

Instructions for Care and Use

Condor RotexTable®

CE

444.GA.RO.EN Last updated on 30.08.21

Contents

	iction	
1.1	About this manual	. 3
1.2	Symbols used in the text	. 3
1.3	General safety instructions	. 3
1.4	Graphical symbols used	. 6
2. Basic re	quirements	. 7
2.1	Intended use	. 7
2.2	Device description	. 8
3. Commi	ssioning	. 9
3.1	Ambient conditions	. 9
3.2	Transport	. 9
3.3	Unpacking	. 9
4. Operat	ion	10
4.1	Charging the battery modules	10
4.2	Connecting the battery module with the RotexTable®	10
4.3	Connecting the spiral control cable	11
4.4	Connecting the foot switch	11
4.5	Switching on	12
4.6	Moving the RotexTable [®]	12
4.7	Connecting the RotexTable [®] with the operating table	13
4.8	Securing the foot and the lower leg in the RotexShoe [®] extension shoe	14
4.9	Fastening and positioning the extension shoe at the RotexTable [®]	
) Setting suitable start points for the operations	
	Setting the height of the horizontal beam with the handheld controller	
	2 Setting the height of the horizontal beam with the foot switch	
	3 Setting the height of the horizontal beam with the hand crank	
	Rotation of the secured foot and the lower leg	
	ion / Traction	
6. Trauma	tology extension	21
	Transport position	
62		21
	Modification for hip operations	22
6.3	Modification for hip operations	22 23
6.3 7. Troubl e	Modification for hip operations	22 23 24
6.3 7. Troubl e 8. Cleani	Modification for hip operations	22 23 24 24
6.3 7. Trouble 8. Cleanin 9. Electro	Modification for hip operations Modification for traumatological treatment. Ashooting and disinfection magnetic compatibility (EMC)	22 23 24 24 25
6.3 7. Trouble 8. Cleanin 9. Electro 9.1	Modification for hip operations Modification for traumatological treatment	22 23 24 24 25 25
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2	Modification for hip operations . Modification for traumatological treatment. ashooting . ag and disinfection . magnetic compatibility (EMC) Electromagnetic emissions. Electromagnetic immunity.	22 23 24 24 25 25 25
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3	Modification for hip operations Modification for traumatological treatment. ashooting and disinfection magnetic compatibility (EMC) Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment.	22 23 24 25 25 25 25 26
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4	Modification for hip operations . Modification for traumatological treatment. ashooting . ag and disinfection . magnetic compatibility (EMC) Electromagnetic emissions. Electromagnetic immunity.	22 23 24 25 25 25 25 26 27
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces	Modification for hip operations . Modification for traumatological treatment. Ashooting . Ag and disinfection . magnetic compatibility (EMC) Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . Sories	22 23 24 25 25 25 25 25 26 27 28
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare	Modification for hip operations . Modification for traumatological treatment . eshooting . ag and disinfection . magnetic compatibility (EMC) Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment . Recommended separation distances . sories . parts .	22 23 24 25 25 25 25 26 27 28 28
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai	Modification for hip operations . Modification for traumatological treatment. eshooting . magnetic compatibility (EMC) . Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . sories . parts .	22 23 24 25 25 25 25 26 27 28 28 28 28
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai 13. Stora	Modification for hip operations . Modification for traumatological treatment. eshooting . ag and disinfection . magnetic compatibility (EMC) . Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . sories . parts . rs .	22 23 24 25 25 25 25 26 27 28 28 28 28 28
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai 13. Stora 14. Techn	Modification for hip operations . Modification for traumatological treatment. eshooting . magnetic compatibility (EMC) . Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment . Recommended separation distances . sories . parts .	22 23 24 25 25 25 25 25 26 27 28 28 28 28 28 28 28 29
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai 13. Stora 14. Techn	Modification for hip operations . Modification for traumatological treatment. ashooting . ag and disinfection . magnetic compatibility (EMC) . Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . sories . parts . rs . ge . ical specifications .	22 23 24 25 25 25 25 26 27 28 28 28 28 28 28 29 29
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai 13. Stora 14. Techn 14.	Modification for hip operations . Modification for traumatological treatment. eshooting ag and disinfection magnetic compatibility (EMC) Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . sories parts rs ge ical specification .	22 23 24 25 25 25 25 26 27 28 28 28 28 28 28 29 29 29
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai 13. Stora 14. Techn 14. 14.	Modification for hip operations . Modification for traumatological treatment. schooting . ag and disinfection . magnetic compatibility (EMC) . Electromagnetic emissions. Electromagnetic immunity . Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . sories . parts . rs . ge . ical specifications . Classification . Example of a nameplate	22 23 24 25 25 25 26 27 28 28 28 28 28 28 29 29 29 29 29
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 13. Stora 13. Stora 14. Techn 14. 14. 14.	Modification for hip operations . Modification for traumatological treatment. eshooting	22 23 24 25 25 25 26 27 28 28 28 28 28 28 29 29 29 29 29 29
6.3 7. Trouble 8. Cleanin 9. Electro 9.1 9.2 9.3 9.4 10. Acces 11. Spare 12. Repai 13. Stora 14. Techn 14. 14. 14. 14.	Modification for hip operations . Modification for traumatological treatment. schooting . ag and disinfection . magnetic compatibility (EMC) . Electromagnetic emissions. Electromagnetic immunity. Electromagnetic immunity for non-life-supporting equipment. Recommended separation distances . sories . parts . rs . ge . ical specifications . Classification . 2 Example of a nameplate . 3 Applied standards . 4 Certificates .	22 23 24 25 25 25 26 27 28 28 28 28 28 29 29 29 29 29 29 30

1. Introduction

1.1 About this manual

This section provides information about the structure of this manual, as well as explanations of the icons and symbols used in the text.

