pull the two parts of the locking rail [1] apart.



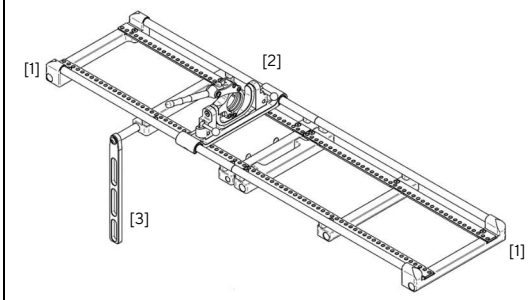


Figure 10 Construction 3

<u>Attention!</u> Slide the lower cover of the operating table slightly towards the head to avoid possible tension on the sterile cover when the Knee Positioner is fixed.

<u>Attention!</u>
Please note: If the sterile cover on the operating table becomes too short at the caudal end and compromises the sterile zone, please extend it accordingly.

Place the locking rail [1] with the sliding rail [2] on the operating table, ensuring that the Knee Positioner is aligned with the axis of the leg.

- Check the bending of the leg and position the locking rail [1] accordingly. Use the crossbars [3] and main holders [4] to secure the locking rail [1].
- Press the locking rail [1] and the crossbar [3] firmly onto the padded surface to prevent slipping.
- <u>Attention!</u> The peek inserts insulate the crossbars [3] and provide additional protection against electrical current.
- Insert the rounded sides of the crossbars [3] into the locking rail [1] of the Knee Positioner and secure the rectangular ends with the main holders [4] on the operating table.

The Knee Positioner should be positioned so that the leg can be fully extended. Before securing it to the sliding rail [2], we recommend extending and bending the leg once to ensure the positioner is correctly aligned.

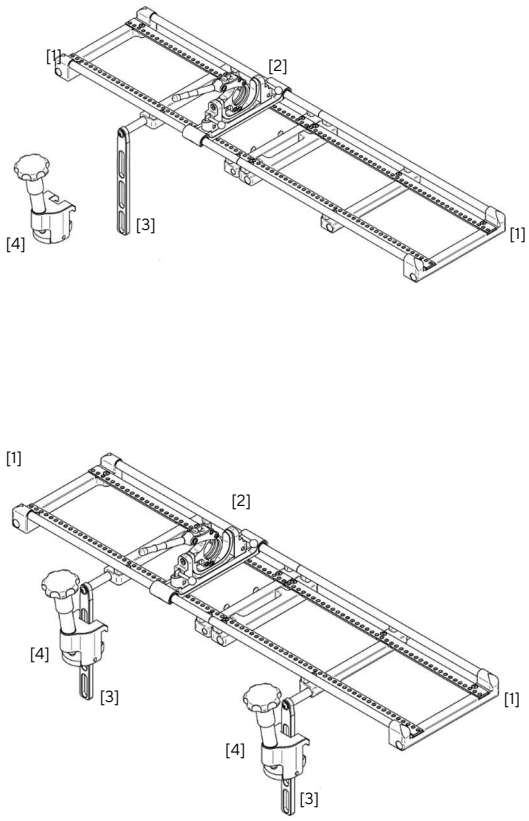


Figure 11 Construction 4

To secure the locking rail [1] to the operating table:

The Condor® Knee Positioner can be attached to any operating table equipped with a standard rail.

- To attach the central holder [4], note the opening of the clamp at the lower end of the central holder [4].
- Place the central holder [4] on the standard rail and tighten it by turning the handwheel clockwise.
- Attention! If the clamping of the central holder [4] is too wide open, inserting the crossbar [3] is not possible. In this case, turn the handwheel back slightly.
- The central holders [4] are disassemble. To disassemble the central holder [4], unscrew the handwheel with the threaded rod counter-clockwise.
- After removing the handwheel with the threaded rod, the individual parts can be prepared for sterilization.

Attention!
Ensure that no more than two sterile towels are positioned above the standard rail and that no cables, tubes, catheters, etc., are attached to the side rail.

Depending on the operating table, you can secure fixation on the locking rail [1] using five different sleeves. The Knee Positioner should be secured with two crossbars [3] and two main holders [4].

