fasciotens®Pediatric

# Instructions for use

fasciotens
ABDOMINAL WALL SOLUTIONS

www.fasciotens.de

# Dear customer,

Thank you very much for choosing fasciotens®Pediatric, the innovative therapy option in the treatment of congenital and acquired abdominal wall defects (e.g. 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 paediatric 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.**

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Germany

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Website: www.fasciotens.de

fasciotens
ABDOMINAL WALL SOLUTIONS

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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 owner or operator of the device insofar as the product has been used by persons who do not belong to the relevant professional groups or who do not have the qualifications required to operate the product or 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, indications and contraindications

## Intended purpose

The intended purpose of fasciotens®Pediatric is for the prevention of fascial retraction in an open abdomen and for stretching of the abdominal wall/fascia in the case of current or previous loss of abdominal wall/fascial tissue.

fasciotens®Pediatric is a medical device of class Is (sterile).

The product is intended exclusively for human medical purposes and may only be used for the treatment of one patient (single use).

*The product is approved for use exclusively in combination with fasciotens®Cradle. Combination with other positioning systems is not permitted.*

## Indications

The combination of fasciotens®Pediatric and fasciotens®Cradle achieves both abdominal wall stretching and flexible patient positioning in newborns and young infants. Typical indications may be either congenital or acquired conditions, e.g. after abdominal surgery.

**Congenital abdominal wall defects:**

- Gastroschisis
- Omphalocele
- Bladder exstrophy
- OEIS complex

**Acquired abdominal wall defects:**

- Abdominal compartment syndrome
- Peritonitis
- Necrotising enterocolitis
- Transplantation

## Contraindications

*Usage may be limited by local factors in the area of application and the general condition of the patient!*

**Local factors:**

- Insufficient mechanical tensile strength of the abdominal wall
- Infections of the abdominal wall
- Other factors that render it impossible to anchor a traction mechanism to the abdominal wall/fascia

**General factors:**

- Severe coagulation disorders
- Very small premature infants weighing < 1,000 g
- Severe sepsis (minimal handling)

## Information about side effects and risks

When using the product, the following undesirable side effects may occur in the short or long term:
Damage to the fascia (a general therapy-specific side effect that is not specifically attributable to the product).

### Target patient groups

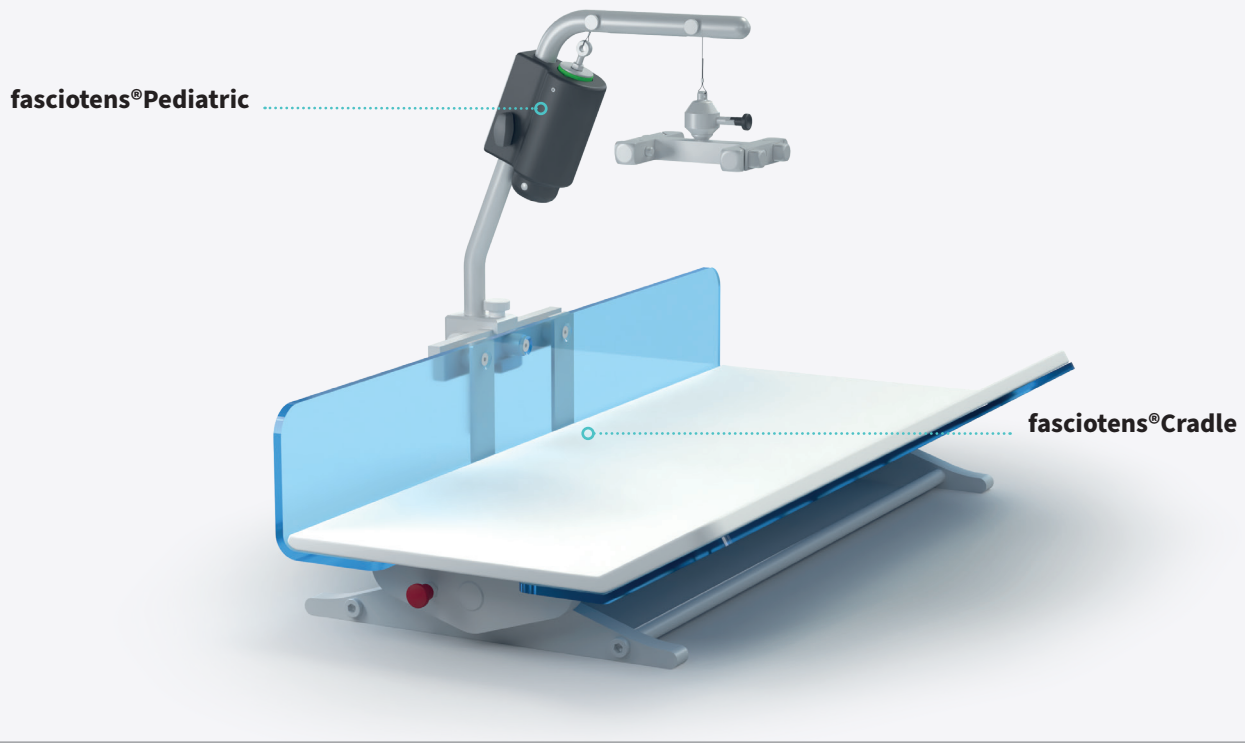
Newborns and young infants with a diagnosed congenital or acquired defect of the abdominal wall

