fasciotens®Cradle

Instructions for use

fasciotens
ABDOMINAL WALL SOLUTIONS

www.fasciotens.de

Dear customer,

Thank you very much for choosing fasciotens®Cradle, the innovative therapy option in combination with fasciotens®Pediatric in the treatment of congenital abdominal wall defects and open abdomen in newborns. Fasciotens® products provide the highest quality, safety and state-of-the-art technology.

This product was developed in partnership with practising surgeons to meet a particular medical need.

To take full advantage of this product's capabilities and to ensure its successful application, please read the Instructions for Use carefully and use the product as instructed. Furthermore, always follow standard safety precautions for general occupational safety, your specific SOPs and all relevant regulatory requirements. We will not assume liability for any damage arising from improper use or use contrary to its intended purpose or incorrect handling.

Any serious incidents that occur in connection with the product must be reported immediately to fasciotens GmbH and the responsible national authority.

This medical device is reserved for use by medical professionals only. Please make sure that all persons using this product only do so after having read and understood the Instructions for Use.

Please keep the Instructions for Use in a safe place; you may want to reread them at a later date.

Instruction in the medical device by a qualified person is required before using the product.

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For your safety

Please observe the Instructions for Use

Any application or handling of the product requires precise knowledge and observation of the Instructions for Use. The product may only be used for the purpose described.

Statements of particular importance are flagged as follows in the Instructions for Use:

Warning!

This is a warning alerting you to risks and dangers.
Ignoring such a warning may lead to life-threatening situations.
Warnings must be observed under all circumstances.

Information!

This is information about specific features that need to be considered under all circumstances.

Liability for proper function and damage

Any liability for damage caused by use of the product is always transferred to the operator or user, insofar as the product is used by persons who do not belong to the relevant professional groups, who do not have the relevant qualifications required to operate the product or who have not received proper instruction in its use. In addition, liability is transferred to the user in case of improper use or if the product is used inappropriately.

Prior to use, the product is to be inspected to ensure it is intact and not damaged in any way.

The warranty and liability conditions of the terms and conditions of sale and delivery of **fasciotens GmbH** are not extended by any previous or subsequent references.

Please ensure that the Instructions for Use are accessible at all times and that they are read and understood.

Intended purpose, indication and contraindications

Intended purpose

The intended purpose of fasciotens®Cradle is for use as a lying support for premature, newborn and young infants in combination with other fasciotens products. fasciotens®Cradle is a class I medical device.

The product is intended exclusively for human medical purposes.

Indication

Typical indications for a combined procedure utilising fasciotens®Cradle and fasciotens®Pediatric for patient positioning in connection with abdominal wall expansion in newborns and young infants may be either congenital or acquired conditions (particularly after abdominal surgery). See the indications listed in the fasciotens®Pediatric Instructions for Use.

Contraindications

- Body length > 60 cm
- Shoulder width > 25 cm

Information about side effects and risks

When using the product, the following undesirable side effects may occur in the short or long term:Pressure sores, e.g. on the back of the head (a general therapy-specific side effect that is not specifically attributable to the product)