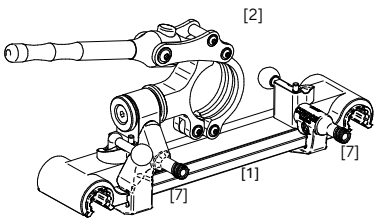


Figure 12 Construction 5

Adjusting the sliding rail [2]:

The sliding rail [2] can be locked and unlocked using two lever locks [7].

Raise both lever locks [7] to adjust the sliding rail [2] freely on the locking rail [1].

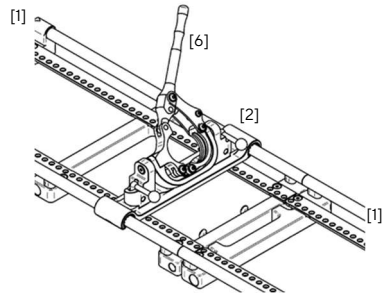


Figure 13 Construction 6

Securing the foot storage [5]:

- Wrap the padded leg with a sterile gauze bandage or similar material onto the foot storage [5].
- Ensure a sufficiently tight fit.

To secure the shoe to the sliding rail [2], open the clamping lever [6] by pressing the push button [6] and simultaneously pulling on the clamping lever [6].

- Now place the open joint of the holder [6] around the ball of the foot storage.

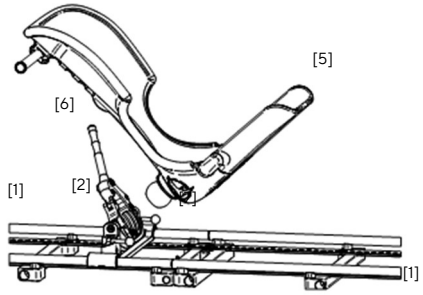


Figure 14 Construction 7

Adjustment:

To adjust the sliding rail [2] in its alignment, use the clamping lever [6].

- Only operate the clamping lever [6] to keep the holder connected to the crossbar [3].
- Secure the clamping lever [6] once you have found the desired alignment. Ensure that the golden lever [6] is pointing towards the knee and not towards the sole of the foot.

Attention: For better usability, the sliding rail [2] has two locking options with the lever lock [7]. In exceptional cases, both lever locks [7] can be used to lock the sliding rail [2].

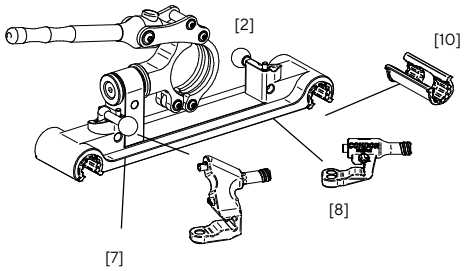


Figure 15 Construction 8

For cleaning:

To clean the sliding rail [2], attach the cleaning adapters [8] underneath the lever lock [7].

Remove the sliding bearings [10] from the sliding rail [2] before cleaning.

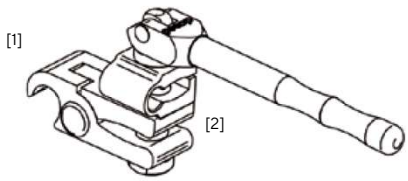


Figure 16

Universal clamp:

The universal clamps are used to connect the holder arm to the instrument in the operation area.

Open the eccentric lock. The “OPEN” inscription can now beread. For simple attachment of the clamp, place your thumb(1) above the clamp. At the back part of the clamp, placeyour index or middle finger (2) between the clamp jaws and spread them apart.

The clamp can only be fastened at the intended points.

The simple attachment of the clamp is enough to protect the clamp from falling down.

Push the clamp to find the suitable position for holding the instruments.

Insert the required instrument into the clamp.

Turn the eccentric lock to close the clamp so that it can no-longer be moved. The “CLOSED” inscription can now be read.

Attention!

Avoid turning the clamping lever in the closed state.

Turning the clamping lever when the clamp is closed could damage the clamp.

Open the lock before turning the clamping lever.

Removing clamps:

Open the eccentric lock of the clamp to remove from the holder arm. Turn the clamping lever.

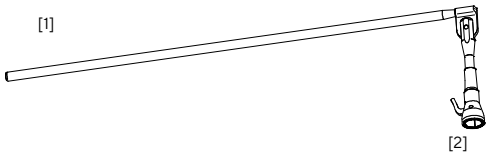
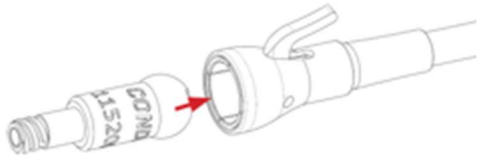
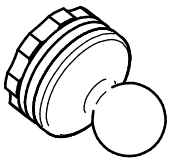
Remove the instrument from the clamp and operation area.