This operating manual gives instructions regarding the use of the RotexTable[®].

This operating 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 announcements. If you have any questions, please contact us.

Any person using the RotexTable[®] must read the operating 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 RotexTable[®] is built according to state of the art technology and complies with accepted safety rules. However, its use may present risks to the patient or third parties or of damages to the device or other property.

Only use the RotexTable[®] if it is in good repair and only for the intended use, with regard to safety and possible dangers, and observing the instructions in this manual. Immediately repair any defects that could possibly affect safety.

The RotexTable[®] is equipped with conductive double castors. With a conductive floor, the RotexTable[®] may be used in areas where explosion is a danger.

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 modifications or attach any parts unless explicitly approved by the manufacturer. 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 sound disposal of operating materials, accessories, and replaced parts.

Summary of the safety instructions



Caution!

If the adapter is not secured, the RotexTable[®] can accidentally detach from the operating table and cause injury. Lock the adapter to prevent injuries.



Caution!

Worn sawtooth straps or buckles can come loose accidentally, resulting in injuries. Check that the extension shoe is securely in place on the RotexTable[®]. Use extension shoes only if the components are in new condition.



Caution!

The feet of the patient can come loose if the liner is too large, and the patient can be injured. Ensure a tight fit and pad the foot if necessary.



Caution!

If significant tensile or compressive forces occur for long application periods, then injury can result. Check the position in the foot area regularly to avoid injury. The duration of application should not exceed 1–2 hours.



Caution!

When releasing the sliding carriage to move freely, it can move down and pinch or crush. Always hold the sliding carriage securely in one hand when releasing to move freely.



Caution!

Extension shoes that have not been correctly secured can become loose, and the patient could be injured. Please check that the clamping claw fits tight on the rotary bracket.



Caution!

If the sliding carriage is blocked, for example by adhesive strips for securing the sterile covers, softtissue damage can occur when adjusting the height. Make sure when making adjustments that the sliding carriage can move freely.



Caution!

When the double castors are secured while adjusting the height, the RotexTable[®] can topple over. Before adjusting the height, make sure that the double castors are not secured. If so, unlock the double castors.



Caution!

If the components for traumatological treatment have not been dismantled, and the horizontal beam swivels downwards after the RotexTable[®] is detached from the operating table, these components could hit against the profile of the vertical beam. Injuries or damage may result. Always remove the exchangeable support for traumatological treatment before you detach the RotexTable[®] from the operating table!



Caution!

If pushed when the traumatological extension is mounted, the RotexTable[®] can tip over and cause injuries. Before pushing, always set the transport position so that the system's centre of gravity is as low as possible.



Notice!

If the RotexTable[®] was transported or stored at cold temperatures, then it needs a certain temperature and amount of time to get acclimated. If the acclimation time is too brief or if temperatures are unsuitable, the RotexTable[®] could be damaged and fail. Acclimate the RotexTable[®] after great temperature fluctuations for at least 12 hours.



Notice!

If the RotexTable[®] is moved by pushing in the direction of the compact side (with the rotator forwards), the tipping limit could be exceeded at obstructions or high thresholds. Only push the RotexTable[®] in the direction of the long side, with the controller board housing forwards. In this case the maximum permissible threshold height is 10 mm.



Notice!

If you remove the spiral control cable between the handheld controller and the horizontal beam, moisture can enter the open sockets during cleaning and damage the device. To prevent moisture entering, never remove the spiral cable before cleaning.



Notice!

If the foot switch connection plug is removed, moisture can enter the open sockets and damage the device. Always place the blind plugs in the foot switch socket to prevent moisture entering.



Notice!

Abrasive cleaning agents may damage the padding surface. Do not use abrasives for cleaning.

