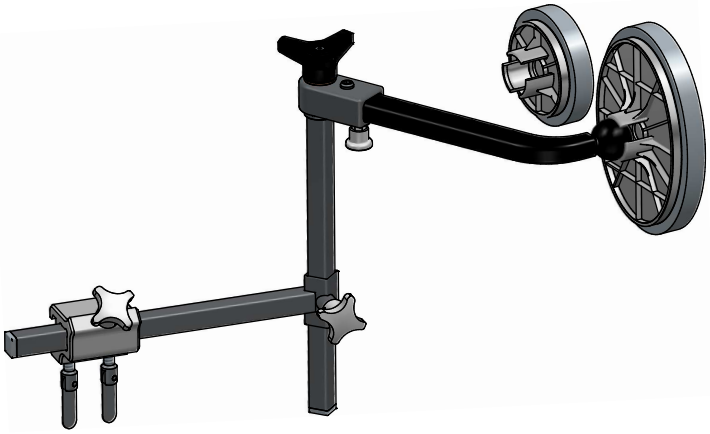
CONDOR® MedTec
EXPAND YOUR POSSIBILITIES



Instructions for Care and Use

Condor® XP-360° (radiolucent lateral support)

444.GA.XP.EN
Last updated on 15.09.21

CE

Contents

1. Introduction

1.1 About these instructions

In this section you will find information about the structure of these instructions for use and explanations of the icons and symbols used.

This document contains instructions on how to use the Condor® XP-360° (radiolucent lateral support). It may contain inaccuracies or print errors.

The information provided here is updated periodically and changes are made as products are updated in later editions. Changes or upgrades may be carried out at any time without prior notice.

If you have any further questions, please do not hesitate to get in touch with us. The instructions for use should be read by anyone using or operating the Condor® XP-360° (radiolucent lateral support).

In addition to the instructions for use and the binding accident prevention regulations in force in the country of use and the site of use, the generally accepted regulations for safe and professional work should also be observed.

1.2 Symbols used in the document

In these instructions for use we use the following designations or icons to highlight particularly important information.

Danger!
Safety notices which refer to danger to people are highlighted with this symbol. This symbol refers to imminent danger, i.e. death or serious injury.

Caution!
This symbol may be used to draw attention to dangerous situations if there is a risk of minor injury.

Warning!
This symbol is used before warning notices if there is a risk of damage to the device or other property.

This symbol is used to highlight helpful information.

- A bullet point in front of text means that this is something you must do

  Indented text is used where describing the outcome of an action.

– A dash in front of text means that this is part of a list.

1.3 General safety information

The radiolucent lateral support (Condor® XP-360°) has been built according to the state of art and generally accepted safety rules. Nevertheless, use of the device may result in risks to the patient or third parties or damage to the device and other property.

Only use the radiolucent lateral support (Condor® XP-360°) in undamaged condition, for the intended purpose, in a safety- and risk-conscious manner, and in line with the instructions for use. Have any faults which might impair the safety of the device rectified immediately.

Store these instructions for use close to hand at the site of use. In addition to the instructions for use, observe the universally accepted legal and other binding regulations on accident prevention and environmental protection. Do not make any modifications, additions or alterations without the approval of the manufacturer. Spare parts must meet the requirements set out by the manufacturer. This is always assured where original spare parts are used. Adhere to the prescribed testing requirements. Ensure that consumables, auxiliary materials and spare parts are disposed of safely and in an environmentally-friendly manner.

Summary of safety notices

Warning!
The marking on the end of the horizontal square column [10] indicates the maximum adjustment range.

Warning!
To allow switching sides, the side rail has no holding mechanism at the end of the horizontal square column [10]. Make sure that this does not accidentally slide out of the tensioning clamp [9].

Warning!
The horizontal square column cannot be used as a rest or support for anyone else. It serves solely to hold the patient in position on his or her side. Ensure that nobody rests on the Condor XP-360° or uses it as a support while operating.

Warning!
The marking on the end of the vertical square column [8] indicates the maximum height adjustment range.

