CONDOR® MedTec
EXPAND YOUR POSSIBILITIES

Instructions for Care and Use

Extension System (ES) | Tibial System

444.GA.EAS.EN
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CE

Content

1. Introduction

1.1 About this manual

These instructions for use include all relevant information for the use of the extension system (ES) including the accessories.

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

This user manual contains instructions regarding the use of the extension system. In the following, it will also be called ES.

This user manual 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 modifications. Thus, changes or improvements are possible at any time without previous notification. If you have any questions, please contact us.

Any person using the ES must read the user manual and observe the instructions.

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.

1.2 Symbols used in the text

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

Danger!
This symbol indicates safety instructions warning of risks to personal health and safety. It indicates imminent danger of death or serious injury.

Caution!
This symbol indicates potentially dangerous situations involving a risk of light injury.

Attention!
This symbol is used with safety instructions indicating a risk of damage to the device or other property.

This symbol indicates additional useful information

• 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 extension system 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 ES only when in proper working condition, within the scope of the intended use, in consideration of safety and potential hazards and in compliance with this user manual. Immediately repair any defects that could possibly affect safety.

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 modify the device without the manufacturer's approval. Spare parts must comply with the requirements stipulated by the manufacturer. Original spare parts always comply with these requirements.

Observe the specified inspection intervals. Ensure safe and environmentally friendly disposal of replaced parts.

Intended use also includes compliance with this manual as well as inspection and maintenance conditions. Before every use, make sure that the entire system is stable and safely supported.

Summary of the safety instructions

Attention!
If the stability of the ES and operating table combination is low, please always use the leg plate support for the ES to prevent the operating table including the ES from tipping over!
Pay attention to instructions on the use of the support in the delivery documents."

Danger !
If RF current flows unintentionally in activated RF surgery devices, there is a risk of burns for patients. Patients must therefore have no contact with electrically conductive pads and metal parts of the extension system. Always place an insulted, waterproof foil between pads and patient.

Danger !
The ES can come loose if the cross strut is not properly attached to the operating table. Always verify that the ES is firmly attached to the operating table.

Danger !
The leg plate or the RotexTable® may become detached from the ES if the connecting pins are not completely latched in. Always verify that the leg plate or the RotexTable® is firmly attached to the ES.

Attention !
During height adjustment or lateral movements, the RotexTable® and the leg plate may collide and damage the device. In this case, swivel the leg plate of the healthy leg outward in order to ensure sufficient freedom of movement for the RotexTable®.

Attention!
In some cases, the leg plates may need to be folded away.

Attention!
When adjusting the height of the operating table again, the height of the support must also be readjusted. For this purpose, the star grip should be opened before moving the operating table and then fixed again at the appropriate height.

Attention!
The support must be adjusted again and positioned vertically if the operating table is moved longitudinally. Check the stability of the system again!

Danger!
If the operating table is moved down without first releasing the height adjustment of the support, damage may occur to the support, the ES and/or the operating table.

Danger!
If the operating table is moved upwards without adjusting the height of the support, the operating table may tip over. Therefore, adjust the height of the support each time you adjust the height of the table.

Caution !
Even though the hand wheel of the traction device runs very smoothly, injuries to the patient through excessive extension are still possible. Proceed very carefully during extension.

Caution !
Extension shoes that have not been properly secured can get loose, and the patient could be injured. Verify the firm attachment of the extension shoe on the traction device.

Attention!
When using the ES, make sure that nothing is under the system. Otherwise, when lowering the operating table, damage to the ES and/or operating table may occur.

Caution !
Please make sure that both leg plates are selected on the operating table control and that they are only moved on both sides. There is a risk of the ES conncting plate breaking if it is moved on one side only!

Danger !
After the operation, make sure that the patient is centrally positioned on the operating table before transporting him out of the operating room! There is a risk of tipping!

Summary of the safety instructions

Attention !
When using an ES on a longitudinally adjustable bed surface, the ES may press against the centre column of the operating table and damage the device. Avoid longitudinal movement, in particular when the ES slants down. Always ensure sufficient space for the longitudinally adjustable bed surface.

Danger !
The maximum permitted weight for side rail adaptation for a drape holder is 5 kg! Also observe the maximum permitted total weight for the ES and the operating table. Make sure that the complete system is stable!

Caution!
The hand wheel of the tension device [8] can be moved very easily. Extend the device with care.

Attention !
Abrasive detergents may damage surfaces. Do not use abrasives for cleaning.

Attention !
Skin disinfectants may cause discolourations in the pads. Immediately remove skin disinfectants from the pad to avoid discolourations.

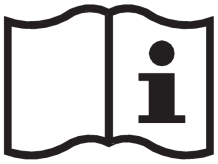
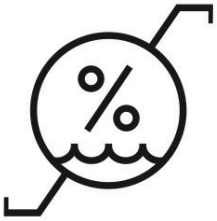
Attention !
Alcoholic detergents damage the faux leather (hardening and tearing). Do not use these agents for cleaning or disinfection.

Attention !
Pointed or sharp objects may damage the pads. Be careful with pointed or sharp objects.

Attention !
Damaged pads may soak up moisture. Always replace damaged pads immediately.

1.4 Graphical symbols used

The following graphical symbols are used in accordance with DIN ISO 15223-1.

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 "temperature range"
	Identification in agreement with ISO 15223-1 standard. Symbol for "relative humidity"

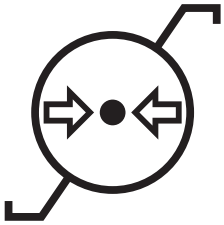
Graphical symbol	Identification
	Identification in agreement with ISO 15223-1 standard. Symbol for "air pressure"
	Identification in agreement with ISO 15223-1 standard. Symbol for "product not sterile"
	Identification in agreement with ISO 15223-1 standard. Labelling of medical devices. Symbol for „Medical Device"
	Identification in agreement with ISO 15223-1 standard, displays a carrier that contains information on a unique product identifier (UDI). Symbol for „Unique Device Identifier".
	Labelling of products developed and marketed in accordance with relevant European legal provisions.
	Marking shows the authorized representative in Switzerland.