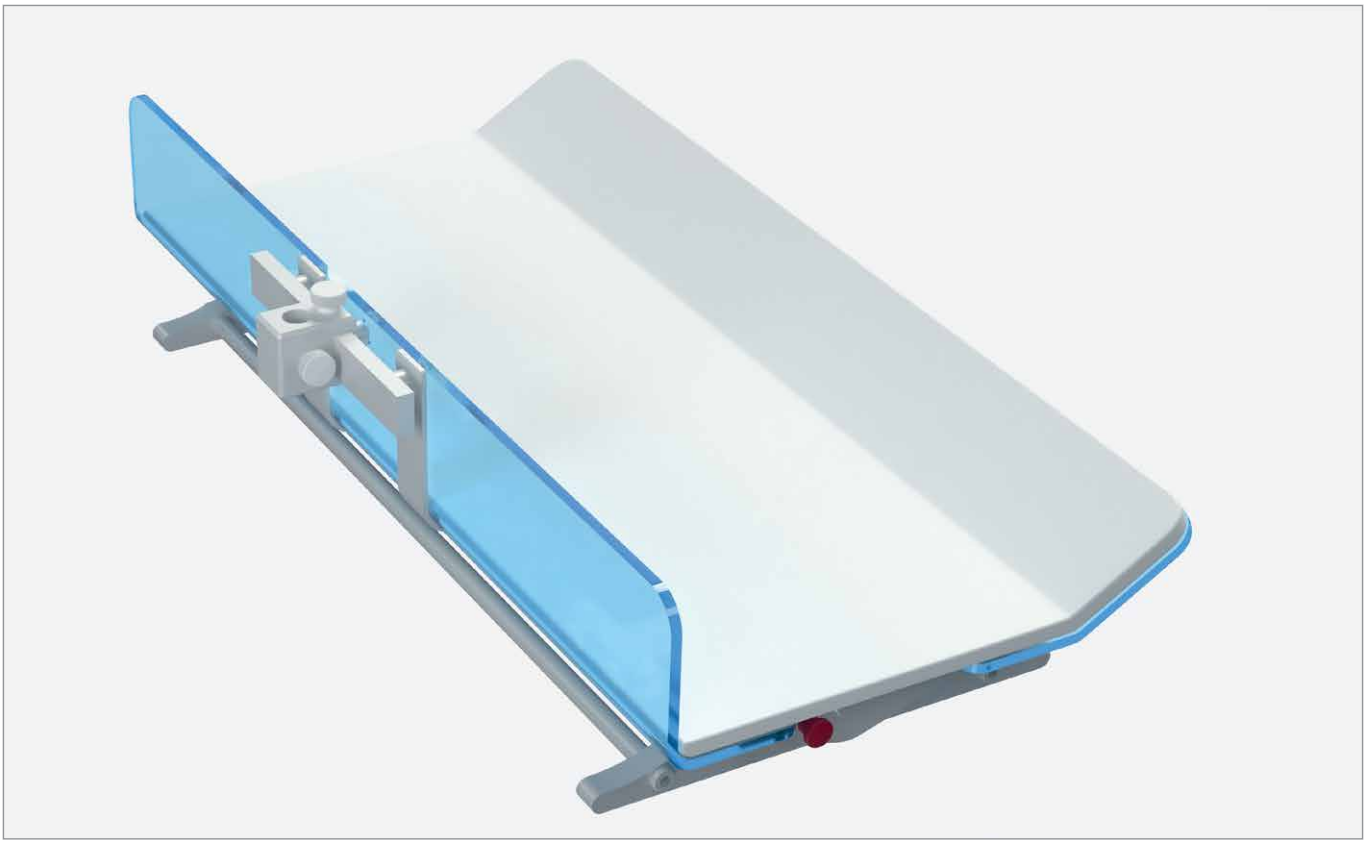
Target patient groups

Newborns and young infants with a diagnosed congenital or acquired defect of the abdominal wall