Warning!
The cushions for the XP 360° are only intended to be used once. Multiple use is not recommended by the manufacturer.

1.4 Graphical symbols used

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

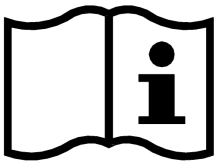
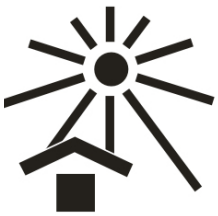
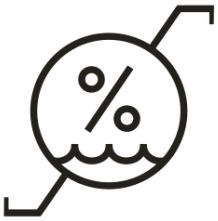
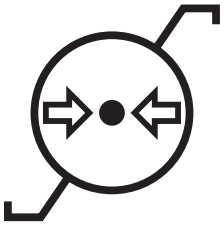
Graphical symbol	Identification
	Identification in agreement with ISO 15223-1 standard. Symbol for 'product number'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'serial number'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'name and address of the manufacturer'
	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 'protect against sunlight'
	Identification in agreement with ISO 15223-1 standard. Identification of packaging material. Symbol for 'protect against wetness'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'temperature range'

Table 1 Graphical symbols used

Bildzeichen	Kennzeichnung
	Identification in agreement with ISO 15223-1 standard. Symbol for 'relative humidity'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'air pressure'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'latexfrei'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'do not re-use'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'product not sterile'
	Labelling of medical devices. Symbol for „Medical Device"
	Identification for a data carrier which contains the Unique Device Identifier contains. Symbol for „Unique Device Identifier".
	Labelling of products developed and marketed in accordance with relevant European legal provisions.

2. Basic requirements

2.1 Intended use

The XP-360° is intended for use only in human medicine. The XP-360° should only be used in combination with an operating table. The radiolucent lateral support should be attached to the operating table prior to the operation and is used to support the patient in a lateral position during the operation. Following the operation, the support should only be removed once the patient has been secured and brought back into original position on his or her back. The XP-360° may only be used by medically trained personnel. Condor® XP-360° is affixed to the the sliding rail of the operating table as a holding accessory.

The XP-360° is used to hold patients in position during operations on vertebrae, the pelvis, and during all other operating procedures which need to be performed while the patient is positioned on their side. The XP-360° enables optimal intraoperative imaging when using x-ray.