Place your thumb (1) above the clamp again.

At the back part of the clamp, place your index or middle finger (2) between the clamp jaws and spread them apart.

Now pull the clamp down from the holder arm.

Condor® Knee Positioner

 Figure 17	Blade holders Standard Hohmann levers can be attached to the blade holder using the Hohmann adapter. The support bar of the blade holder [1] can then be inserted into the clamp. This blade holder allows you to clamp instruments that are fitted with a ball for fastening. Press the toggle opening [2] and insert the instrument with ball attachment. Release the toggle opening. The clamped instrument and the blade holder are now firmly connected Special feature: Through the connection via a ball joint,movements in the operation field can be compensated and optimal setting positions achieved
 Figure 18	Connect the cleaning adapter to the water supply line, insert into the blade holder and then rinse.
 Figure 19	Hohmann adapter: Due to the large variety of Hohmann retractors, Condor offers the option of combining the Hohmann retractors with the Condor Knee positioner using an adapter.

4.1 Patient group / indication / contraindication

The surgeon decides exclusively on the indication for the operation. The Knee Positioner is specially designed for orthopaedic surgery and robot-assisted arthroplasty.

There is no general exclusion of patients who are eligible for the Condor Knee Positioner.

The Condor® Knee Positioner ensures safe and sterile use during orthopaedic surgeries and can be controlled directly by the surgeon to ensure precise positioning and adjustment throughout the operation. It enables precise guidance during surgery and is optimally adapted to various surgical robots, improving the precision and efficiency of procedures. The ability to rotate the leg allows the surgeon to react flexibly to the requirements of the operation.

The Condor® Knee Positioner must not come into contact with an MRI. In principle, the surgeon is responsible for the operation and the indication for surgery.

4.2 Operative user

The Knee Positioner may only be used on patients by trained surgeons who must have at least a medical specialist qualification or country-specific requirements. Other user groups are doctors, OR nursing staff and staff in the reprocessing unit for medical devices.

4.3 Combination with other medical devices

The Condor Knee Positioner may be used mounted to all operating tables that are fitted with a standard side rail.
Euro 25 mm x 10 mm
U.S. 28.85mm x 9.53 mm
UK 31.75mm x 6.35 mm
JP 32mm x 9mm
AU 38.10mm x 6.35mm
Edge design: Radius of 0.3-1.5 mm or bevel 45° of 0.3-0.5 mm

Use of sterile drapes according to hospital standard.

Attention!
Ensure that no more than two sterile towels are positioned above the standard rail and that no cables, tubes, catheters, etc., are attached to the side rail.

5.Instructions for use and reprocessing Condor® Knee Positioner

5.1 Service life

The Condor® Knee Positioner is classified within the product group of reusable positioning aids. The end of the product lifespan is primarily determined by wear and damage from use. As the usage duration increases, a passive layer forms on the instruments, influenced by factors such as material composition, surface texture, and processing conditions. The passive layer on the instruments neither signifies a quality deficiency nor does it affect the system's function. Experience suggests that the risk of corrosion decreases as the passive layer becomes stronger.

To ensure the longevity of function, safety, and quality standards, we recommend adhering to the following instructions for processing the non-sterile delivered instruments and reprocesssing the contaminated instruments.

Attention!

Only sterilize the knee positioner when it has been disassembled!

5.2 Pretreatment

It is recommended to carry out reprocessing of the contaminated instruments as soon as possible after use. They should be transported in closed containers. After the use of recyclable instruments, attention should be paid to them not being damaged during transport. Prior to cleaning, the instruments have to be disassembled as far as possible (see also our operating instructions) and eccentric locks must be loosened.

Both wet and dry disposal methods should avoid prolonged waiting times before processing due to the risk of corrosion and cleanability, for example, overnight or over the weekend. The Working Group on Instrument Reprocessing recommends, whenever possible, preferring dry disposal of instruments. Practical experience shows that waiting times of up to 6 hours for dry disposal are unproblematic.