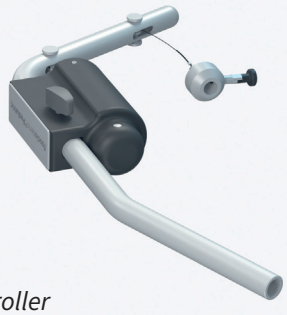
### Intended users

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

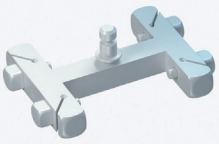
# Product design

fasciotens®Pediatric is designed exclusively for use in combination with fasciotens®Cradle (see picture).



*Traction controller*



*Suture retention frame*

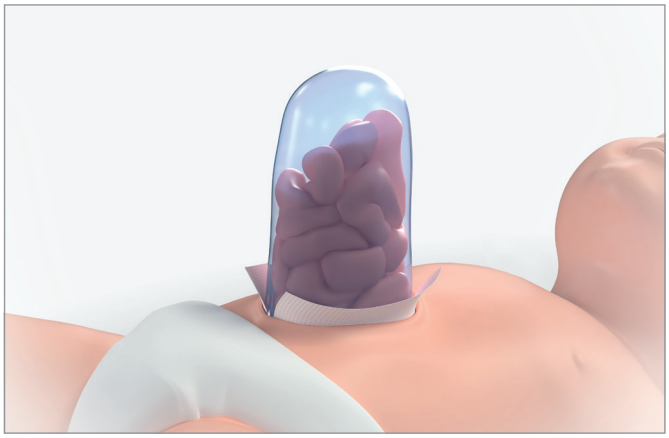
# Preparing the patient

fasciotens®Pediatric should be ready for use before birth or before the planned decompression surgery in case of a diagnosed abdominal wall defect or if a laparostoma is created, for instance in the event of confirmed abdominal compartment syndrome.

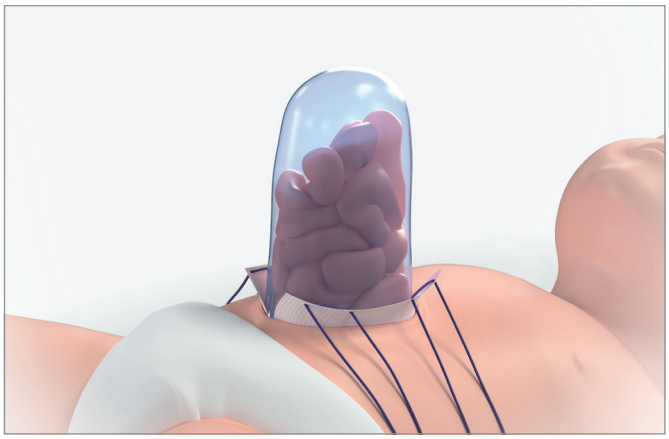
## Surgical preparation

Below is an example of a possible procedure for preparing the patient for surgery.