Intended users

- Surgeons with experience in paediatric surgery
- Nurses and paediatric nurses

Product presentation

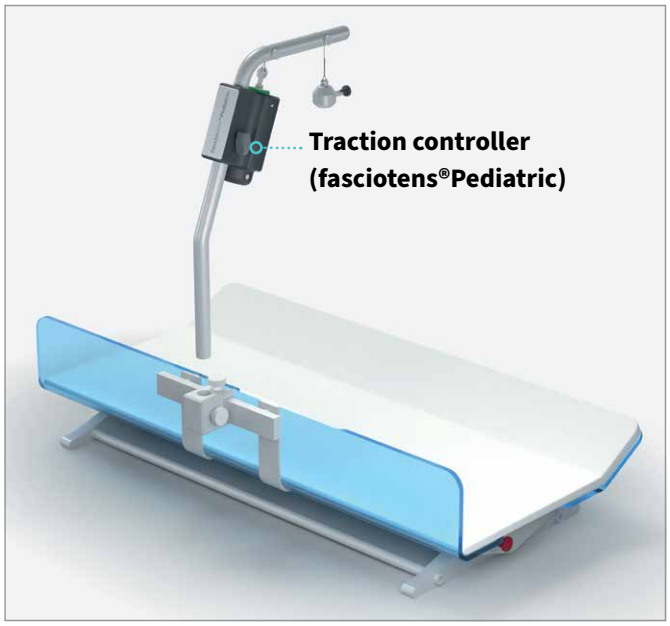


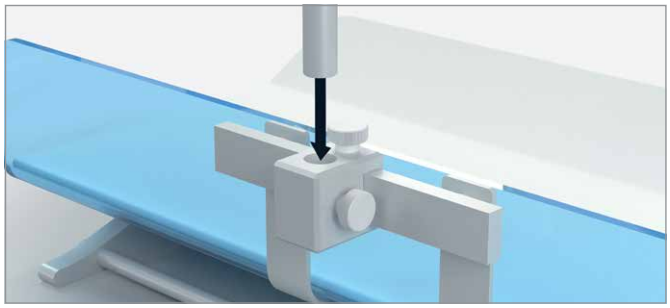
fasciotens®Cradle is a reusable medical device and should be ready for use in the event of the planned use of fasciotens®Pediatric.

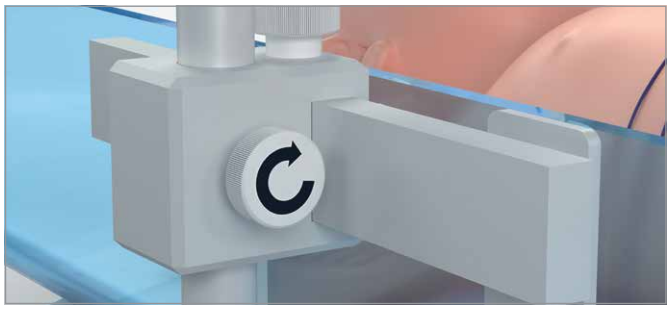
Combination with and attachment of fasciotens®Pediatric

fasciotens®Cradle is used in combination with fasciotens®Pediatric. Please note the corresponding Instructions for Use for assembling fasciotens®Pediatric.

1. Guide the traction controller (fasciotens®Pediatric) into the connection point on the fasciotens®Cradle. Then lock the traction controller by turning the side thumb screw clockwise.







Always check that the traction controller of fasciotens®Pediatric is secure after locking and after any change made (e.g. height adjustment).

2. For the further assembly of fasciotens®Pediatric, please proceed according to the fasciotens®Pediatric Instructions for Use.

Patient positioning

Adjusting to patient and defect size

To adjust the product to best suit the patient and defect size, use of the height and length adjustment is recommended.

The product must be positioned on a secure and flat surface!

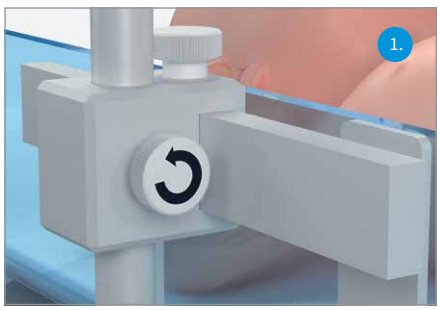
When treating children who are able to move, precautions must be taken to prevent falling out of the fasciotens®Cradle and incurring of any subsequent injuries.