5.3 Cleaning

Cleaning comprises 3 steps:

1. Precleaning

1.1. Manual precleaning

1.2. Precleaning in the ultrasonic bath

2. Automatic cleaning according to DIN EN ISO 158833-1 and -2 (in a washer-disinfector unit)

We recommend the use of detergents that are effective against prions (please take notice of the manufacturer´s instructions for application). Current studies analysing decontamination of infectious prions show that a consecutive cleaning with an alkaline detergent (pH value > 10) and disinfection or sterilisation is the most effective method. Please carry out the cleaning steps according to the instructions of the cleaning agent manufacturer! The following points refer to the alkaline cleaner Deconex 28 Alka One from Borer Chemie, with which our products were validated.

1.Precleaning

1.1. Manual cleaning

Soak the contaminated components in cold water (at least drinking water quality) for at least 10 minutes. Please note: The instruments should not, however, lie in water and / or cleaning and disinfection agents over a longer period of time, e. g., overnight / over the weekend.

- Submerse the components and clean them with a soft brush for at least 1 min, making sure that all surfaces are treated. In case of heavy contamination, the duration of the pre-cleaning may differ from those indicated. Cannulings and blind holes should be treated specifically with a brush suited for this purpose.
- Thoroughly rinse the components in running water (at least drinking water quality). The water has to run through the can-nulings; blind holes have to be filled and emptied repeatedly.

Phase	Step	Temperaturr	Time	Water quality	Additonal information
1	Soaking	Cold (not tempered)	10 min	At least drinking water quality	
2	Brushing	./.	1 min		Soft brush
3	Rinsing	Cold (not tempered)	1 min	At least drinking water quality	

1.2. Precleaning in the ultrasonic bath

Place the pretreated components in an ultrasonic bath (frequency: 35 to 40 kHz) heated to approx. 40°C, containing cleaning agent (e.g., Deconex 28 Alka One, Borer Chemie) according to the manufacturer's instructions for use and then sonicate the instruments for 10 minutes. After cleaning in the ultrasonic bath, rinse the instruments for 1 min under cold running water (at least drinking water quality).

Phase	Step	Temperature	Time	Water quality	Additional information
1	Ultrasonic bath	Max. 40°C	10 min	At least drinking water quality	Cleaning solution: 0.5 % Deconex 28 Alka One. Borer Chemie)
2	Brushing	./.	1 min		Soft brush
3	Rinsing	Cold (not tempered)	1 min	At least drinking water quality	

2. Automatic cleaning (in a washer-disinfector unit cleaning according to DIN EN ISO 158833-1 and -2)

Before you start with the machine cleaning, you should have carried out a pre-cleaning according to point 1. For the automatic cleaning the instruments have to be placed in perforated baskets suited for cleaning (avoid areas that cannot be reached by the water).

Hollow-body instruments must be connected to hollow-body rinsing systems of washer-disinfectors. An alkaline cleaner (pH > 10) should be used according to the manufacturer's instructions for use. Pay attention to the correct dosage! The products are validated for alkaline cleaning. Acidic cleaning agents and disinfectants must not be used.

Also observe the instructions of the equipment manufacturer. A typical cycle should include the following steps and should be carried out according to the instructions to the cleaning manufacturer's instructions:

Example of a cleaning cycle incl. disinfection:
(please note the specifications of the cleaning agent manufacturer)

- At least 2 minutes of pre-washing using cold water (at least drinking water quality and max. 45°C)
- Treat with alkaline cleaning agent for the appropriate exposure time, concentration and temperature as specified by the cleaning agent manufacturer (e.g. at least 5 min with Deconex 28 Alka One, Borer Chemie at 70°C / 55° validated).
- Carry out intermediate rinse(s) according to the cleaning agent manufacturer's instructions. (e.g. 1 min with 40-45°C warm drinking water, then 1 min with deionised / fully demineralized water (DI water))
- Thermal disinfection with DI water and max. 93°C – A_0 Value ≥ 3000 (e.g. 5 min at 90°C)
- Drying cycle (max. 120°C)

The information given above may vary depending on loading and programme.

After the programme has finished, the instrument must be taken out of the machine immediately and cooled down to room temperature. They should not remain in the washer-disinfector after the washing process.

- After disinfection, check all components for visible contaminations (especially in the cannulings and blind holes). If necessary, repeat the cycle or clean manually.
- All parts, especially hinges must be dried with clean compressed air after disinfection.