Table 1 Graphical symbols used

2 Basic requirements

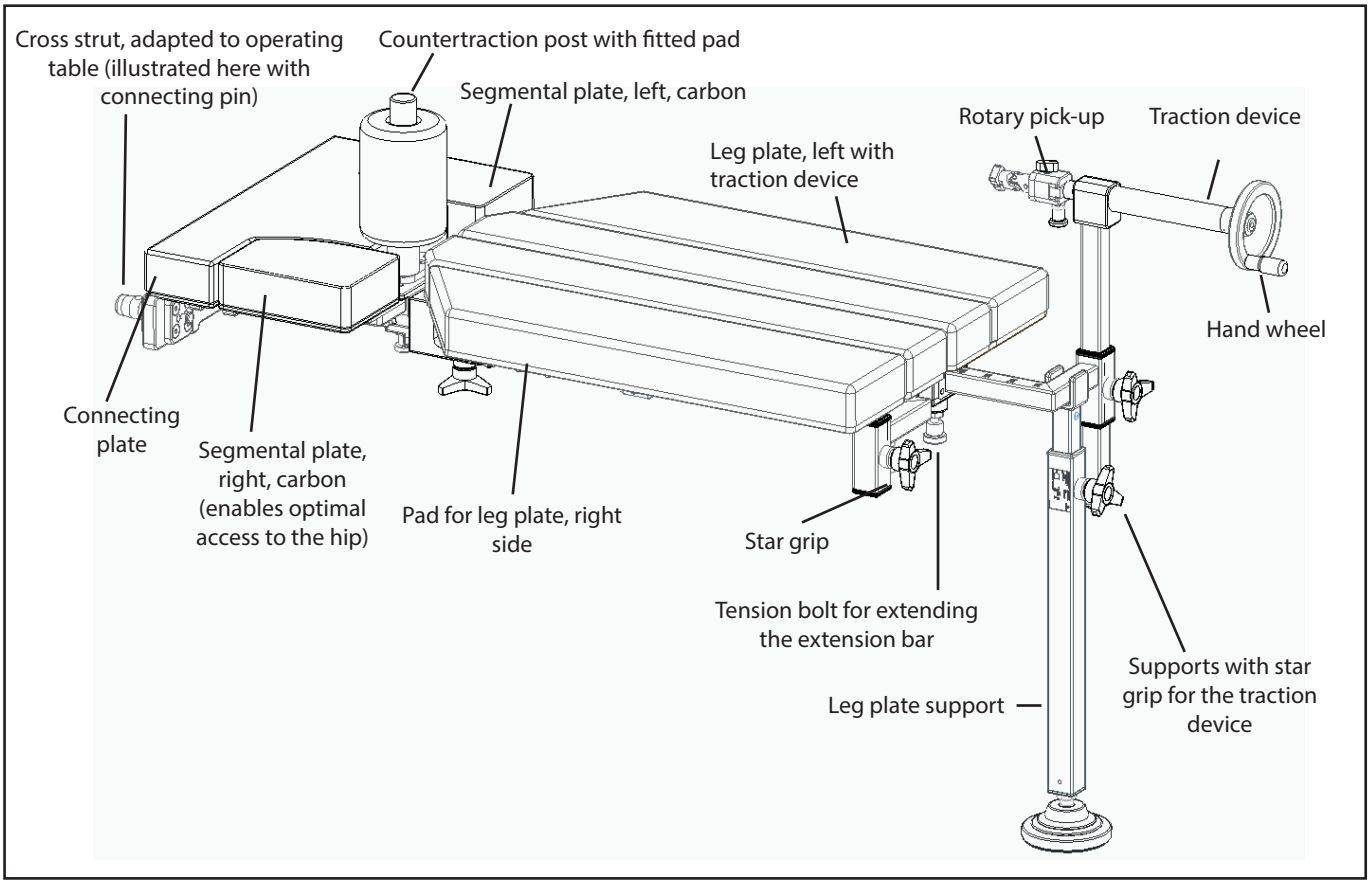
2.1 Intended use

The extension system (ES) is an accessory for a medical device. It is intended for human medical applications exclusively and must only be used in conjunction with an operating table. It is optimised for application in combination with the RotexTable by Condor®.
The ES is used to position the hip and lower extremities of patients during operations on the hip, thigh, lower spine, as well as during induction and emergence. It is equipped with leg plates and enables countering during extension and traction. If the safe load capacity of the operating table permits this, the ES may be used for patients weighing up to 225 kg. If the load capacity of the operating table including manufacturer-supplied extensions of the bed surface is lower, then this lower safe load capacity of the operating table applies. Ensure the stable positioning of the system when it is bearing the entire work load before each use.

During use, the ES is connected to a specific operating table. For adaptation to a specific operating table, the model of the operating table has to be indicated in the order. The operating table and ES may only be used by persons who have familiarised themselves with the product by reading this manual. The ES may only be used in complete accordance with the user manual. We will not accept liability for property damage or personal injuries caused by third-party accessories or noncompliance with the intended use.
The specified application is the intended use. This use is made fully apparent to the owner or user from the labelling and the user manual. The ES may only be used in complete accordance with the user manual.

No liability shall be assumed for potential product damage or personal injury due to non-approved accessories or contradicting intended use, non-compliance with maximum limits or requirements regarding function checks and visual inspections.

2.2 Device Description



3. Storage

In its original packaging, the extension system may be exposed to the following ambient conditions for a period of 15 weeks:

Ambient temperature	+50°C -5°C
Relative humidity	95% 10%
Pressure	1060 hPa 500 hPa

4. Operation

4.1 Connecting the extension system to the operating table

The ES can be attached to operating tables of various manufacturers. The cross strut of the ES is adapted to specific models of an operating table manufacturer. The model of the operating table needs to be indicated in the order.

The ES is attached to the seat part of the operating table unless another option has been expressly approved.

Attachment to the operating table should be according to the specifications of the manufacturer of the operating table. For further details please consult the operating instructions of the operating table.

- Always verify that the extension system is firmly attached to the operating table.

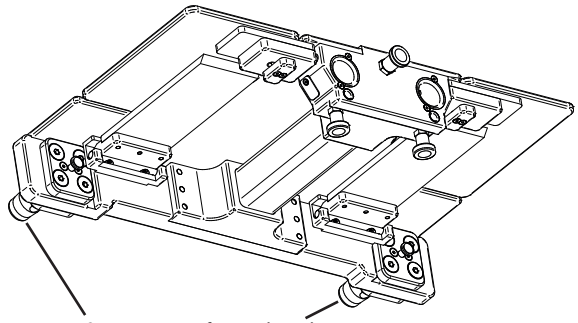
The stability of the operating table, RotexTable® and extension system depends on various factors:

– Structure and weight of the operating table
– Position of the rollers on the operating table trolley
– Position of the longitudinal adjustment of the bed surface (if available)

Always make sure that the system of operating table, RotexTable®, ES and patient is stable before use.

Attention!
If the stability of the ES and operating table combination is low, please always use the leg plate support for the ES to prevent the operating table including the ES from tipping over!
Pay attention to instructions on the use of the support in the delivery documents."

The connecting plate is shown here with connecting pins without pad



Danger !
If RF current flows unintentionally in activated RF surgery devices, there is a risk of burns for patients. Patients must therefore have no contact with electrically conductive pads and metal parts of the extension system. Always place an insulted, waterproof foil between pads and patient.

Danger !
The combination of operating table with extension system can tip over if the stability is insufficient. Make the system as stable as possible. Check that the entire system is standing firmly.

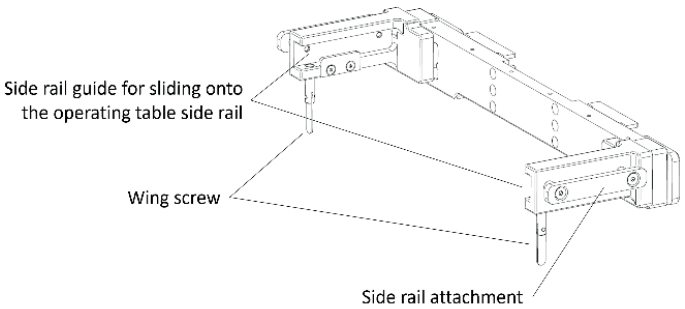
Danger !
The extension system can come loose if the cross strut is not properly attached to the operating table. Always verify that the extension system is firmly attached to the operating table.