The decision about the therapy and its preparation lies exclusively with the treating physician. To conserve the structures of the abdominal wall, we recommend distribution of the ventrally applied traction by means of a sutured commercial surgical mesh. Ideally, a doubled mesh border should be stitched into the fascia. Here we recommend short spaces between stitches (small steps, small bites).



After applying the surgical mesh, two surgical sutures are inserted through either side of the mesh in a U-shape at similar distances. We recommend initially leaving the ends of the U-shaped suture approx. 25 cm long on both sides.



*The abdomen should be covered immediately after application of the mesh and suture material and before the product is used on the patient.*

*Multifilament suture material (USP 2) must always be used to secure to the suture retention frame to ensure that the sutures are securely retained.*

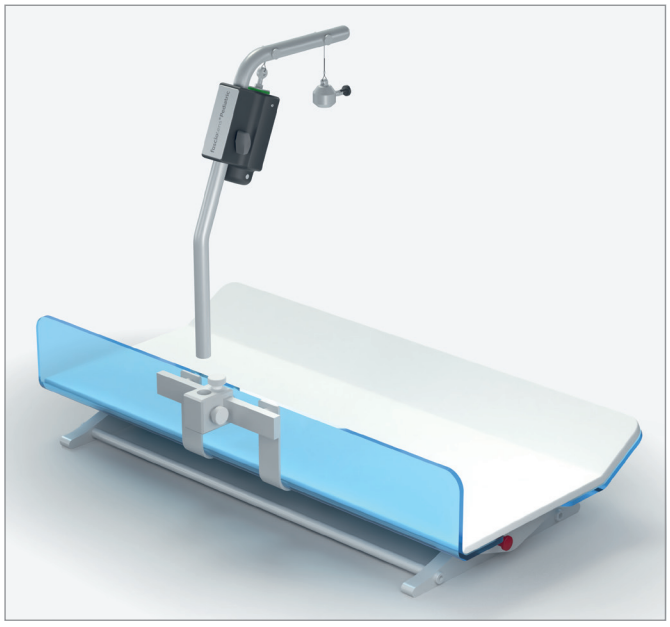
# Assembly

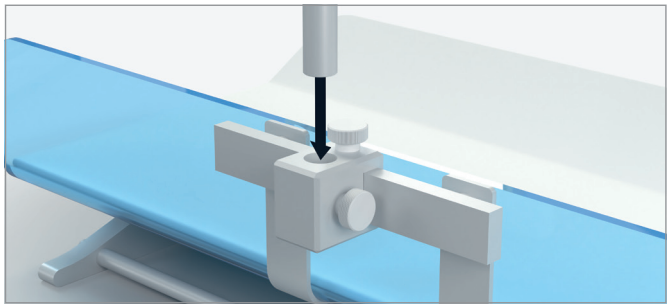
*If the sterile packaging is damaged before use of fasciotens®Pediatric, ensure that the product is no longer used. Contact the manufacturer.*

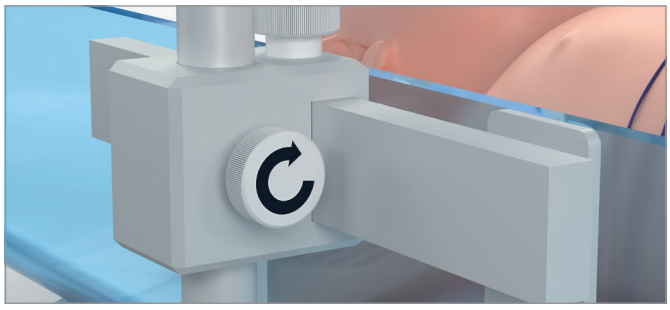
## Attaching fasciotens®Pediatric to fasciotens®Cradle