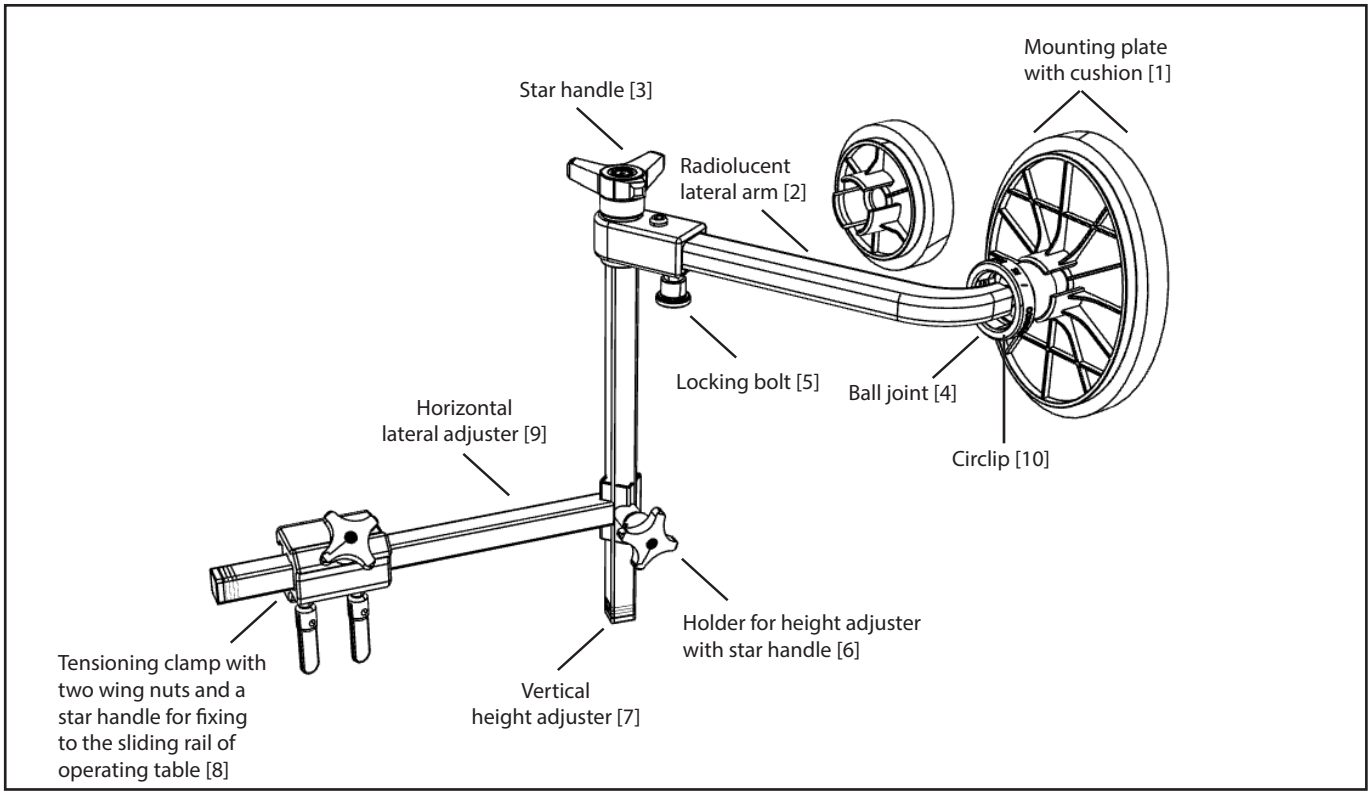
The device is unique in its convenient adjustment and how easy the adjustment mechanisms are to operate. The locking bolt [5] on the radiolucent lateral arm [2] enables repositioning of the radiolucent sections. The XP-360° can be adapted to the specific operation and patient requirements. The 3D ball joint [4] on the base assists with patient positioning and ensures an optimum distribution of pressure. Furthermore, two different cushion types enable custom adjustment options. The easy-click system allows for a quick changeover. The individual using the operating table and the XP-360° must have been briefed on how to use these correctly. It must be used entirely in accordance with the instructions for use. We cannot be held liable for any damage to the product or individuals caused by third-party accessories or if the intended use has been mutually abolished.

The purpose is the defined use. Operators and users must adhere fully to the markings and instructions to use it as intended. The XP-360° must be used entirely in accordance with the instructions for use.

The maximum load the XP-360° may support is 30 kg. If the operating table sliding rail does not permit this load, then the restriction with the lowest weight load applies.

- Using the device properly also involves following the instructions for use and fulfilling the inspection and maintenance requirements.
- The Condor® XP-360° may only be used by medically trained personnel.
- Check that the product is intact before every use.

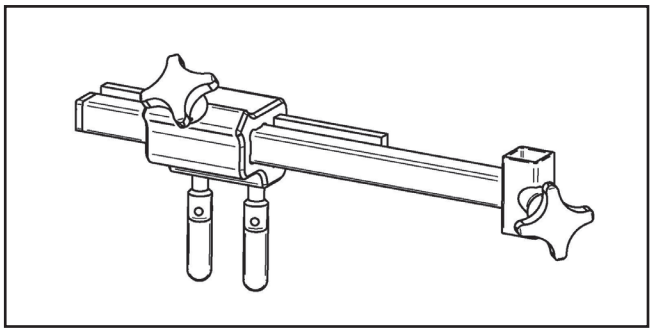
2.2 Description of device



3. Use

Please read the operating instructions through carefully before starting to use the XP-360°.