1.4 Graphical symbols used

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

Graphical symbol	Identification
REF	Identification in agreement with ISO 15223-1 standard.
	Symbol for "product number"
	Identification in agreement with ISO 15223-1 standard.
JN	Symbol for "serial number"
	Identification in agreement with ISO 15223-1 standard.
	Symbol for "name and address of the manufacturer"
П	Identification in agreement with ISO 15223-1 standard.
	Symbol for "date of manufacture"
~~~	Identification in agreement with ISO 15223-1 standard.
l	Symbol for "observe instructions for use"
	Identification in agreement with ISO 15223-1 standard.
	Symbol for "store away from sunlight"
LATEX	Identification in agreement with ISO 15223-1 standard.
	Symbol for "latex-free"
	Identification in agreement with ISO 15223-1 standard.
	Symbol for "not re-usable"

Graphical symbol	Identification
NON STERILE	Identification in agreement with ISO 15223-1 standard. Symbol for "product not sterile"
MD	Labelling of medical devices. Symbol for "Medical Device"
UDI	Identification for a data carrier which contains the Unique Device Identifier contains. Symbol for "Unique Device Identifier".
Ń	Identification of a Type B applied part according to EN 60601-1.
CE	Labelling of products developed and marketed in accordance with relevant European legal provisions.
max. 220kg	Specification for the maximum load for the RotexTable of 220 kg. In case of lower weight allowance of the operating table, the lower value applies.

2. Basic requirements

2.1 Intended use

The RotexTable[®] is exclusively intended for human medical uses. The RotexTable[®] is a leg positioning device. It is an accessory for a medical device. It may only be used in combination with an operating table. Provide the operating table model when ordering your RotexTable[®] and you will receive the adapter for the corresponding operating table model at delivery.

The RotexTable[®] can be transported. It may be moved together with the operating table, but only without a patient; it may not be moved together with the secured patient.

The RotexTable[®] is used to support the patient during operations on the lower extremities, as well as during patient preparation and post-operative transfer to anesthesia recovery. With the installed traumato-logical extension, the RotexTable[®] is also used to support the pa-tient during traumatological treatment of the legs, for instance during fracture treatment. The traumatological extension especially enables work on the legs of the patient under X-ray observation. The device is used to raise and lower the legs. The fine adjustment in terms of rotation, extension, traction, adduction and abduction are optimised.

The device is characterised in particular by easy set up and operation of the adjustment equipment. The device can be connected using various adapters to a wide range of operating tables. The locking mechanism of the double castors is not actuated during the operation, particularly when raising and lowering the legs. The system "operating table – RotexTable®" is secured by the operating table's locking mechanism. The RotexTable® may be used for patients weighing up to 220 kg. If the load capacity of the operating table is lower, then this lower safe load capacity of the operating table applies.

The RotexTable[®] is permitted to be operated inside rooms for medical use of the application groups 0, 1 and 2 according to DIN VDE 0100-710. Their electrical installation must meet the regulations of the VDE 0100-710:2004-06 or the IEC 60364-7-710:2002.

The user of the operating table and the RotexTable[®] must be instructed in the proper use.

The RotexTable[®] may only be handled by persons who have familiarised themselves with the product by means of this manual. It may only be used in complete accordance with the operating manual. We will not accept liability for property damage or personal injuries caused by third-party accessories or non-compliance with the intended use. The specified application is the intended use. For the operator or user, the labels and the manual yield the complete intended use. The operating table may only be used in complete accordance with the operating manual.



Use as intended includes compliance with the instructions in this manual and observing the inspection and maintenance intervals.

2.2 Device Description



3. Commissioning

3.1 Ambient conditions

The RotexTable[®] may be exposed to environmental conditions which are within the following limits:

Operation		
Ambient temperature	5°C -+ 40°C	
Relative humidity	20% – 90% bei 30°C – not condensing	
Pressure	800hPa – 1060hPa (corresponds to an estimated height of ≤ 2000m)	



Notice!

If the RotexTable[®] was transported or stored at cold temperatures, then it needs a certain temperature and amount of time to get acclimated. If the acclimation time is too brief or if temperatures are unsuitable, the RotexTable[®] could be damaged and fail. Acclimate the RotexTable[®] after great temperature fluctuations for at least 12 hours.

3.2 Transport



Notice!

If the RotexTable[®] is moved by pushing in the direction of the compact side (with the rotator forwards), the tipping limit could be exceeded at obstructions or high thresholds. Only push the RotexTable[®] in the direction of the long side, with the controller board housing forwards. In this case the maximum permissible threshold height is 10 mm.

The RotexTable $^{\circ}$ is packed ready for shipment when it leaves the plant.

- If you wish to transport the RotexTable[®], set the horizontal beam to the up position.
- Unlock the square pipe and pull the pipe from the adapter.
- Swivel the horizontal beam down.



If it hits something while lowering, the downward motion is stopped automatically.

Lower the hanging horizontal beam.

3.3 Unpacking

If possible, transport the RotexTable[®] to its final location in its original packaging. Inspect its condition.

Report any transport damage immediately. To do so, please contact us; see the last page of this manual for the address and phone number.

4. Operation

4.1 Charging the battery modules

A battery module supplies the RotexTable[®] with energy for raising and lowering the horizontal beam.

The battery modules are charged with an external charging unit.The external charging unit is attached to the wall with a mounting rail and connected to the mains.

The battery module has a snap lock on the top of its back side. By this means, the module can be inserted in the charging unit and snapped into place.