Attention!
Insufficient drying can lead to corrosion of the instruments! Therefore, make sure that the instruments are completely dry after disinfection.

After disinfection, store the product under the following conditions: completely dry, protected from dust, in a closed container, under low-germ conditions (see section Storage).

Attention!
When storing for several days, disinfect the product again before sterilization!

The medical devices must be sterilised in the context of reprocessing after disinfection (chapter 6.4). Inspect parts for damage that may affect their functionality.

Damaged and defective instruments have to be sorted out and replaced. Instruments that are to be returned to Condor® for repair must also be sterilised beforehand (individual packaging, see section Sterilization). Please use our form for returns at the end of these instructions for use.

After the instruments have been cleaned and cooled down, areas such as joints, threads, etc. have to be treated with appropriate care products (medical white oil) according to the manufacturer's range of application.

At a glance

1. Place disassembled or opened products in the washer-disinfector. Ensure that the products do not touch each other.
2. Enable active rinsing by connecting to the rinsing connection of the washer-disinfector.
3. Start the program.
4. At the end of the program, disconnect the products (if necessary) and remove them from the washer-disinfector.
5. Check and pack the products as soon as possible after removal.

Phase	Step	Temperature	Time	Water quality	Additional information
1	Pre-rinsing	Cold (not tempered)	2 min.	Drinking water	./.
2	Cleaner dosage				Alkaline cleaner, according to manufacturer's instructions
3	Cleaning	55°C	5 min	At least drinking water	
4	Neutralization	./.	./.		Neutralization according to detergent manufacturer's instructions not carried out
5	Intermediate rinsing 1	Cold (40-45°C)	1 min	Fully demineralized water (DI)	
6	Intermediate rinsing 2	Cold (40-45°C)	1 min	Fully demineralized water (DI)	
7	Thermal disinfection	Max. 90°C	5 min	Fully demineralized water (DI)	A0 value ≥3000
8	Drying	120 °C	15 min		

5.4 Inspection, functional test and care instructions

5.4.1 Inspection and functional test

Further use is confirmed by the successful control of the product. The control release and packing in a sterile barrier system releases the product for the next use.

After each cleaning, the products must first cool down and be macroscopically clean, i.e. free from visible contamination.

- Inspect instruments and in particular their ends and working ends for breaks, cracks, deformation, damage and functionality.
- DIN 96298-3 (Medical instruments - Definitions, measuring methods and tests, Part 3: Tests) can be used as support for the functional test.
- Worn, corroded, deformed, porous or otherwise damaged products must be replaced. Alternatively, appropriate measures can be taken (e.g. surface treatment, repair), see also the recommendation of the Instrument Reprocessing Working Group (AKI): http://www.a-k-i.org
- Do threads run freely?
- Can all joints move freely?
- Are there any sharp edges?

Products listed with one of the following defects must not be used:

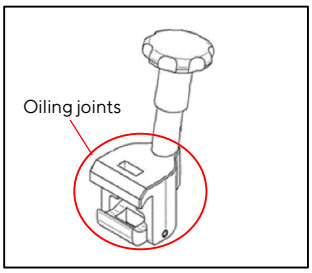
Functional restriction	Recommended action
Stiff / smooth-running	Repair / product will be readjusted e.g.
Frictional corrosion / contact corrosion	Repair
Surface corrosion	Repair: surface treatment
Scratches	Repair: surface treatment
Water stains	Repair: surface treatment
Coating wear	Repair: surface treatment
Sharp edges	Repair: surface treatment
Pitting corrosion	Replacement!
Breakage e.g. at the joint	Replacement!

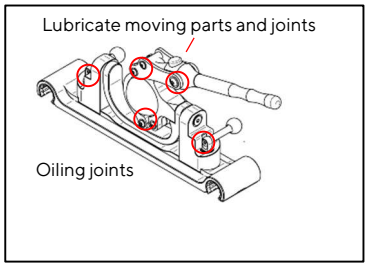
Damaged and defective instruments must be sorted out and replaced.