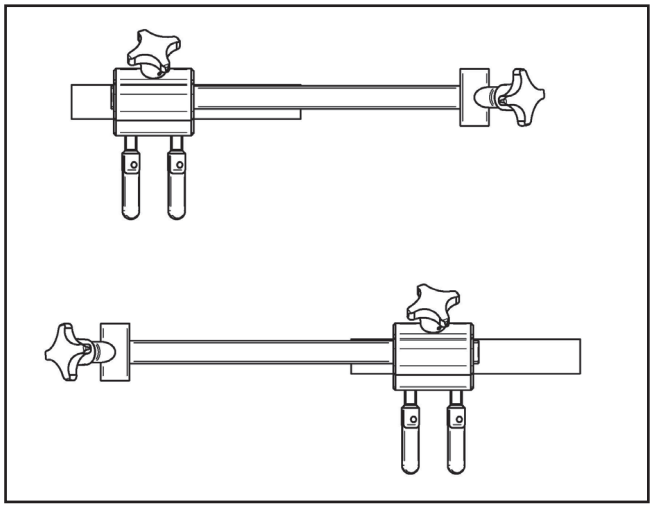
3.1 Attaching the tensioning clamp
Position the central clamp on the sliding rail. Tighten the two wing nuts on the sliding rail. Ensure these are securely positioned.



- Loosen the star handle screw on the tensioning clamp [8] to adjust the side rail laterally.
- The maximum adjustment range is reached when the horizontal lateral adjuster [9] sits flush with the tensioning clamp [8].

Warning!
The marking on the end of the horizontal lateral adjuster [9] indicates the maximum adjustment range.

Lock the star grip screw and check that it sits securely.



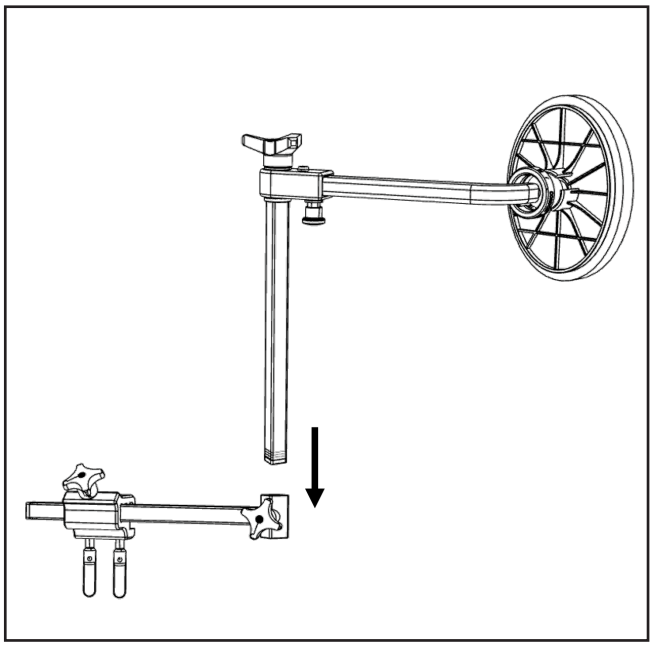
Warning!
To allow switching sides, the side rail has no holding mechanism at the end of the horizontal lateral adjuster [10]. Make sure that this does not accidentally slide out of the tensioning clamp [8].

Ensure that the wing nuts on the sliding rail are firmly locked in place to ensure the entire radiolucent lateral support (Condor XP-360°) is secure

3.2 Attaching the radiolucent lateral arm

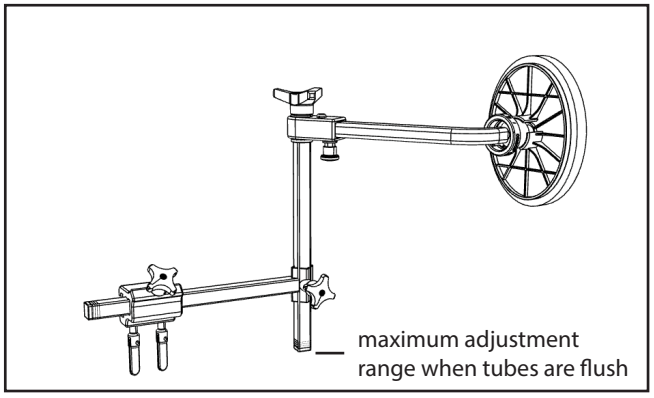
Position the vertical height adjuster [8] in the holder for the height adjuster [7]. Loosen the star handle screw on the holder for the height adjuster [7] to select the suitable position.