- Connect the external charging unit to the mains supply. The green LED in the charging unit lights up. It indicates that the charging unit is connected to the mains voltage.
- Now set the battery module with its bottom side onto the external charging unit and let it snap into this position.
 - The yellow LED in the charging unit lights up, indicating that the unit is charging. The charging process starts automatically and ends when the battery module is charged, after about 4 hours.

4.2 Connecting the battery module with the RotexTable®

The battery module has a snap lock on the top of its back side. The snap lock clicks into the mounting rail on the wall mount and on the vertical beam.





In the display under the main switch, after each actuation, the charge status of the battery is shown for about 10 seconds. Error messages, such as an overload, are also displayed here. To delete error messages, switch the device off by pushing in the main switch. Then switch the device back on by pulling out the switch.

- To remove the battery module, grip the handhold on the upper back side.
- Pull up to disengage the snap lock and lift the battery module up and out
- To fasten the battery module to the vertical beam of the RotexTable[®], place the lower part of it on the control unit and press the upper side back until the snap lock clicks in place.



In the same way, the battery module on the external charger or mounting rail of the wall mounting can be attached or detached.

4.3 Connecting the spiral control cable



Notice!

If you remove the spiral control cable between the handheld controller and the horizontal beam, moisture can enter the open sockets during cleaning and damage the device. To prevent moisture entering, never remove the spiral cable before cleaning.



The spiral control cable connects the handheld controller with the horizontal beam. Only with this spiral cable is electrical lifting and lowering of the horizontal beam possible.

• Connect the plug of the spiral control cable into the socket on the bottom of the handheld controller.



 Insert the plug on the other end of the spiral control cable into the socket behind the hand wheel on the horizontal beam.

4.4 Connecting the foot switch

The socket for the foot switch is located on the vertical beam above the carriage.



Notice!

If the foot switch connection plug is removed, moisture can enter the open sockets and damage the device. Always place the blind plugs in the foot switch socket to prevent moisture entering.



- Connect the plug of the foot switch cable into the socket on the vertical beam above the carriage.
- Lay the foot switch at the desired position on the floor.
- Switch the RotexTable® on as described in the following.

4.5 Switching on

The controller with the mounted battery module is located in the lower section of the vertical beam. The red main switch is located on the front side of the controller.

The main switch is also used as an emergency-stop switch; the RotexTable[®] is completely de-energised when the main switch is pushed in.



- To switch on the RotexTable[®], pull the main switch all the way out so that you hear a clear click.
 - In the display under the main switch, after each actuation, the charge status of the battery is shown for about 10 seconds.

Error messages, such as an overload, are also displayed here. To delete error messages, switch the device off by pushing in the main switch. Then switch the device back on by pulling out the switch.

4.6 Moving the RotexTable®



Notice!

If the RotexTable[®] is moved by pushing in the direction of the compact side (with the rotator forwards), the tipping limit could be exceeded at obstructions or high thresholds. Only push the RotexTable[®] in the direction of the long side, with the controller board housing forwards. In this case the maximum permissible threshold height is 10 mm.

The RotexTable[®] can be moved over thresholds without problem and without the device reaching the tipping limit, if the device is moved with the long side forwards. If the RotexTable[®] is moved with the rotator forwards, the tipping limit can be exceeded at obstructions or high thresholds due to the high centre of gravity.





Pushing is prohibited!

To make this clear, there is a sticker on the device in the corresponding position of the vertical beam.



- Unlock RotexTable[®] double castors. To unlock, pull up the retaining lever.
- Move the RotexTable[®] to the location of use and in front of the operating table.

4.7 Connecting the RotexTable[®] with the operating table

Order adapters for the various operating table models together with the RotexTable[®]. This adapter is attached to the operating table and is then available for the RotexTable[®].

The RotexTable[®] may be used for patients weighing up to 220 kg. If the load capacity of the operating table is lower, then this lower safe load capacity of the operating table applies.

Ensure that you have mounted the correct adapter for your operating table.



When uncoupling the RotexTable® and the operating table, make sure that you secure the horizontal beam against falling down. Hitting the floor can lead to deformations and later adaptation problems.

tionstisch verbunden ist.

If the adapter is not secured, the RotexTable® can accidentally detach from the operating table and

cause injury. Lock the adapter to prevent injuries.

The retaining levers on the RotexTable[®] double castors remain unlocked as long as the RotexTable[®] is

connected with the operating table.mit dem Opera-

Lock the adapter, securing the RotexTable® from being acciden-

Caution!

tally released.

First move the horizontal beam to the uppermost position and then place it vertically.

- Unlock RotexTable[®] double castors. To unlock, pull up the retaining lever.
- Move the RotexTable[®] in front of the operating table.



The adapter is specially made for the corresponding operating table model; the appearance and form therefore vary for the different operating table models. When the RotexTable[®] is delivered you will be given clear instructions on how to connect your operating table with the RotexTable[®].

Lift the horizontal beam and attach the adapter to the operating table.

4.8 Securing the foot and the lower leg in the RotexShoe[®] extension shoe

Detailed information and operating instructions for the RotexShoe[®] can be found in the corresponding instructions for use about this product! This must be read and applied by every person that uses or operates the extension shoe.

The RotexShoe[®] is used to fix the foot and lower leg for operations in hip arthroplasty, hip arthroscopy and trauma surgery in the thigh area and the hip.