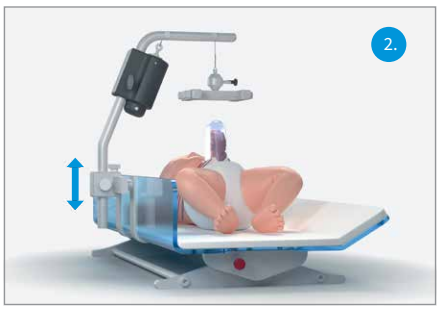
When positioning the patient on the mattress, an additional underlay, such as bed sheets, gauze cloths or similar material, must be placed underneath without wrinkles.

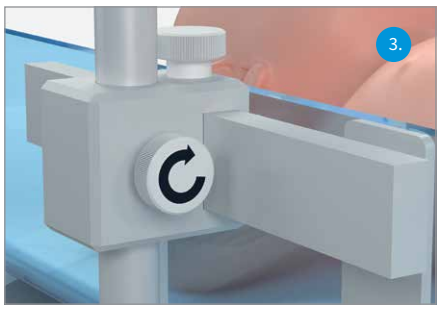
The product can also be placed in incubator systems.

Height adjustment

1. **Release the height adjustment** by turning the side thumb screw on the fasciotens®Cradle block anticlockwise, ensuring that the traction controller is secured using one hand.
2. **Move the traction controller up or down** to bring it and the thread retainer closer to or further away from the abdomen, depending on the volume of the prolapse.
3. **Lock the height adjustment** by turning the side thumb screw on the fasciotens®Cradle block clockwise.



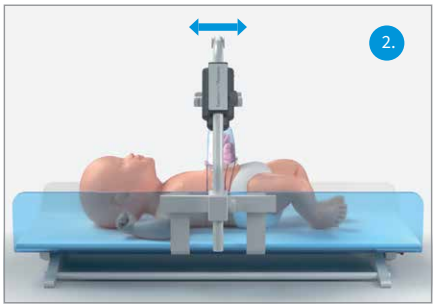




The traction controller and thread retainer must not come into contact with the patient or organs.

Length adjustment

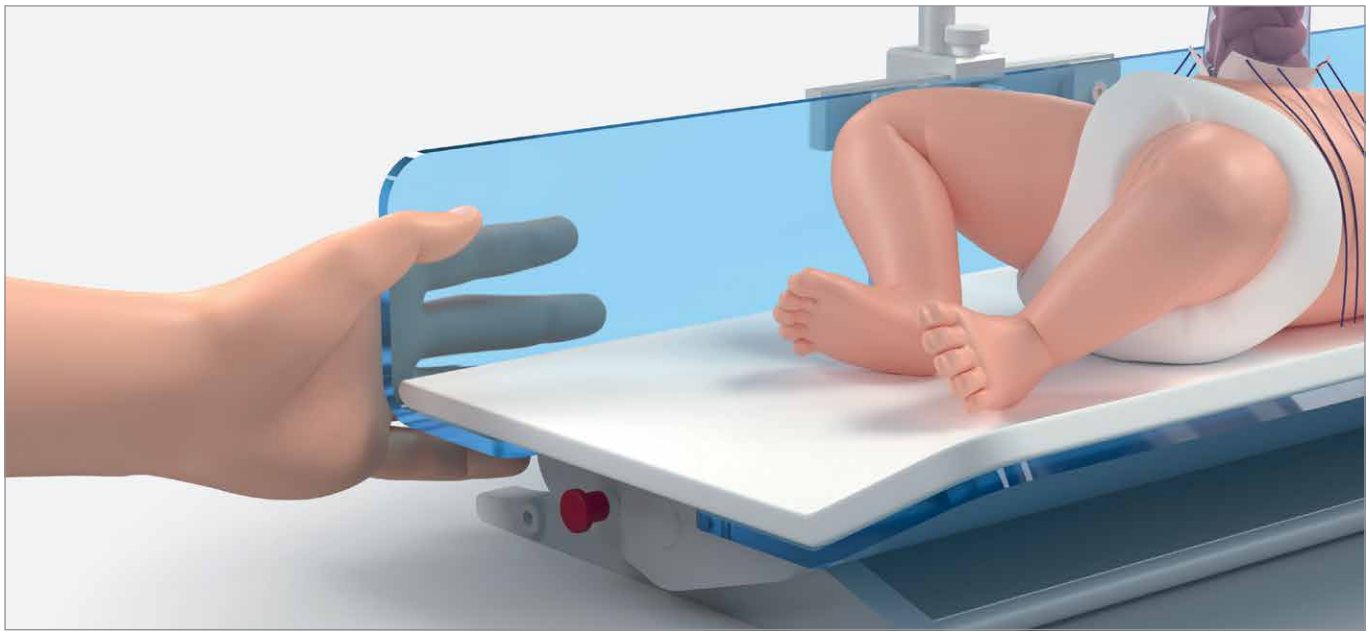
1. **Release the length adjustment** by turning the upper thumb screw on the fasciotens®Cradle block anticlockwise.
2. **Move the block over the rail** of the fasciotens®Cradle to the left or right so that fasciotens®Pediatric is positioned precisely over the defect, depending on its location.
3. **Lock the length adjustment** by turning the upper thumb screw on the fasciotens®Cradle block clockwise.