4.2 Connecting the extension system to the operating table with cross strut at side rail of the OR -table

The ES can be attached to operating tables from various manufacturers. With the cross struts RO.0001.2016.SC/ RO.0098.2019.US/ RO.0310.2020.JP adaptation takes place via the side rail of the operating table.

Attachment to the operating table:
If not explicitly released otherwise, the ES is attached to the seat part of the operating table.

- First remove the leg plates from the operating table.
- Slide the ES with its cross strut onto the side rails of the operating table up to the stop.
- Make sure that the side rail adaptation is stable on the operating table.



Caution!
Make sure that the ES is attached to a continuous piece of the operating table side rail. There must be no gap between the operating table and the ES cross strut.

- Tighten the wing screws firmly on both sides!
- Then check that the ES is firmly seated on the operating table and make sure that the combination of ES and operating table is stable!

General notes:

Caution!
Observe the maximum load specifications for the ES and the operating table. If the load capacity of the operating table including manufacturer-supplied extensions of the bed surface is lower, then this lower safe load capacity of the operating table applies.

Caution!
Please make sure that both leg plates are selected on the operating table control and that they are moved exclusively on both sides. There is a risk of the ES connecting plate breaking if it is moved on one side only!

Caution!
If the leg plate joints are folded down for use of the ES so that you can slide the connecting plate onto the side rail of the operating table, make sure not to move the leg plate joints again as long as the ES is mounted to the operating table.

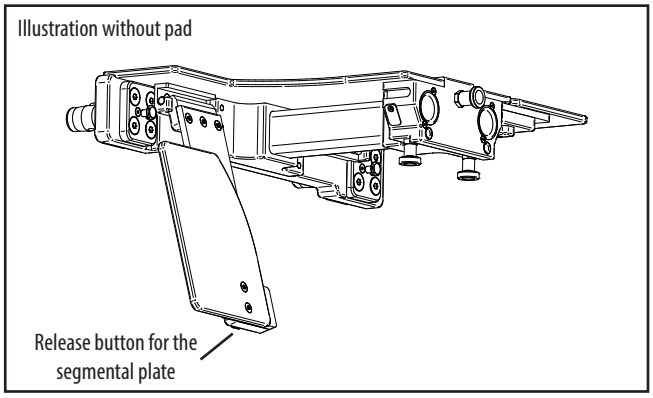
Caution!
Make sure that the operating table **is not** moved to the „zero position“ if the leg plate joints are folded down.

The cross struts with side rail adaptation are compatible with various operating table dimensions:

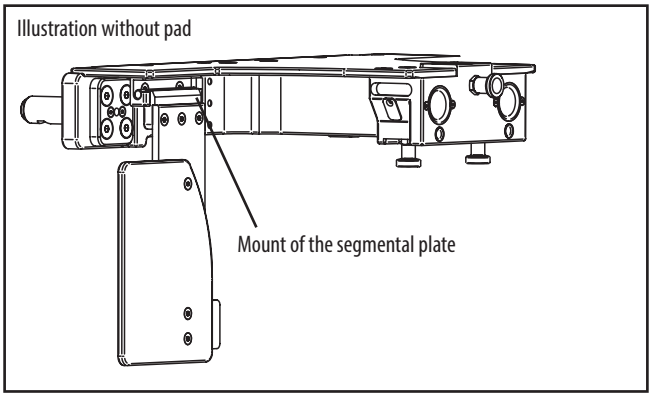
Item number ES cross strut	**Designation ES cross strut**	**Side rail dimension of the operating table [mm]**	**Width of the operating table [mm]**
RO.0001.2016.SC	Universal Cross strut for connection at slide rail	24-33x12	545-615
RO.0098.2019.US	Universal Cross strut for connection at US - side rail	24-33x12	545-615
RO.0310.2020.JP	Universal Cross strut for connection at JP - side rail	26-33x12	531-615

4.3 Removing and attaching segmental plates

The connecting plate of the extension system has removable segmental plates to enable optimal access to the patient's hip joints.



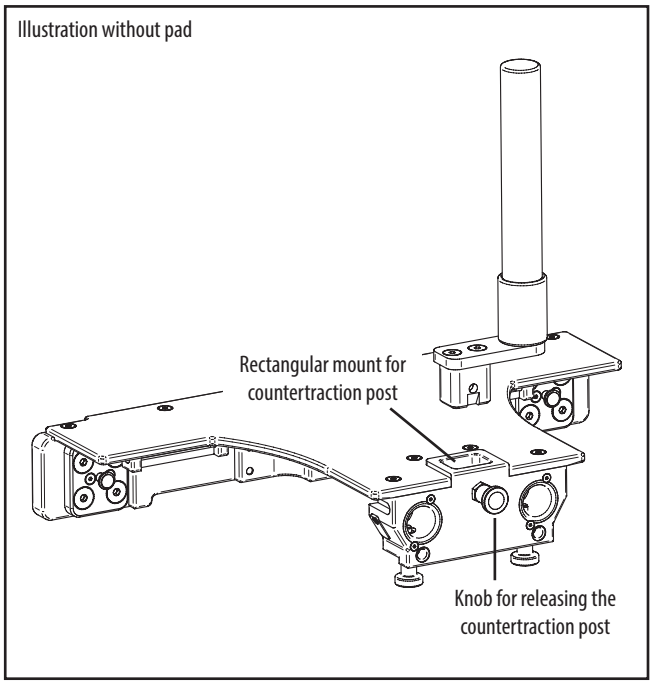
- In order to remove the segmental plate, pull the release button outwards and swing the segmental plate down.



- Lift the segmental plate all the way up from its mount.
- To attach the segmental plate, insert it into its mount and swing it upwards until the lock latches in.
- Check the segmental plate for secure fit.

4.4 Attaching and removing the countertraction post

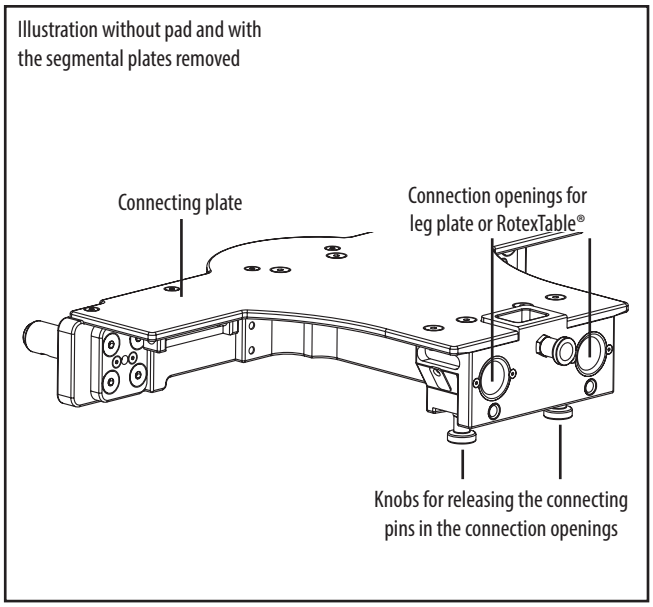
The extension system enables countering during extension and traction. A countertraction post with fitted pad is needed for that.