The entire extension shoe is only used in the non-sterile area and does not come into contact with injured tissue and open wounds.

To avoid pressure marks the shell of the extension shoe should contact the patient's skin. The disposable inlays are placed on the foot and parts of the calf. The extension shoe consists of a robust shell with the respective accessories (usually disposable inlay incl. mounting brackets).

Before each use, check the quick fasteners for a proper function. If they show wear, the shoe is to be sent to the manufacturer for repair.



Caution!

The feet of the patient can come loose if the liner is too large, and the patient can be injured. Ensure a tight fit and pad the foot if necessary.



Caution!

If significant tensile or compressive forces occur for long application periods, then injury can result. Check the position in the foot area regularly to avoid injury. The duration of application should not exceed 1–2 hours.



For a correct padding, positioning and fixation in the extension shoe please take note of the RotexShoe[®] Instructions for Use and Preparation!



Please observe that the entire procedure takes place in the non-sterile area. None of the products is used sterilely or is approved for the sterilisation process.



Note that disposable inlays and mounting brackets are only for single use!

Documentation

In order to record that you have only used the single-use products as intended, scan in the corresponding sticker on each package, or stick it to the documentation form.

This is proof that you only used the product once in the case of damage.

4.9 Fastening and positioning the extension shoe at the RotexTable®

When the foot of the patient is secured in the extension shoe, the extension shoe has to be attached to the RotexTable[®].

With the help of a bracket (interface) the shoe can be connected sideways to the correspondent rail of the extension device and be fixed appropriately.

Depending on the shoe model fastening and fixation is possible via a locking bolt or a wing screw (for an image description see also instructions for use and preparation of Condor[®] RotexShoe).

Make sure that the extension shoe is attached firmly and securely to the RotexTabe $^{\circ}!$



The clamping claw on the sole of the extension shoe can now be pushed sideways onto the rotary bracket on the rotator on the horizontal beam slide. When sliding onto the sliding carriage rotary bracket, it must be possible to move the sliding carriage along the horizontal beam.



Caution!

When releasing the sliding carriage to move freely, it can move down and pinch or crush. Always hold the sliding carriage securely in one hand when releasing to move freely.

- Release the sliding carriage to move freely using the switching claw with the red ball.
- The slide carriage can now be moved on the horizontal beam.





Caution!

Extension shoes that have not been correctly secured can become loose, and the patient could be injured. Please check that the clamping claw fits tight on the rotary bracket.

- When the foot of the patient is secured in the carbon outer shell, push the lamping claw on the sole of the extension shoe sideways onto the rotary bracket of the rotator.
- Here you must clearly hear the locking bolt click.
- If you wish to release the foot holder from the rotary bracket of the rotator, pull the locking bolt on the clamping claw down and push the clamping claw sideways off of the rotary
 bracket.

4.10 Setting suitable start points for the operations

Different distances between the operation table and the RotexTable[®] are needed for open hip operations and arthroscopic hip surgeries, due to different requirements for the operations. The appropriate starting points for hip operations and arthroscopic surgeries are marked both on the horizontal beam and the slide carriage.



When the extension shoe with the patient's foot is secured on the freely movable sliding carriage, the optimal start point can be set.

With the switching claw you can secure the sliding carriage or switch it to be movable on the horizontal beam. If the sliding carriage has been secured, a safety switch prevents the horizontal beam from being raised or lowered electrically. This safety switch serves as protection against accidentally raising or lowering when the sliding carriage is secured, as such a manoeuvre could result in soft tissue damage.



Caution!

When releasing the sliding carriage to move freely, it can move down and pinch or crush. Always hold the sliding carriage securely in one hand when releasing to move freely.

- Release the sliding carriage to move freely using the switching claw with the red ball.
- Now turn the hand wheel on the end of the horizontal beam until the markings on the sliding carriage and horizontal beam match up
- Change the distance between the operating table and the RotexTable[®] using the hand wheel. The sliding carriage also changes its position on the horizontal beam at the same time.
- Lastly, secure the sliding carriage with the switching claw again.
- With the switching claw you can secure the sliding carriage or switch it to be movable on the horizontal beam.

4.11 Setting the height of the horizontal beam with the handheld controller

The height of the horizontal beam can be adjusted electronically with the handheld controller.





Caution!

If the sliding carriage is blocked, for example by adhesive strips for securing the sterile covers, softtissue damage can occur when adjusting the height. Make sure when making adjustments that the sliding carriage can move freely.



Caution!

When the double castors are secured while adjusting the height, the RotexTable[®] can topple over. Before adjusting the height, make sure that the double castors are not secured. If so, unlock the double castors. When the RotexTable[®] is switched on with the main switch and the sliding carriage is free to move, the height of the horizontal beam can be freely adjusted. During this procedure, double castors must be unlocked.

 Unlock RotexTable[®] double castors. To do so, pull up the locking lever on the double castors.



Caution!

When releasing the sliding carriage to move freely, it can move down and pinch or crush. Always hold the sliding carriage securely in one hand when releasing to move freely.

- Release the sliding carriage to move freely using the switching claw with the red ball.
- Press the "Lower" button to move the horizontal beam down and the "Raise" button to lift it up.

	<u> </u>	7	_
	1	Ę	3
		-	

If the the horizontal beam hits an obstacle when being lowered or raised or when it reaches the end position, the electric drive shuts off. You can then only move the horizontal beam in the opposite direction.