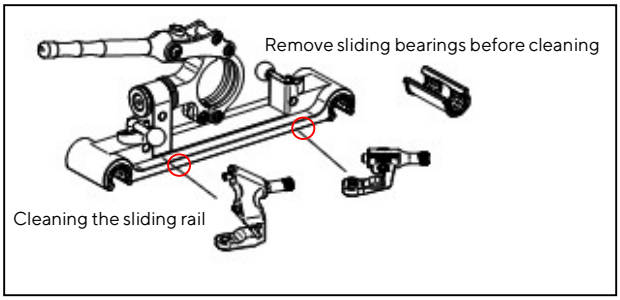
Repairs are to be carried out exclusively by Condor! The corresponding instruments must also be sterilized beforehand. Please use our form for returns at the end of these instructions for use.

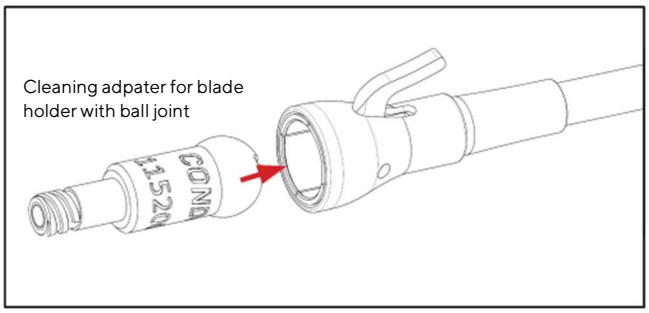
5.4.2 Care

In order to guarantee a long shelf life for the products, some instructions on care should be followed. These are illustrated below as examples for various products, and are to be adopted for similar mechanical components in other items.









5.5 Sterilization

The instruments can be sterilized packaged individually (in standard sterilization bags), in dedicated container systems or all-purpose sterilization containers. Containers should not be overloaded (please take notice of the manufacturer´s instructions).
Devices or special protection are not required for transportation in a sterile state!
Approved sterilization packaging must be used for sterilization, subsequent transport and storage.

Sterilization should be carried out applying a validated method with steam and fractionated pre-vacuum. (e.g. sterilizer according to EN 285 and validated according to DIN EN ISO 17665-1). A residence time of 5 minutes must be adhered to at a temperature of 134°C. All joints and eccentric catches must be in open position during sterilization.

After sterilization, store the product in sterile packaging protected from moisture, temperature fluctuations, direct sunlight and dust.The medical devices must be stored on suitable carriers for cleaning, e.g. sieve trays or sieve baskets. The operating and loading instructions of the washer-disinfector manufacturer must be observed.

Attention!

Improper storage can lead to loss of sterility - the manufacturer accepts no liability in this respect. The manufacturer accepts no liability in this respect

Sterilization is performed with moist heat (**saturated steam**).

The Knee Positioner was validated as follows (**worst case**):

Lower switching point 200 mbar - upper switching point 2000 mbar as part of fractionations 1-4. Sterilization validation was carried out at 132°C and 180 seconds. Drying takes place at 200 mbar and 600 seconds in a sterilization container, incl. sieve tray.

This is a worst-case scenario. We would like to point out that medical device operators must validate and apply their own reprocessing and sterilization processes.

The actual product drying depends directly on parameters that are the sole responsibility of the medical device operator (load configuration and density, sterilizer condition, etc.) and must therefore be determined by the user. The drying time should not be less than 15 minutes.

After sterilization, store the product in sterile packaging protected from moisture, temperature fluctuations, direct sunlight and dust.

Steam sterilization	
	Procedure
Pre-vacuum cycles	At least 3 x
Medium	Saturated steam (DIN EN ISO 17665:2024-09)
Sterilization time and duration	5 minutes (or longer);at least at 132°C
Drying	At least 10 min

No further accessories are required for sterilization.

Acceptance criteria for a successful sterilization cycle and drying

Value	Acceptance criterion	Basis	Instruction for action
Visual	No perceptible moisture	DIN EN ISO 17665-1, Point 6.1.2 g	/

Please note that the medical device operator must fulfill his obligations (according to RKI and normative requirements) and that regular tests of the steam condensate must be carried out.

Attention!

Improper storage can lead to loss of sterility - the manufacturer accepts no liability in this respect.

5.6 Concluding advice

The above instructions have been validated Condor® MedTec GmbH for the preparation of the Condor® Knee Positioner for reuse. The responsibility lies with the reprocessor to ensure that the actual processing performed with the equipment, materials, and personnel in the processing facility achieves the desired results. Normally, validation and routine monitoring of the process are required for this purpose. Any deviation from the provided instructions by the reprocessor should be carefully evaluated for its effectiveness and potential adverse consequences. Finally, we confirm that all products leave our facility only after undergoing appropriate quality control. However, complaints are still possible. Please inspect the goods for completeness and functionality and inform us immediately of any complaints. Do not use disputed goods!