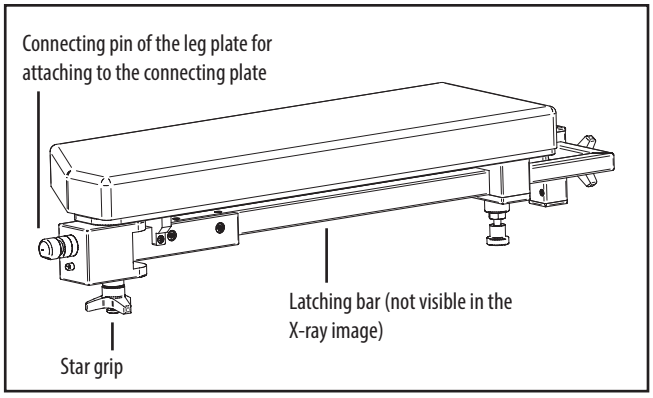
- Insert the countertraction post along with its pad into the rectangular mount of the ES so that it latches in.
- Check the countertraction post for firm seat.
- In order to remove the countertraction post, pull the knob and lift it out upwards.

4.5 Attaching and removing leg plates

The connecting plate of the extension system has at its narrow end two connection openings where leg plates or the RotexTable® can be attached.



The methods for connecting a leg plate or a RotexTable® to the ES are identical. Only the leg plate is shown here.



Danger !
The leg plate or the RotexTable® may become detached from the extension system if the connecting pins are not completely latched in. Always verify that the leg plate or the RotexTable® is firmly attached to the connecting plate of the extension system.

- Push the connecting pin into the mount on the ES until it latches in audibly.
- Verify that the leg plate or the RotexTable® is firmly latched to the connecting plate of the ES.
- To prevent the operating table from tipping, we recommend attaching a support to the leg plate after it has been attached. For more information, see chapter 4.5.
- To remove the leg plate or RotexTable®, release the connecting pin in the connection opening. Pull the knob down to do so.
- Remove the leg plate or the RotexTable®.

Swivelling leg plates

Attention !
During height adjustment or lateral movements, the RotexTable® and the leg plate may collide and damage the device. In this case, swivel the leg plate of the healthy leg outward in order to ensure sufficient freedom of movement for the RotexTable®.

If, during use, the ES is attached to a RotexTable® and a leg plate at the same time, it may become necessary to push the RotexTable® beyond the middle line position. If the leg plate is secured close to the axle, the vertical axle of the RotexTable® may interfere with the leg plate. Similarly, during a height adjustment of the RotexTable® or operating table, the ES may interfere with the horizontal axle of the RotexTable®. In both cases, swivel the leg plate outward in order to ensure sufficient freedom of movement for the RotexTable®.

The ES enables the adduction necessary to care for fractures of lower extremities.

There is a gear tooth system underneath the leg plate. Rotate to open the gear tooth system completely. The leg plate can be adjusted in 9° steps. It can be adjusted outwards to max. 36°, (or max. 55° for the standard 55° variant), and inwards to max. 45°.

- In order to swivel the leg plate, rotate the hand grip underneath it, so that the gear tooth system is released.
- Make sure that the gear tooth system is completely free.
- Now turn the leg plate in the corresponding direction.
- In order to fasten the leg plate, rotate the gear tooth system using the star grip so that it comes together.

Folding away leg plates

Attention!
In some cases, the leg plates may need to be folded away.

In the centre under the leg plate, there is a pushbutton.

- Slightly pull out the traction bars. Press this pushbutton to take off a segment of the leg plate.
- While doing this, hold on to the plate.
- Hold and carry the plate only at the pad.

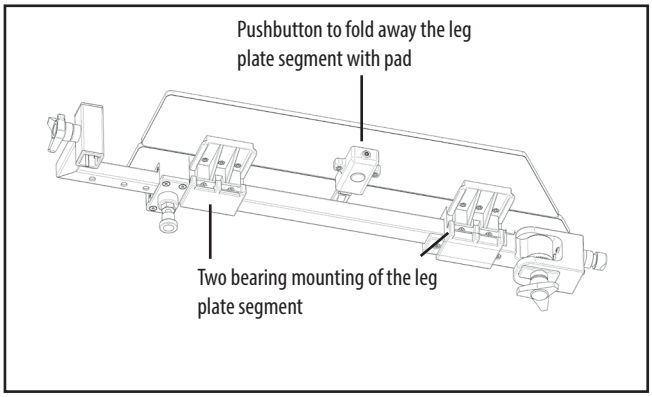
Otherwise, the pad and the plate may become loose.

- Fold down the leg plate.
- Lift the leg plate out of the two bearings.

The foldable segment of the leg plate can be placed on the transport carriage of the ES.

- To reattach the leg plate, mount the plate from the top in the two bearings.

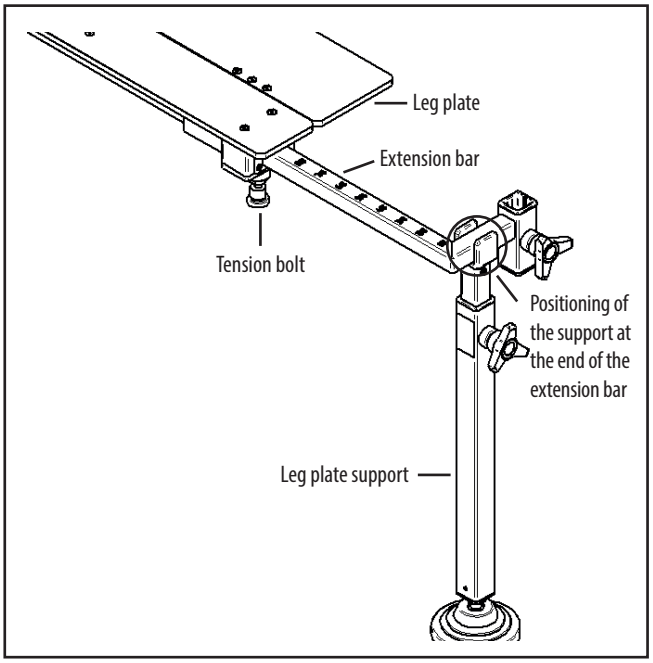
Fold up the leg plate and make sure that they are firmly attached.



4.6 Attaching and adjusting the leg plate support on the ES

„The leg plate support (also called „“support““ in the following) serves to prevent the combination of operating table and ES from tipping over.
It is recommended for some operating tables. Please observe the instructions in the delivery documents. If the support is indicated accordingly, it is to be used as follows:“

- Attach the support to the extension bar of the ES before starting the operation.
- To do this, pull out the extension bar of the leg plate.
- Place the end of the extension bar in the holder of the support.
- Fix the height of the support using the star grip after the final adjustment of the operating table height and the position of the ES leg plate has been reached (e.g. swivelled outwards).