If the horizontal beam is overloaded when moving up, the controller stops the movement. A corresponding symbol is shown in the controller display.

Avoid driving the horizontal beam downwards onto the ground when it is vertical. This can lead to deformations and later adaptation problems.

4.12 Setting the height of the horizontal beam with the foot switch

If the foot switch has not yet been connected, do so now. See "Connecting the foot switch" on page 11 for details.





Caution!

If the sliding carriage is blocked, for example by adhesive strips for securing the sterile covers, softtissue damage can occur when adjusting the height. Make sure when making adjustments that the sliding carriage can move freely.



Caution!

When the double castors are secured while adjusting the height, the RotexTable[®] can topple over. Before adjusting the height, make sure that the double castors are not secured. If so, unlock the double castors.

When the RotexTable[®] is switched on with the main switch and the sliding carriage is free to move, the height of the horizontal beam can be freely adjusted. During this procedure, double castors must be unlocked.

• Unlock RotexTable[®] double castors. To do so, pull up the locking lever on the double castors.



Caution!

When releasing the sliding carriage to move freely, it can move down and pinch or crush. Always hold the sliding carriage securely in one hand when releasing to move freely.

Release the sliding carriage to move freely using the switching claw with the red ball.



• Press the left foot switch to lower the horizontal beam and the right foot switch to raise it.

If the RotexTable[®] cannot be adjusted electrically, use the checklist stated in chapter 7. "Troubleshooting".

4.13 Setting the height of the horizontal beam with the hand crank

If the electrical system fails unexpectedly, it is also possible to adjust the height of the horizontal beam using the hand crank. The hand crank should be kept near the RotexTable[®] so that it is in easy reach if needed.



Caution!

If the sliding carriage is blocked, for example by adhesive strips for securing the sterile covers, softtissue damage can occur when adjusting the height. Make sure when making adjustments that the sliding carriage can move freely.



Caution!

When the double castors are secured while adjusting the height, the RotexTable[®] can topple over. Before adjusting the height, make sure that the double castors are not secured. If so, unlock the double castors.





Caution!

When releasing the sliding carriage to move freely, it can move down and pinch or crush. Always hold the sliding carriage securely in one hand when releasing to move freely.

- Release the sliding carriage to move freely using the switching claw with the red ball.
- Insert the hand crank into its mount on the top of the vertical beam.
- Turn the horizontal beam up or down manually.



The receptacle opening of the hand crank is covered. If the cover is moved to the side, the electrical system is automatically shut off so that no electrical adjustment is possible.

4.14 Rotation of the secured foot and the lower leg

Adjusting the direction of rotation

When the foot of the patient is secured, the foot can be rotated finely in the set direction using the rotator. If the switch lever for the direction of rotation is set horizontally, rotation is free. When the switch lever is set up or down, the ratchet mechanism engages when turning in the set direction.



- Push the switch lever for the rotator to the desired direction of rotation.
- With the lever arms of the rotator, turn the secured foot of the patient carefully in the desired direction.
- The rotator ratchets further in small increments.
- To release the ratchet function, set the switch lever for the rotator in the horizontal position.

5. Extension / Traction

When the patient's foot is secured, the leg can be extended delicately using the hand wheel.





Caution!

When the double castors are secured while adjusting the extension, the RotexTable® can topple over. Before adjusting the extension, make sure that the double castors are not secured. If so, unlock the double castors.

- Secure the sliding carriage using the switching claw with the red ball.
- Turn the hand wheel on the end of the horizontal beam until the required tensile force is applied.

Using the hand wheel, increase the distance between the operating table and the RotexTable[®]; this applies a tensile force to the secured foot.

6. Traumatology extension

The RotexTable[®] can be prepared for the traumatological treatment of legs. A traumatological extension enables work on the legs of the patient under X-ray observation, aligned both vertically and horizontally. In this way, the RotexTable[®] can be used to treat leg fractures, for example.

The previous instructions on operating the normal variants apply equally for the Rotex Table[®] with traumatological extension. When the RotexTable[®] is prepared for the traumatological treatment, the sliding carriage of the normal version is replaced by an exchangeable carriage. The rotation device on the front or back of the horizontal beam can be attached onto this exchangeable sliding carriage depending on the application.

See "Modification for hip operations" on page 20 and "Modification for traumatological treatment" on page 21 for details.

6.1 Transport position

In order to minimise the danger of tipping over when pushing, ensure that the system's centre of gravity is as low as possible. The risk of damage is also reduced when the external measurements of the system are significantly more compact. For this reason, bring the RotexTable[®] into the transport position before pushing.



Caution!

If pushed when the traumatological extension is mounted, the RotexTable[®] can tip over and cause injuries. Before pushing, always set the transport position so that the system's centre of gravity is as low as possible.



In order to set the transport position, release the rotator with vertical support and exchangeable support from the exchangeable carriage of the horizontal beam, and insert this in the holder at the bottom of the vertical beam.

6.2 Modification for hip operations

Fasten the rotator to the front of the horizontal beam for hip operations.



The components that are not required can be stored in a holder at the bottom of the vertical beam.



- For this, secure the vertical support using the clamping device inside the exchangeable support.