Instruments returned to Condor® for repair should also be sterilized before being dispatched (packaged individually, refer to item "sterilization"). For this, please use our template (form) at the end of these instructions for use.

Condor® MedTec GmbH verifies that the above instruc-tions are suitable for the preparation of instruments for reprocessing. We would like to refer you to further literature:

- DIN Taschenbuch 100/1 „Medizinische Instrumente 1“, Beuth Verlag GmbH Berlin, Wien, Zürich, ISBN-13: 978-3-410-20746-7
- DIN Taschenbuch 100/2 „Medizinische Instrumente 2“, Beuth Verlag GmbH Berlin, Wien, Zürich, ISBN-13: 978-3-410-20749-8
- Recommendations of the Robert Koch Institute at www.rki.de/EN
- AKI (Instrument Preparation Working Group) – Proper Maintenance of Instruments (Red Brochure) at www.a-k-i.org

Proof of the basic suitability of the products for effective steam sterilization was provided by an independent, officially accredited and recognized test laboratory using the steam sterilizer and the fractionated vacuum process as well as a commercially available instrument oil based on paraffinic white oil without additives (oiling of the joints and friction surfaces). Typical conditions in hospitals and medical practices as well as the procedure described above were taken into account.

Do not use gravitation sterilization, flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

6. Maintenance

Careful handling, inspections, and maintenance ensure the functionality and operational safety over many years. Inspections are for safety and minimize the risk of malfunctions while improving reliability. Therefore, we recommend having maintenance/overhauls performed at regular intervals. For example, with regular use (2-3 / week) every two years.

Have maintenance carried out exclusively by Condor. Condor® MedTec GmbH offers a complete overhaul of their systems after the warranty expires.

Maintenance improves reliability. It is an essential prerequisite for maintaining functional and operational safety. We therefore recommend that maintenance is carried out at regular intervals. Condor® MedTec GmbH offers a general overhaul of its systems after the warranty has expired.

7. Repairs

Only have repairs carried out by the manufacturer.Please contact us in case of malfunctions:

Condor® MedTec GmbH
Dr.-Krismann-Str. 15
33154 Salzkotten
GERMANY
Tel. +49 5258 9916-0
Fax +49 5258 9916-16
info@condor-medtec.de
www.condor-medtec.de

Please note that only products that have been decontaminated will be sent to the manufacturer. Please enclose proof of the return shipment.

All serious incidents relating to the product must be notified to the manufacturer and the competent authority of the member state in which the user is located.

8. Spare parts

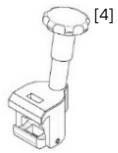
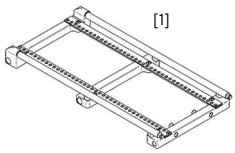
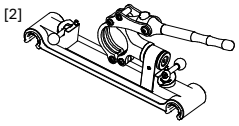
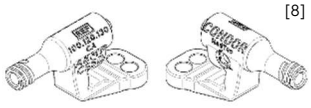
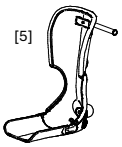
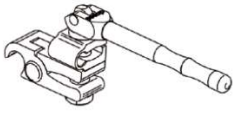
If needed, spare parts are available exclusively through Condor® MedTec GmbH. When ordering technical descriptions or spare parts from the manufacturer, please make sure to have the article number ready. You can find this information on the laser engraving on the respective product.

Order number Set: 100.035.570 KS or 100.035.570 KSB

9. Product training

Generally, the products may only be used after instruction by the medical device consultant. Please use the contact details given in chapter 10 to arrange an appointment.