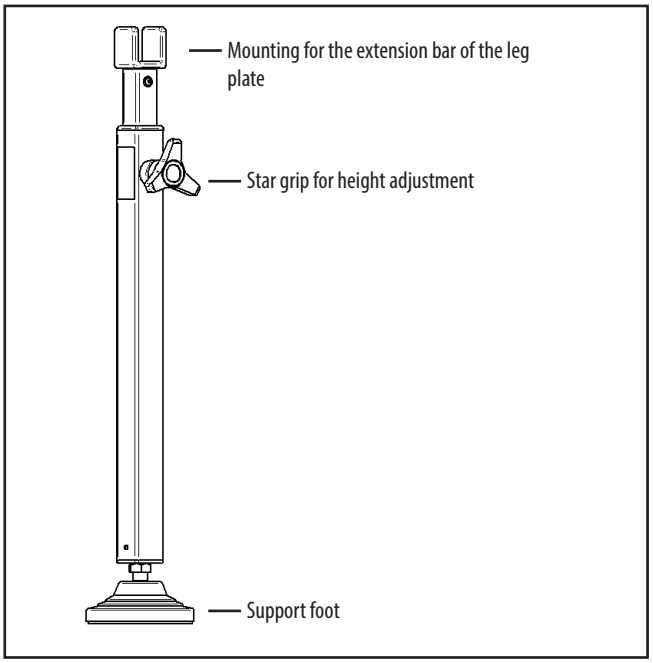


Attention!
When adjusting the height of the operating table again, the height of the support must also be readjusted. For this purpose, the star grip should be opened before moving the operating table and then fixed again at the appropriate height.

Attention!
The support must be adjusted again and positioned vertically if the operating table is moved longitudinally. Check the stability of the system again!

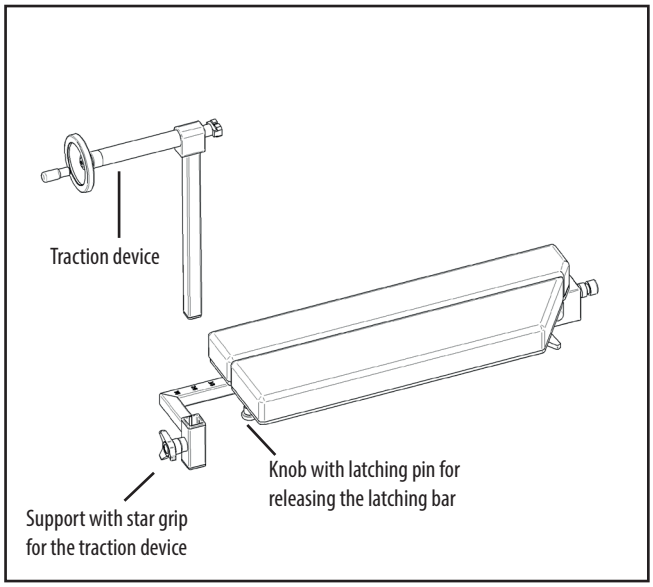
Danger!
If the operating table is moved down without first releasing the height adjustment of the support, damage may occur to the support, the ES and/or the operating table.

Danger!
If the operating table is moved upwards without adjusting the height of the support, the operating table may tip over. Therefore, adjust the height of the support each time you adjust the height of the table.



4.7 Attaching a traction device to the leg plate

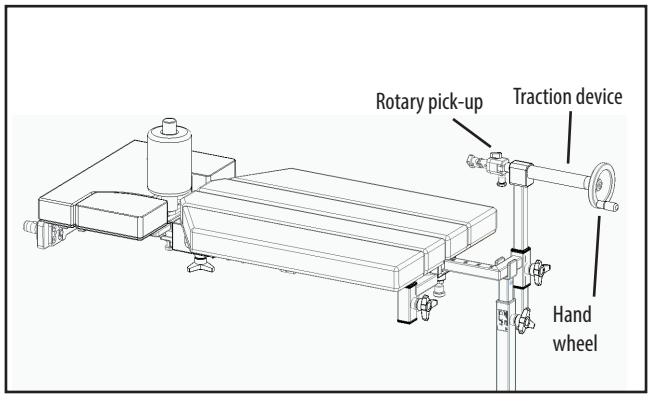
Underneath the leg plate is an extendible latching bar at whose end is a mount for the traction device. The latching bar runs outside the X-ray window so that imaging is unimpeded. The latching bar latches by means of a releasable latching pin. This enables presetting the appropriate distance of the traction device.



- Insert the traction device in the support and then tighten the star grip.
- Verify the firm seat of the traction device.
- Using the hand wheel, unscrew the traction device to the recommended starting point.

If the adjusting area of the traction device is not sufficient, set the distance of the traction device roughly using a latching bar, so that you can achieve a suitable starting position for it.

- Release the latching bar by pulling out the knob.
- Pull it out by a suitable distance until the latching pin latches back in.
- Verify that the latching bar is latched in securely.



After the patient's foot has been strapped into the RotexShoe, the shoe needs to be attached to the traction device. The shoe is attached to the traction device with a clamping claw and a corresponding rotary pick-up.

Caution !
Even though the hand wheel of the traction device runs very smoothly, injuries to the patient through excessive extension are still possible. Proceed very carefully during extension.

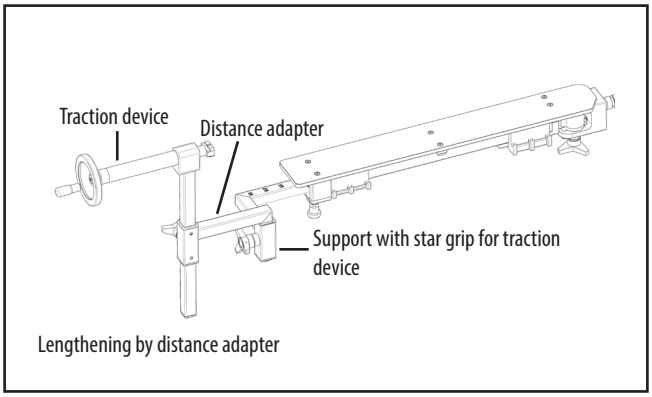
Caution !
Extension shoes that have not been properly secured can get loose, and the patient could be injured. Verify the firm attachment of the extension shoe on the traction device.

- Slide the clamping claw on the sole of the extension shoe sideways onto the rotary pick-up of the traction device.
- Fasten the clamping claw to the rotary pick-up.

For details please see the instructions for the RotexShoe.

4.8 Working with the Distance Adapter for Traction Device

The distance adapter for the traction device enables length adjustment of the ES by means of the traction bars. This may be required for particularly tall or short patients.