- Push the exchangeable support together with the vertical support into the holder at the bottom of the vertical beam.



- With the release button, push the rotator forwards onto the exchangeable sliding carriage until it clicks into place. Check that the rotator is fitted securely.
- If you wish to release the rotator from the exchangeable sliding carriage, press in the release button and push it downwards towards the handwheel.

6.3 Modification for traumatological treatment

For traumatological treatment, the rotation device is mounted on the back in the direction of the vertical beam. For this, the exchangeable support with clamping device is attached to the exchangeable sliding carriage. A vertical support is secured inside the exchangeable support, which then carries the rotator.

Using the clamping device, horizontal rotations and height adjustments of the vertical support are also possible. This expands the rotator's setting options.



- With the release button, push the exchangeable support forwards onto the exchangeable carriage until it clicks into place
- Insert the vertical support into the opening from above. Secure the vertical support with the clamping device. Check that the vertical support fits securely. Check that the exchangeable support fits securely.



- With the release button, push the rotator forwards onto the exchangeable carriage until it clicks into place. Check that the rotator is fitted securely.
- If you wish to release the rotator from the vertical support, press in the release button and push the rotator towards the handwheel.
- Press in the release button and push the exchangeable support towards the handwheel to release it from the exchangeable sliding carriage.



Caution!

If the components for traumatological treatment have not been dismantled, and the horizontal beam swivels downwards after the RotexTable[®] is detached from the operating table, these components could hit against the profile of the vertical beam. Injuries or damage may result. Always remove the exchangeable support for traumatological treatment before you detach the RotexTable[®] from the operating table!

A sticker on the horizontal beam warns of the clamping point between the rotator and the vertical beam.



Clamping point

7. Troubleshooting

If the RotexTable[®] cannot be adjusted electrically, check the following.

Cause	Remedy
Is the sliding carriage free to move?	Release the sliding carriage to move freely using the swit- ching claw with the red ball. Pull the switching claw all the way.
Is the cover for the hand crank on the tip of the vertical beam closed correctly?	Close the cover.
Is the main switch pulled out all the way?	Pull the main switch out until you hear a clear click.
Are both plugs of the spiral control cable inserted?	Insert both plugs into the socket.
Are the battery modules charged?	Charge the battery modules.
Is there an error message on the controller display?	Switch the controller off and then back on.

8. Cleaning and disinfection

The RotexTable® can only be cleaned using a wipe disinfectant.

We recommend the clinic's internal care products for cleaning.



Notice!

If the foot switch connection plug is removed, moisture can enter the open sockets and damage the device. Always place the blind plugs in the foot switch socket to prevent moisture entering.



Notice!

If you remove the spiral control cable between the handheld controller and the horizontal beam, moisture can enter the open sockets during cleaning and damage the device. To prevent moisture entering, never remove the spiral cable before cleaning.

Use only suitable cleaning agents for the plastic parts and control elements. Make sure that no fluids get in or onto the device during cleaning. Moist wiping is typically sufficient.



Notice!

Abrasive cleaning agents may damage the padding surface. Do not use abrasives for cleaning.

Disinfectants containing alcohol can cause inflammable gas mixtures. For this reason, also use aldehyde-based surface disinfectants.

The agent should be mentioned in the list of the VAH (German Association of Applied Hygienics). The VAH list of disinfectants is available from the following address:

mhp-Verlag GmbH Marktplatz 13 65183 Wiesbaden GERMANY

Please observe the application instructions of the disinfectant supplier.

9. Electromagnetic compatibility (EMC)

Portable or mobile RF communication devices may affect medical equipment. Electrical equipment intended for medical use requires special EMC precautions. Observe the EMC instructions in this manual for installation and commissioning.

9.1 Electromagnetic emissions

Guidelines and manufacturer's declaration – electromagnetic emissions

The RotexTable[®] is intended for use in the environment specified below. Users of the RotexTable[®] should make sure that it is used in such an environment.

Interference emissions	Compliance	Electromagnetic environment – guidelines
RF emissions, CISPR 11	Group 1	The RotexTable [®] uses RF energy only for its internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The RotexTable® is suitable for use in all
Harmonic emissions according to IEC 61000-3-2	Class A	establishments other than domestic and those directly connected to the public low-voltage power supply network that
Voltage fluctuations/flicker emissions according to IEC 61000-3-3	Conformed to	also supplies buildings used for domestic purposes.

9.2 Electromagnetic immunity

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or cera- mic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient / burst according to IEC 61000-4-4	Not applicable: internal power supply		The quality of the mains supply voltage should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	Not applicable: internal power supply		The quality of the mains supply voltage should be that of a typical commercial or hospital environment.
Voltage dips, short inter- rupts and variations on po- wer supply lines according to IEC 61000-4-11	Not applicable: internal power supply		The quality of the mains supply voltage should be that of a typical commercial or hospital environment. If the user of the RotexTable® requires continued operation even during interruption of the power supply, supply of the RotexTable® from an uninterruptible power supply or from a battery is recommended.
Power frequency magnetic fields (50/60 Hz) according to IEC 61000-4-8	Not applicable: internal power supply		Power frequency magnetic fields should be those of a typical commercial or hospi- tal environment.
Note UT is the AC mains volta	ge prior to application of the	e test level.	

9.3 Electromagnetic immunity for non-life-supporting equipment