Inclined positioning

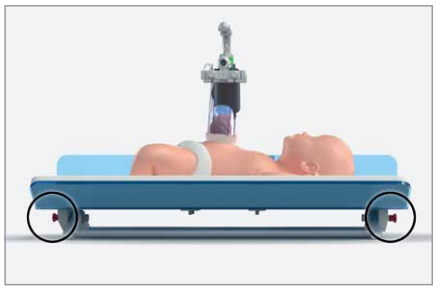
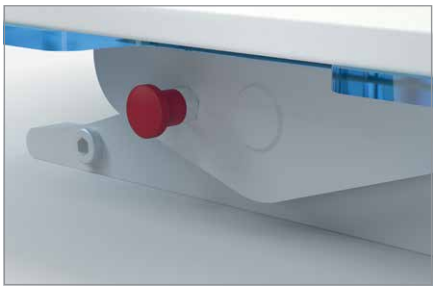
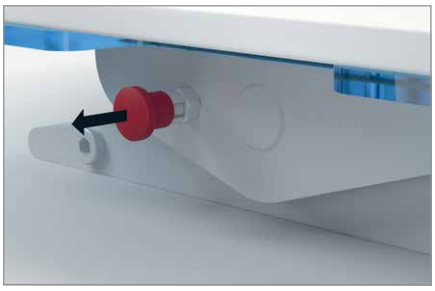
The patient may be positioned inclined to the left or right side. The following angles are possible for inclining the patient to the side:

1. Hold the fasciotens®Cradle firmly with one hand.

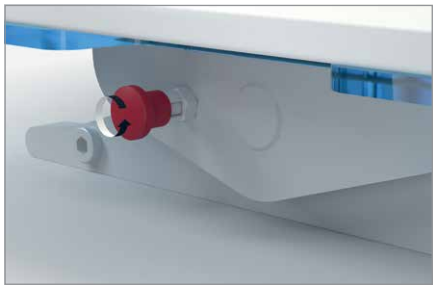
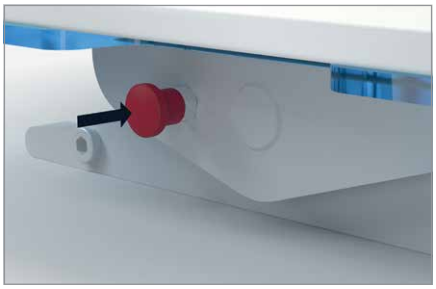


Please use positioning aids (such as rolled towels) to help secure the patient in the fasciotens®Cradle. It is also essential to secure the fasciotens®Cradle with at least one hand when the patient is positioned on their side.

2. **Release the locking bolts at the head and foot end** by pulling both of them out and turning them 90°.