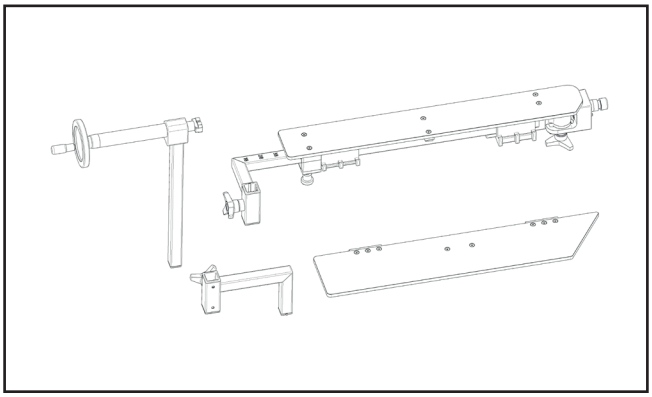


Lengthening by distance adapter

Distance adapter for extension of the traction device

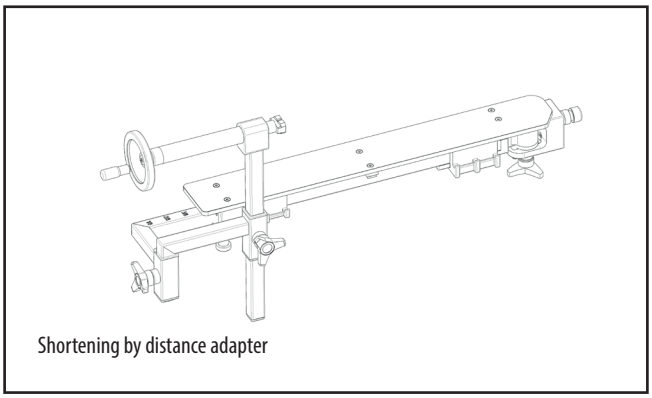
- Pull out the traction bar of the leg plate to the desired length.
- Insert the distance adapter for the traction device into the supports with star grip for the traction device.
- Ensure secure fitting of the distance adapter.
- Secure the extension with the star grip.
- Insert the traction device into the support with star grip at the distance adapter for the traction device.
- Select the suitable height of the tension device and rotate the star grip to secure the tension device.
- Make sure that the tension device is securely fitted.
- To reattach the leg plate, mount the plate from the top in the two bearings.

Fold up the leg plate and make sure that they are firmly attached.



Distance adapter for shortening of the traction device

- Slightly pull out the traction bars.
- Fold away the leg plate and secure the removed leg plate segment.
- Insert the distance adapter for the traction device into the support with star grip at the traction bar.
- Make sure that the distance adapter faces towards the patient.
- Insert the traction device into the support with star grip at the distance adapter for the traction device.
- Select the suitable height of the tension device and rotate the star grip to secure the tension device.
- Make sure that the tension device is securely fitted.


Shortening by distance adapter

4.9 Working with the extension system

Ensure the stable positioning of the system, including the patient, before each use. When using the leg plate support, also observe the instructions in chapter 4.5!

Attention!
When using the ES, make sure that nothing is under the system. Otherwise, when lowering the operating table, damage to the ES and/or operating table may occur.

Setting the home position of the traction device

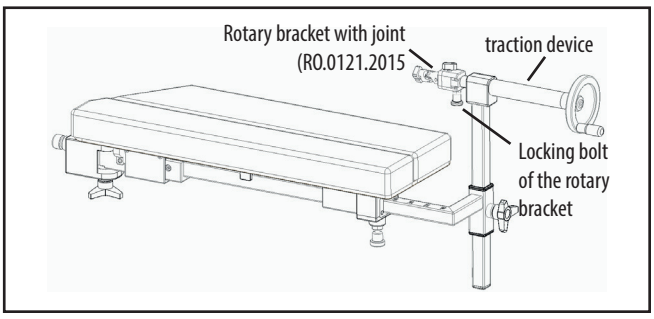
If the adjusting area of the traction device is not sufficient, set the distance of the traction device roughly using a latching bar, so that you can achieve a suitable starting position for it.

- Using the hand wheel, unscrew the traction device to the recommended starting point, in order to be able to use the maximum adjustment range.
- Release the latching bar by pulling out the knob.
- Pull it out by a suitable distance until the latching pin latches back in.
- Verify that the latching bar is latched in securely.
- Using the hand wheel, unscrew the traction device to the recommended starting point, in order to be able to use the maximum adjustment range.

Attach the rotation adapter to the traction device

The ES can be equipped with different rotation adapters. A rotation adapter with joint (RO.0121.2015) is supplied as standard.

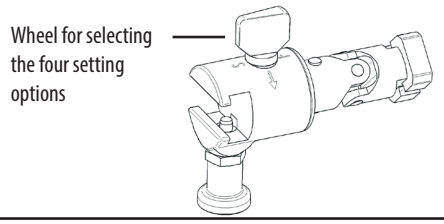
- Attach the rotation adapter to the traction device. This engages by means of a locking bolt.
- To release the Rotary bracket, pull the locking bolt to thus unlock the attachment.



The rotation adapter (RO.0202.2019) gives you four optional setting options for fine adjustment of the foot rotation:

1. fixed locked foot position
2. freely rotating foot position
3. fine rotation inward
4. fine rotation outward

Rotation adapter ES with four setting options for fine adjustment of foot rotation RO.0202.2019



Attaching an extension shoe to the traction device

After the patient's foot has been strapped into the RotexShoe, the shoe needs to be attached to the traction device. The shoe is attached to the traction device with a clamping claw and a corresponding rotary pick-up.

Caution !
Extension shoes that have not been properly secured can get loose, and the patient could be injured. Verify the firm attachment of the extension shoe on the traction device.

- Using the hand wheel, unscrew the traction device to the recommended starting point, in order to be able to use the maximum adjustment range.

For details please see the instructions for the RotexShoe.

Patient positioning instructions

Check in the instructions for use of the operating table whether it permits asymmetric movement of one-piece attachment modules. For operating tables with the function of an asymmetric leg plate adjustment, this must not be used as long as the ES is attached!

Caution !
Please make sure that both leg plates are selected on the operating table control and that they are only moved on both sides. There is a risk of the ES conncting plate breaking if it is moved on one side only!

Preoperative:
Position the patient's pelvis on the connecting plate of the ES so that the patient is lying against the counter traction post. Make sure that no pressure points can occur.

Postoperative:
Move the patient back to a central position over the operating table column immediately after the operation! To do this, position the patient in the direction of the head section of the operating table before transferring him to the transporter/ carrier.

Danger!
After the operation, make sure that the patient is centrally positioned on the operating table before transporting him out of the operating room! There is a risk of tipping!

Space for longitudinally adjustable bed surface

Attention !
When using an extension system on a longitudinally adjustable bed surface, the extension system may press against the centre column of the operating table and damage the device. Avoid longitudinal movement, in particular when the extension system slants down. Always ensure sufficient space for the longitudinally adjustable bed surface.

Space for the leg plate on the extension system

Attention !
During height adjustment or lateral movements, the RotexTable® and the leg plate may collide and damage the device. Swivel the leg plate outward in this case in order to ensure sufficient freedom of movement for the RotexTable®.

If, during use, the ES is attached to a RotexTable® and a leg plate at the same time, it may become necessary to push the RotexTable® beyond the middle line position. If the leg plate is secured close to the axle, the vertical axle of the RotexTable® may interfere with the leg plate. Similarly, during a height adjustment of the RotexTable® or operating table, the ES may interfere with the horizontal axle of the RotexTable®. In both cases, swivel the leg plate outward in order to ensure sufficient freedom of movement for the RotexTable®.

The ES enables the adduction necessary to care for fractures of lower extremities.

There is a gear tooth system underneath the leg plate. Rotate to open the gear tooth system completely. The leg plate can be adjusted in 9° steps. Depending on the leg plate variant, these can be swiveled outward by max. 36° or 55° (leg plate variant: standard 55°) and inward by max. 45°.

The standard 55° leg plates facilitate the use of the X-ray unit for fracture treatment. Both legs can be clamped in the traction devices and, thanks to the extended swivel radius, the X-ray unit can be positioned between the patient's legs.