Guidelines and manufactu	rer's declaration – electroma	gnetic immunity	
The RotexTable® is intended that they are in such an envir		environment specified below.	Users of the RotexTable® should make sure
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Conducted RF disturbance according to IEC 61000-4-6 Radiated RF disturbance IEC 61000-4-3	3 V _{eff} 150 kHz bis 80 MHz 3 V/m 80 MHz bis 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should not be used at a closer distance to the RotexTable® including its cables than the recommended separation distance estimated using the equation applicable to the frequency of the trans- mitter. Recommended separation distance For 80 MHz to 800 MHz For 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) accor- ding to the manufacturer of the transmitter and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		25.
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RotexTable [®] is used exceeds the applicable RF compliance level, the RotexTable [®] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RotexTable [®] .		
b	Over the 150 kHz to 80 MHz frequency range, field strengths should be less than 3 V/m.		ns should be less than 3 V/m.

9.4 Recommended separation distances

Recommended separation distance between portable and mobile RF communications equipment and the RotexTable®

The RotexTable[®] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the RotexTable[®] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RotexTable[®] as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer of the transmitter.			
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

10. Accessories

The following accessories can be used together with the RotexTable[®]. They are included in the original equipment and can be re-ordered separately.

Accessories	Article number
Foot switch	RO.0024.2014
RotexShoe [®] (extension shoe) - Size S	RO.0074.2018 RO.0081.2019
RotexShoe [®] (specialised in minimal toal hip replacement)	RO.0027.2018
Disposable inlay incl. mounting brackets	RO.0148.2018
Disposable inlay incl. mounting brackets Size S	RO.0148.2018 S
Charging unit with wall mount	RO.0044.2012
Rechargeable battery	RO.0045.2012
Connection cable	RO.0023.2014
Fulcrum/Hypomochlion	RO.000.010
Pad for Fulcrum/Hypomochlion	RO.000.005
Hand crank	RO.000.022

The RotexTable[®] as well as all accessories are latex-free.

11. Spare parts

Replacement parts can be ordered exclusively with Condor[®] MedTec GmbH.

To order technical information or replacement parts from the manufacturer, please have ready the article number and serial number. This information can be found on the nameplate.

12. 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.

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

In the event of a unit failure, they must provide the following information provide:

- The complete sequence of digits from the bottom edge of the type plate.

The type plate is located on the lower part of the RotexTable®

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.

Inspection 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. For this reason, we recommend carrying out an inspection at regular intervals.

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. For this reason, we recommend carrying out maintenance at regular intervals.

13. Storage

The RotexTable[®] may be exposed to the following ambient conditions, within the stated regulatory limits:

Storage	
Ambient temperature	-10°C – +50°C
Relative humidity	10% – 95%
	800hPa – 1060hPa
Pressure	(corresponds to an estimated
	height of \leq 2000 m)

14. Technical specifications

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

	
RotexTable®	1
Height adjustment range (middle of the horizontal beam)	1043 mm – 170 mm
Horizontal adjustment range	400 mm
Battery capacity	24 V, 2,9 Ah, Pb
Battery type	BAJ1 (J1BA-001), Fa.Linak
Schutzklasse	III, internal powered
IP-Code	IPX4 = Protection from splash water on all sides according to DIN EN 60529
Weight	92 kg
Safe workload	50 kg, corresponds to a patient weight of 220 kg. If the load capacity of the opera- ting table is lower, then this lower safe load capacity of the operating table applies.
Service life	12 years, if handled with care and if inspections and maintenance are carried out regularly. This does not apply to wear parts such as drives, controller and buttons for the foot switch and the handheld controller.
Features	Battery operation
External charging unit	
Charging unit type	CHJ2 (J1CH-001), Fa.Linak
Input AC of the charger	100 V – 240 V AC / 50 – 60 Hz
Food switch	
IP-Code	IPX7 = protection against damage after brief immersion (max. 1 m water depth/up to 30 min) according to DIN EN 60529

14.1 Klassifizierung

According to Annex VIII, rule 1 of the Medical Device Regulation MDR (EU) 2017/745, the RotexTable[®] is a class 1 medical device.

14.2 Example of a nameplate



14.3 Applied standards

The RotexTable[®] meets the applicable basic safety and performance requirements in accordance with Appendix I of the Medical Device Regulation (MDR), regulation (EU) 2017/745 of European Parliament and the council on medical products as well as the applicable national regulations such as the Medical Devices Act.

In addition, the RotexTable[®] meets the following standard requirements:

- DIN EN 60601-1
- DIN EN 60601-1-2
- DIN EN 60601-1-6
- DIN EN ISO 14971

The following standard was additionally consulted: – DIN EN 60601-2-46

14.4 Certificates

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

15. Disposal

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.

This device is covered by the EC directive 2002/96/EC (WEEE). It is not certified for use in private households and may not be disposed of in a municipal or local electronic waste collection. Condor[®] MedTec GmbH is responsible for legal disposal of this device. Please contact us or the responsible sales agency for further details.

If transferring this device to a commercial third party, the seller is contractually obliged to notify the buyer of the legal requirements for disposal after discontinuation of use. If neglecting to do so, the seller is responsible for proper disposal of the device after the third party has discontinued its use.

16. Copyrights

All contents of these instructions for use are protected by copyright, in particular texts, photographs, and diagrams. Unless expressly indicated otherwise, the copyright holder is Condor[®] MedTec GmbH. Please ask Condor[®] if you wish to use the contents of this document.

We wish you every success with the Condor RotexTable[®]. Please contact us for any further questions and suggestions.