Warning!
The marking on the end of the vertical height adjuster [8] indicates the maximum height adjustment range.



Lock the star grip screw and check that it sits securely.

The maximum adjustment range is reached when the horizontal lateral adjuster [9] sits flush with the vertical height adjuster [7].

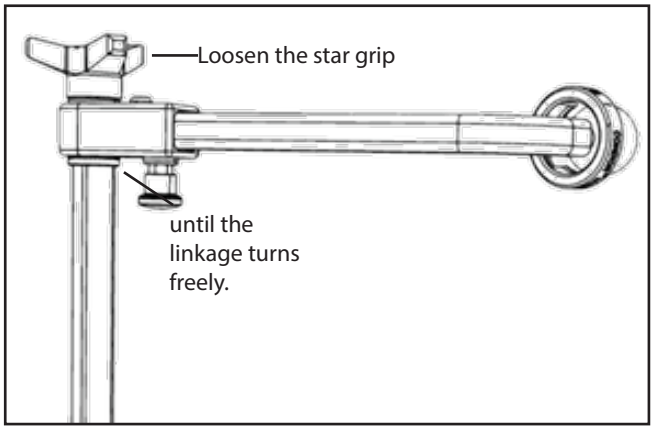


Lock the star grip screw and check that it sits securely.

Warning!
The horizontal lateral adjuster cannot be used as a rest or support for anyone else. It serves solely to hold the patient in position on his or her side. Ensure that nobody rests on the XP-360° or uses it as a support while operating.

3.3 Adjusting the radiolucent lateral arm

- Loosen the star handle [3] to swivel the radiolucent part of the lateral support horizontally.
- Lock the star grip [3] in place once you have found the ideal position. When doing so, ensure that the connections are secure and that the device is stable.
- Inserting the mounting plate with cushion [1] into the 3D ball joint [4] helps to automatically align the cushion surface along the surface of the body.



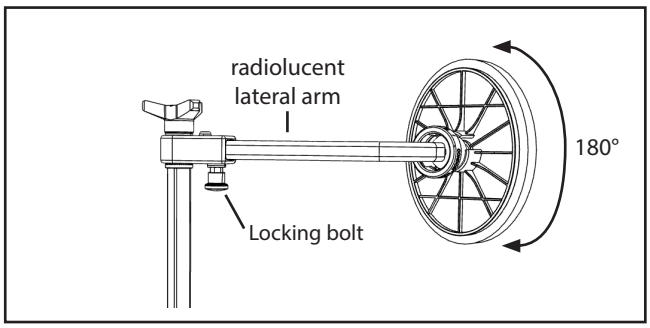
Ensure that the cushion is properly secured and that the mounting plate [1] for the cushion does not come into contact with the patient.

Caution!
The lateral support is only designed for unvarying patient positioning. If the patient position is manipulated too much, the cushion could detach from the ball. For this reason, check that the cushion is seated securely if there has been any manipulation.

Make sure that the cushion is fastened correctly and that the mounting plate [1] for the cushion does not come into contact with the patient.

3.4 Lateral adjustment of the Condor® XP-360°

- Pull the locking bolt [5] in the direction shown.
- Hold the locking bolt [5] like this.
- Now pull the radiolucent lateral arm [2] out of the retaining sleeve.



- The mechanism is now unlocked.
- Turn the radiolucent lateral arm [2] 180°.
- Now push the radiolucent lateral arm [2] back in the direction of the locking bolt.

The locking bolt [6] does not need to be pulled out again to lock the mechanism.