- In order to swivel the leg plate, rotate the hand grip underneath it, so that the gear tooth system is released.
- Make sure that the gear tooth system is completely free. Now turn the leg plate in the corresponding direction.
- In order to fasten the leg plate, rotate the gear tooth system using the star grip so that it comes together.

Applying tension

Caution !
Even though the hand wheel of the traction device runs very smoothly, injuries to the patient through excessive extension are still possible. Proceed very carefully during extension.

4.10 Addition: Side rail adaptation ES for vertical drape support

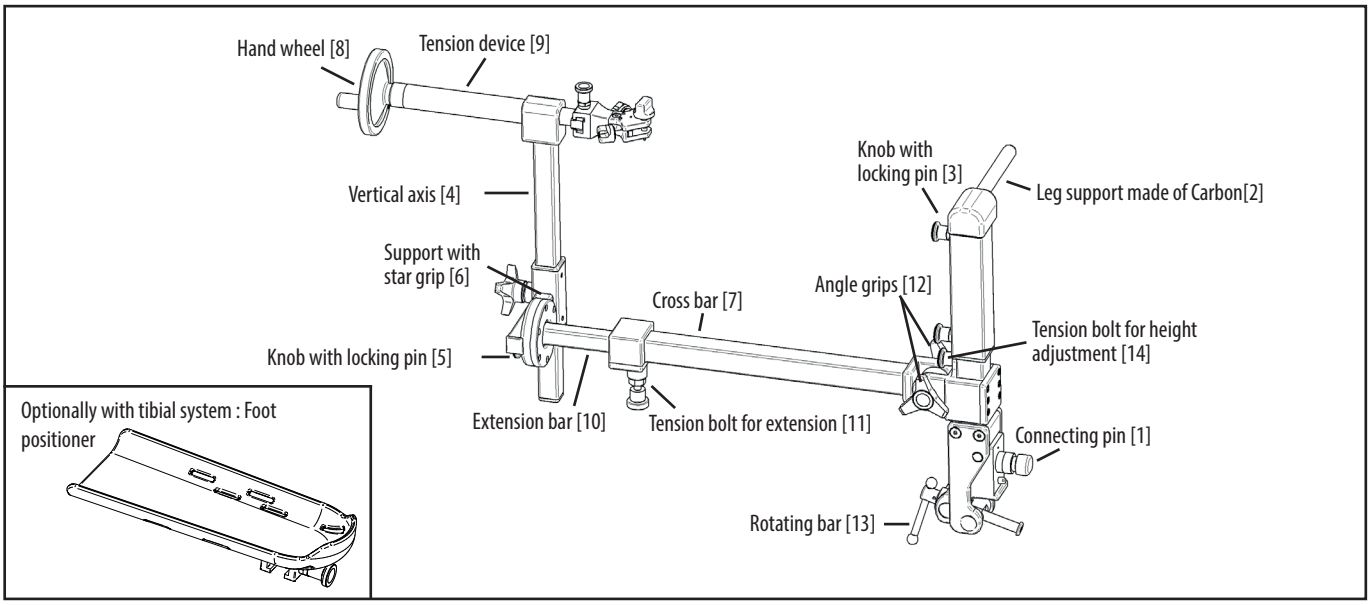
ES drape support for vertical drapes can be attached to the ES using a side rail adaptation (RO.0230.2021). For this purpose, the side rail adaptation for the ES is attached to its extension bar. A radial clamp and thus a cover holder can be attached to the side rail.

Danger!
The maximum permitted weight for side rail adaptation for a drape holder is 5 kg! Also observe the maximum permitted total weight for the ES and the operating table. Make sure that the complete system is stable!

5. ES accessories: Tibial System

Connecting the tibial system with the ES

The tibial system serves as bearing support for treatment of tibial fractures. It is used as accessory in connection with the ES. It may only be used for human medical treatments. It may only be used by medical personnel.

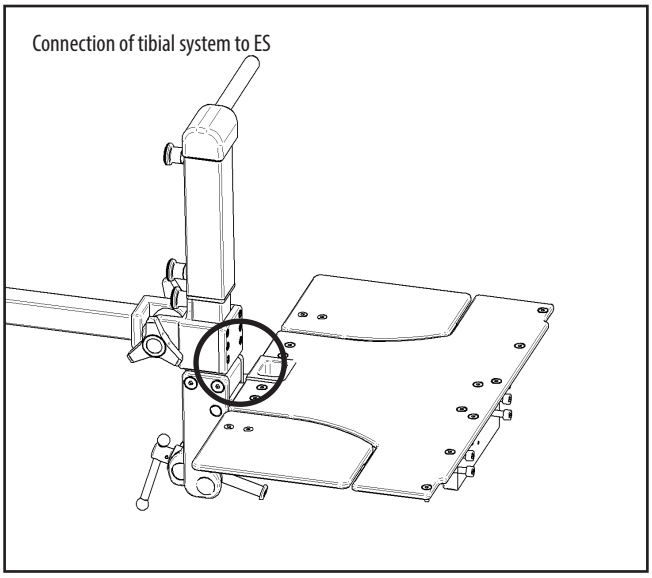


First, remove the leg plates of the ES. Afterwards, the tibial system can be attached to the ES with a connecting pin [1].

- For removal of the leg plate, lift the fractured leg.
- To release the leg plate, unlock the connecting pin at the connection opening. To do so, pull down the knob with the locking pin.
- Remove the leg plate.

For attachment of the tibial system , proceed as follows:

- Insert the connecting pin [1] of the tibial system into the connection opening of the ES.
- Check the secure connection of the tibial system at the connecting plate of the ES.



Removal of the tibial system from the connecting plate

- To release the tibial system , unlock the connecting pin by pulling down the knob to unlock the connecting pin of the ES.
- The tibial system can now be removed.
- Reinsert the leg plate of the ES and check secure fitting of the connecting plate.

Changing the OP side of the tibial system

- The tibial system can be individually set and used on both sides. When setting up the system , the leg support [2] and the vertical tension device [4] must face outwards to the side of the fractured leg.
- To change the position of the leg support [2], pull the knob with locking pin [3] and lift the leg support [2].
- Rotate the leg support [2] by 180° to the desired side.
- Push in the leg support to lock the knob with locking pin [3] into place.
- For repositioning of the vertical axis [4], remove it from the support [6] by unscrewing the star grip.
- Afterwards, pull at the knob with locking pin [5] and rotate the support with star grip for the vertical axis [4] also by 180°.
- Afterwards, reinsert the vertical axis [4] into the support [6] and lock it with the star grip.
- Check secure fitting of the leg support [2] and the support with star grip at the cross bar [7] and the vertical axis [4].

Positioning of the fractured leg on the tibial system

- Position the fractured leg over the padded leg support [2]. The pad of the bar must be positioned behind the thigh over the hollow of the knee.
- Position the vertical tension device [4] in the support with star grip [6].
- Select the suitable height and tighten the star grip.
- Screw out the tension device [9] at the hand wheel [8] to the recommended start point.

Caution!
The hand wheel of the tension device [8] can be moved very easily. Extend the device with care.

If the adjustment range of the traction device [9] is not sufficient, roughly set the distance of the tension device at the extension bar [10] to obtain a suitable start position of the tension device [9].