The following set components are available for you:

Description	Articel-Nr.	Figure
Set-articles		
Main holder (for Knee Positioner)	100.055.060 KS1	 Figure 20 Main holder
Crossbar (for Knee Positioner)	100.020.012 KS1	 Figure 21 Crossbar
Locking rail (for Knee Positioner)	100.390.134 KSG	 Figure 22 Locking rail
Sliding rail (for Knee Positioner)	100.120.130 KS	 Figure 23 Sliding rail
Cleaning adapter	100.120.130 CA	 Figure 24 Cleaning adapter
Foot storage with ball (for Knee Positioner), fold-down	100.300.200 KS	 Figure 25 Foot storage
Universal clamp (for Knee Positioner)	100.050.020 ES1	 Figure 26 Universal clamp

Condor® Knee Positioner

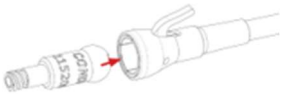
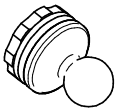
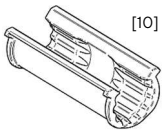
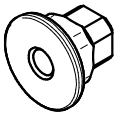
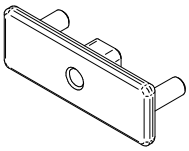
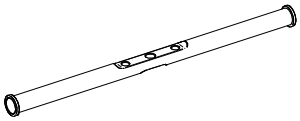
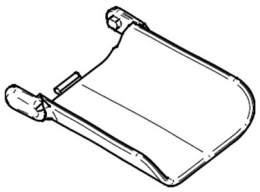
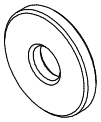
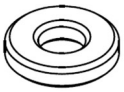
Blade holder Knee Positioner	100.400.020 KS1	 Figure 27 Blade holder
Cleaning adapter for blade holder with ball joint	115.200.008 CA	 Figure 28 Cleaining adapter for blade holder
Adapter	115.030.020 K1	 Figure 29 Adapter

Figure 29 Hohmann adapter

Spare parts		
Slide bearing	GL.0368.2023	[10]  Figure 30 Slide bearing
Ball with flange	GL.0375.2023	 Figure 31 Ball witj flange
Lock nut	GL.0017.2025	 Figure 32 Lock nut
Adapter plate	GL.0020.2025	 Figure 33 Adapter plate
Support bar	GL-0023.2025	 Figure 34 Support bar
Foot storage Part 2	100.300.200 KSF	 Figure 35 Foot storage Part 2
Assembly group Connecting screw	100.020.032 KS	 Figure 36 Connecting screw with washer

Washer for connecting screw	GL.0019.2025	 Figure 37 Washer for connecting screw
Assembly group Star grip screw	100.030.028 KS	 Figure 38 Star grip screw with washer
Washer for star grip screw	GL.0006.2025	 Figure 39 Washer for star grip screw

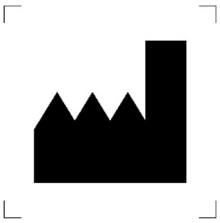
Accessory		
Adhesive bandage, sterile	38613	

10. Disposal

10.1 Packaging

Condor® MedTec GmbH will take back the complete packaging on request. Where possible, parts of the packaging will be re-used. If you do not want to make use of this, you can dispose of the packaging via the paper and household waste. When designing the product, it was ensured that as few composite materials as possible were used. This design concept permits a high level of recycling. After the product lifespan ends, please dispose of the surgical instruments professionally or use a recycling system. For all disposal measures, observe the national directives and disposal guidelines.

11. Technical specifications

Manufacturer	Adress and Contact details
	Condor® MedTec GmbH Dr.-Krismann-Str. 15 33154 Salzkotten GERMANY Tel. +49 5258 9916-0 Fax +49 5258 9916-16 info@condor-medtec.de www.condor-medtec.de

11.1 Classification

According to Annex IX, Rule 1 of the Medical Devices Directive 93/42/EEC or Annex VIII of the Medical Device Regulation (MDR) – (EU) 2017/745, Rule 1, the Condor® Knee Positioner is classified as a Class I medical device.

11.2 Applied standards

The Condor® Knee Positioner fulfil the following standard requirements:

- EN ISO 13485: 2016 + AC: 2016
- 93/42/EWG Anhang II ohne (4) I 93/42/EEC Annex II without (4) Reg.-Nr. / Reg. No. 44 232 117867

11.3 Certificates

The current certificates can be downloaded from our homepage (www.condor-medtec.de/downloads).

12. Copyrights

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For reconsignment please note this!

- **Loan instruments back**
- **Instruments back for repair**

Please complete this form and enclose it to your reconsignment.

We hereby confirm the correct desinfection, cleaning and sterilisation of the (loan) instruments enclosed.

Instruments:	Certificate/label:
Hospital (address):	
Departments:	
Responsible:	
Date, Stamp, Signature:	

Stand: 29.01.19