Ensure that the radiolucent part is securely positioned in the sleeve. If the tensioning lever does not lock into place, check that you have carried out the process properly.

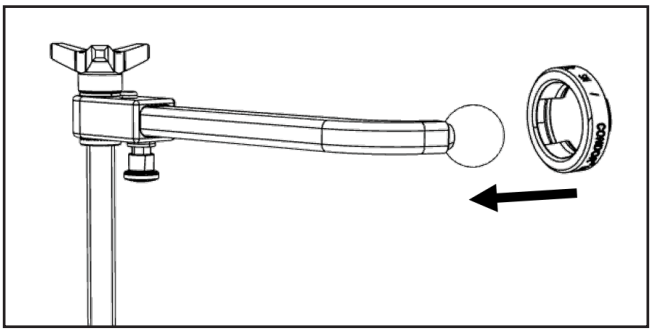
3.5 Fastening the circlip and cushion

XP-360° comes equipped with two different cushion sizes. The cushions are only intended to be used once. We do not recommend the use of additional padding or cloths.

The circlip [10] is used to prevent the cushion from slipping off the ball joint unintentionally.

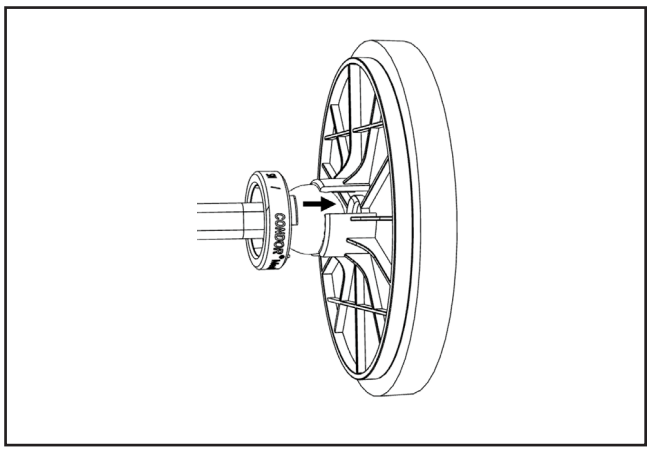
The circlip is to be fastened each time the lateral support is used.

- To this end, use the closed side of the circlip [10] to push it onto the ball joint.



Select a suitable cushion [1].

- Place the mounting plate on the ball [4] of the lateral arm.
- Push the circlip [10] into the recesses of the cushion [1].
- The mounting plate and cushion are now also secured on the lateral arm.
- Check that the mounting plate is fitted securely to the 3D ball joint. [4].



Remove the mounting plate and cushion.

- Pull the circlip out of the recesses in the mounting plate.
- Detach the mounting plate and cushion from the lateral arm.

Warning!
The cushions for the XP 360° are only intended to be used once. Multiple use is not recommended by the manufacturer.

In contrast to the cushion, the circlip is not a single-use product and can be used several times. If the circlip loses its securing properties due to wear, it must also be replaced. Further information on reordering spare parts and accessories can be found in Chapter 5.

Caution!
The lateral support is only designed for unvarying patient positioning. If the patient position is manipulated too much, the cushion could detach from the ball. For this reason, check that the cushion is seated securely if there has been any manipulation.

4. Cleaning and disinfection

The radiolucent lateral support should be cleaned and disinfected after every patient. The metal and plastic components should only be disinfected using wipes.

We recommend using the clinic's own cleaning agents.

Warning!
Remove the horizontal lateral adjuster from the central clamp before cleaning. Doing so will ensure that all surface structures are cleaned.

Warning!
Plastic parts should be treated only with suitable cleaning agents. Damp wiping is generally perfectly adequate.
A weak alkaline cleaner can be used for cleaning, e.g. mild detergent, soapy water, or the clinic's own cleaning agent.

Alcoholic disinfectants may generate flammable gas mixtures. That's why you should use an aldehyde surface disinfectant too. The agent should be included in the list of the Association for Applied Hygiene.