- Unlock the cross bar [7] by pulling out the connected tension bolt extension [11].
- Pull out the cross bar to a suitable length until the knob is locked into place with the latching pin.
- Check secure locking of the cross bar [7].
- The cross bar [7] has 5 options for locking at the extension bar [10].
- Removal of the cross bar [7] from the extension bar [10] is not possible by simply pulling out the locking pin [11].

Connection of the tibial system in the wire bracket holder
Use the standard wire bracket.

- For connection of a standard wire bracket, slide the wire bracket holder on the support [6] of the tibial system and press the star grip for locking.
- The knob of the locking pin at the wire bracket holder is only used to remove the wire bracket holder.
- At the angle grips [12], the suitable angle is set for the respective operation.

Inclination and height adjustment

For setting of an optimum inclination for the hip joint, a rotating bar [13] can be found under the connection to the ES. Rotate the rotating bar [13] to adjust the overall alignment of the tibial system. The entire leg is additionally inclined in the hip joint.

- The leg should not be lowered under traction.
- First, set the tibial system before final positioning with the hand wheel [8] of the tension device.

For optimum inclination of the lower leg, two angle grips [12] can be found at the horizontal axis.

- Open the outer angle grip to set the ideal angle. The gear tooth system at the star grip [12] enables adjustment in steps of 9°.
- Close the grip and check secure fitting.
- While the angle grip [12] is open, always hold on to the entire extension bar [10].
- By further opening the angle grip [12], the entire gear tooth system is opened. Make sure to hold the extension bar [10] during opening.

Additionally, the height of the cross bar [7] must be set at a tension bolt for height adjustment [14].

- Pull out the locking pin and slide the extension bar along the vertical axis [4] until the respective height is set.
- Make sure that the extension bar locks into place.
- The extension bar [10] can be adjusted over 120 mm.
- The extension bar [10] can be set to five different heights at the vertical axis [4].

Check tight and secure fitting of all components after each adjustment.

6. Cleaning and disinfection

Cleaning the metal and plastic components

The metal and plastic components of the extension system may only be cleaned with a disinfectant wipe.

Attention !
Abrasive detergents may damage surfaces. Do not use abrasives for cleaning.

A weakly alkaline detergent, i.e. low-intensity bleach, soapsuds or clinical cleaners may be used for cleaning.

Cleaning the pads

The pad cushions the seat and bed surfaces.

Damaged pads may soak up moisture and germs. Immediately replace such pads for hygienic reasons. Contaminated pads must be cleaned immediately and disinfected if required. Observe general hygiene requirements.

Attention !
Abrasive detergents may damage surfaces. Do not use abrasives for cleaning.

Attention !
Skin disinfectants may cause discolourations in the pads. Immediately remove skin disinfectants from the pad to avoid discolourations.

Attention !
Alcoholic detergents damage the faux leather (hardening and tearing). Do not use these agents for cleaning or disinfection.

Do not use automated cleaning or disinfection methods.

A weakly alkaline detergent, i.e. low-intensity bleach or soapsuds may be used for cleaning.

Disinfecting the pads

We recommend the use of surface disinfectants with the following proven combinations of active ingredients:

– Aldehydes
– Quaternary ammonium bases (QAB)
– Guanidine derivatives

These agents have a longer evaporation period, while the disinfecting component remains on the surface. On a surface that has been cleaned from coarse particles, >95% lethality is achieved after only a few minutes. The above surface disinfectants do not degrade the pads and pass hygiene inspections. Due to its fast evaporation and lack of a long-term effect, alcohol does not provide any significant benefits.

Quaternary ammonium bases remain on the surface as organic salts. This has the advantage of being effective even with residual moisture. The drawback is a certain stickiness due to the buildup of a saline layer. We recommend removing this saline layer periodically every 3-6 months using cleaners with non-ionogenic tensides. This prevents stickiness and significantly improves the longevity of the materials.

During skin disinfection of the patient with alcoholic agents it is very important to ensure that the disinfectant does not come into contact with the pads. Alcoholic disinfectants damages the pads surfaces by causing the material to harden, form cracks, etc. Such defects, as well as any defects resulting from the improper use of cleaners and disinfectants, are not covered by the warranty.

Because hand disinfectants frequently consist of or contain alcohol, they are not suitable for use on the pads.

Caution !
Disinfectants containing alcohol can cause inflammable gas mixtures. Do not use alcoholic disinfectants.

7. Inspections and maintenance

Careful handling, inspections and maintenance uphold the function and operational safety for many years. Inspections improve safety and minimise the risk of malfunctions. To ensure the operational reliability of the product, an annual inspection/ maintenance has to be carried out according to generally accepted rules of technology.

Please note that according to operator regulations only persons, companies or institutions may be assigned to do service (maintenance, inspection, repair and upgrading) that have the technical knowledge, conditions and the required means for the proper execution of these tasks.

Maintenance improves reliability. It is a critical prerequisite for maintaining the functional and operational safety. We therefore recommend conducting maintenance in regular intervals.

Inspecting the pads

Attention !
Pointed or sharp objects may damage the pads. Be careful with pointed or sharp objects.

Attention !
Damaged pads may soak up moisture. Always replace damaged pads immediately.

- Periodically check the pads for damage and soiling.

Checking the extension system

- Verify the proper working condition of the device before each operation. Have defective parts replaced immediately.

8. Repairs

In case of malfunctions and pending repairs or maintenance, please contact the manufacturer Condor® MedTec exclusively.

The manufacturer will assign an appropriate service provider to you.

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GERMANY

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www.condor-medtec.de

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.

9. Replacement parts

Replacement parts you may need should only be acquired from Condor® MedTec GmbH.

Always have the article number at hand when ordering technical descriptions or replacement parts from the manufacturer. This information is on the laser inscription or label of the respective product.

10. Disposal

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

Fabricant	
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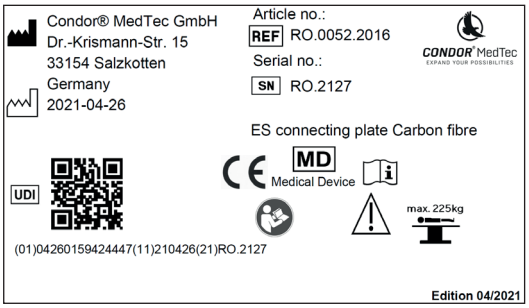
CH REP	Swiss AR Services GmbH Industriestrasse 47 CH-6300 Zug, Switzerland

11.1 Working load and weight

Safe working load	225 kg
Total weight ES	approx. 45 kg
Weight of the connecting plate	approx. 10 kg

Table Working load and weight

11.2 Example of a nameplate



11.3 Classification

According to Annex VIII, Rule 1 of the Medical Device Directive MDR (EU) 2017/745, the ES is a class 1 medical device.

11.4 Applied standards

The ES complies with the applicable essential safety and performance requirements according to Annex I of the Medical Device Regulation (MDR), Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices applicable national regulations such as the Medical Devices Act.

The ES also complies with the following standard requirements:

- EN ISO 13485

11.5 Certificates

- Current certificates are available for download on our website (https://condor-medtec.de/en/downloads/).

12. Copyright

We wish you every success with the Condor® Extension System (ES). Please contact us for any further questions and suggestions.