3. **Move the fasciotens®Cradle to the desired left or right side position.**
4. **Lock the fasciotens®Cradle in the desired angle** by turning back the locking bolts at the head and foot end and locking them in place.

Check that the locking bolts and fasciotens®Cradle are securely and firmly locked in place by exerting moderate force on the side facing you and then letting go. The alignment of the fasciotens®Cradle must not change as you do this.

Service life, cleaning and disposal

Service life

fasciotens®Cradle is a reusable medical device. Its service life depends in general on how much wear and damage it encounters. Continuous cleaning has no effect on the performance of the product.

Cleaning

fasciotens®Cradle must be cleaned and disinfected in the following cases:

- Before each re-application during surgical revisions
- In the case of heavy soiling during use on the patient
- After completed use for one patient and before the next use for another patient

Furthermore, always follow standard safety precautions for general occupational safety, your specific SOPs and all relevant regulatory requirements. These are designed to reduce the risk of transmission of microorganisms to the patient from known and unknown infection sources. These precautions should be applied to all patients, regardless of their known or suspected infection status, if contact with blood or other body fluids is to be expected.

fasciotens recommends the following procedure for a scrubbing/wipe disinfection, taking into account the instructions of your institution:

- Cleaning and disinfection should not be carried out while the patient is being treated, or the patient should be separated from the product.
- Wearing of personal protective equipment (PPE), such as special medical gloves
- Cleaning of all organic materials (visible dirt or body fluids) from the fasciotens®Cradle before disinfecting
- The product or individual product parts should not be immersed or soaked in liquids
- Use of soft, non-abrasive cloths or compresses for cleaning and disinfecting fasciotens®Cradle

The following disinfectants and cleaning agents suitable for clinical use are suitable for cleaning the product according to the manufacturer's instructions:

Product	Approval by fasciotens
Mikrozid® sensitive wipes	• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle
Mikrozid® universal wipes	• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle
Mikrobac® tissues	• Approval according to the manufacturer's data sheet from Hartmann • Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle
Bacillol® / 30 tissues	• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle
Dismozon®plus	• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle
Antifect N / Liquid®	• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle
Incides N	• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle

Storage instructions for fasciotens®Cradle

fasciotens®Cradle must

- be stored in a clean, cool and dry location,
- be protected from mechanical damage,
- not be dropped and be handled with care,
- be protected from direct sunlight.

Maintenance

Careful handling, inspections and maintenance will keep the product functional and safe for many years. Inspections ensure safety and minimise the risk of malfunctions. We therefore recommend having maintenance/refurbishing of fasciotens®Cradle performed at regular intervals (at least every three years).

Maintenance must be carried out exclusively by fasciotens GmbH.

Disposal of fasciotens®Cradle

You can dispose of the packaging as paper and household waste.

In the design of the product, care was taken to avoid the use of composite materials as far as possible. This design concept allows for a high degree of recycling. At the end of the product's service life, please dispose of it properly or send it to a recycling system. The national regulations and disposal guidelines must be observed for all disposal measures.

Warranty

The legal warranty period of 24 months applies to our products. Should any initial defect occur in your product within this period, please inform our Customer Support immediately.

In case of deficiencies that may result in a hazard for patients, staff or third parties, the device may no longer be used and is to be replaced.

Damage resulting from improper use, external mechanical impacts, transport damage, applications that do not comply with the intended purpose, or applications carried out by unauthorised persons is not covered by this warranty, nor is such damage covered by the liability of fasciotens GmbH.

Support

If you have any issues or questions, please contact our Customer Support team by email **(support@fasciotens.de)** or call us on **+49 (0)221 17738 500**.

Symbols used

Symbols	Labelling
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Product number”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Batch code, lot”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Name and address of the manufacturer”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Please observe the Instructions for Use”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Product not sterile”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Medical device”
	Labelling of products placed on the market in accordance with the relevant European legal requirements.
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Protect from sunlight”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Keep dry”

Notes

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