You can request the Association for Applied Hygiene's list of approved disinfectants from the following address:
mhp-Verlag GmbH
Marktplatz 13
65183 Wiesbaden
GERMANY

Please follow the instructions for use of the disinfectant manufacturer.

5. Accessories:

The following accessories can be used in combination with the XP-360°. They come included with the product and can be reordered individually.

Accessories:	Item number
Horizontal lateral adjuster	OTZ.0031.2017
Vertical height adjuster incl. radiolucent arm and circlip	OTZ.0001.2017
Circlip for cushion (included in OTZ.0001.2017)	OTZ.0001.2017 P2
Tensioning clamp for fixing to the operating table sliding rail	OTZ.0036.2017
Small cushion, Ø 93 mm	OTZ.0049.2019
Large cushion, oval, 186 x 136 mm	OTZ.0050.2019

The XP-360° and its cushion are latex-free.

6. Storage

The XP-360° may be exposed to ambient conditions which lie within the following threshold values:

Operation	
Ambient temperature	+10°C to +40°C
Relative humidity	30 % to 75 %
Air pressure	700 hPa to 1060 hPa
Storage	
Ambient temperature	-20°C to +50°C
Relative humidity	10 % to 95 %
Air pressure	500 hPa to 1060 hPa


The disposable cushions must be stored away from sunlight. That is why they come in dark packaging bags and should only be taken out just before use.

7. Repairs

Repairs should only be carried out by the manufacturer.

Please refer to Condor® MedTec GmbH in the event of any malfunction. You will find the contact details in Chapter 10.

Any serious incidents arising in connection with the product must be reported to the manufacturer and the relevant authorities of the member state in which the user is based.

8. Spare parts

Spare parts are only available for order from Condor® MedTec GmbH.

Please have the item number to hand when ordering technical descriptions or spare parts from the manufacturer. You can find this information on the laser inscription on the respective product.

9. Disposal

Packaging

Condor® MedTec GmbH can take back all packaging on request. Where possible, parts of the packaging will be recycled. If you have no use for the packaging, you may dispose of it via paper recycling or general waste.

Care was taken in the design of the product to ensure that the use of composites was kept to a minimum. This design concept enables much of the packaging to be recycled.

Please submit surgical instruments for professional disposal or to a recycling system once their product lifespan has expired.

National regulations and disposal guidelines must be observed for all disposal measures.

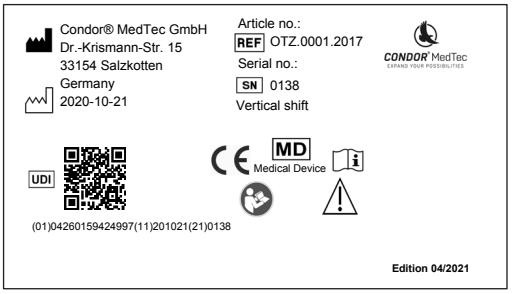
10. Technical data

Manufacturer	
	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

10.1 Classification

According to Annex VIII of Medical Device Directive 93/42 EEC and amending Directive 2007/47/EC or Annex VIII, Rule 1 of the Medical Device Regulation (MDR) - (EU) 2017/745, the radiolucent lateral support is certified as a Class I medical device.

10.2 Rating plate example



10.3 Applied standards

The radiolucent lateral support (Condor® XP-360°) meets the essential requirements for medical products under Annex I of Council Directive 93/42/EEC (Medical Device Directive). National regulations, for instance the German Law of Medical Devices (*Medizinproduktegesetz*, MPG), have also been applied. The application of Directive 93/42/ EEC represents a harmonisation of standards and is hereby verified.

Following the switch to the Medical Device Regulation (MDR), the essential safety and performance requirements under Annex I of EU regulation 2017/745 shall apply automatically.

10.4 Certificates

- All of the current certificates are available for download on our homepage (https://condor-medtec.de/downloads/).

11. Copyright

We hope you are satisfied with the Condor® XP-360° radiolucent lateral support and are on hand for any questions or suggestions you may have.