*Please refer to the Instructions for Use for fasciotens®Cradle.*

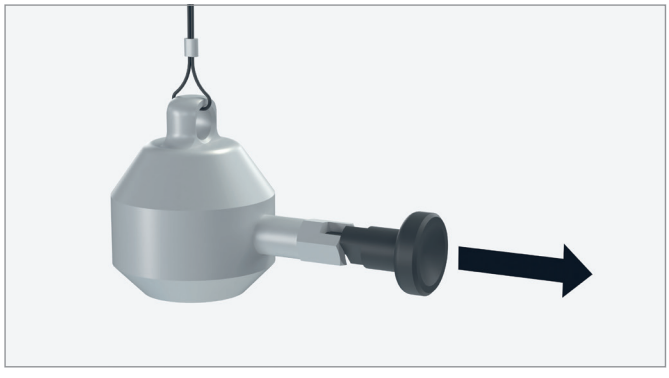
1. Guide the traction controller into the connection point on the fasciotens®Cradle. Then lock the traction controller by turning the side thumb screw clockwise.

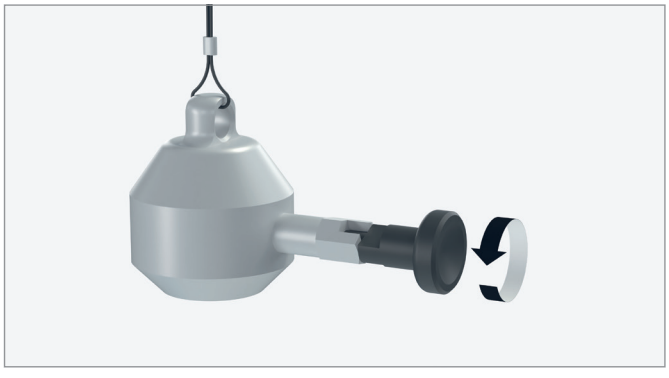




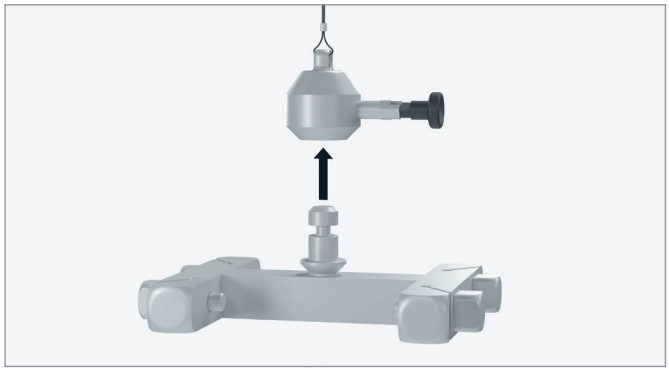


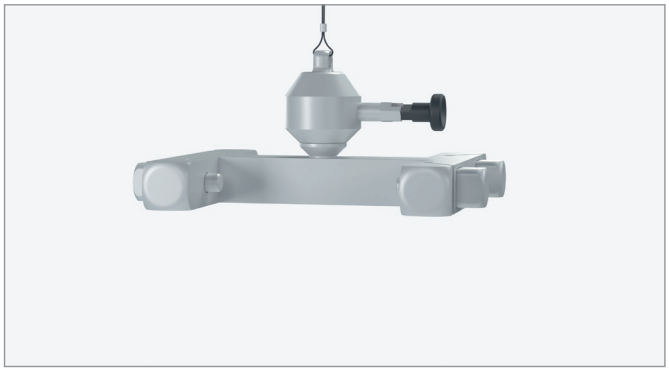
2. Pull out the black locking bolt and turn it 90°. The locking bolt stops in an open position.



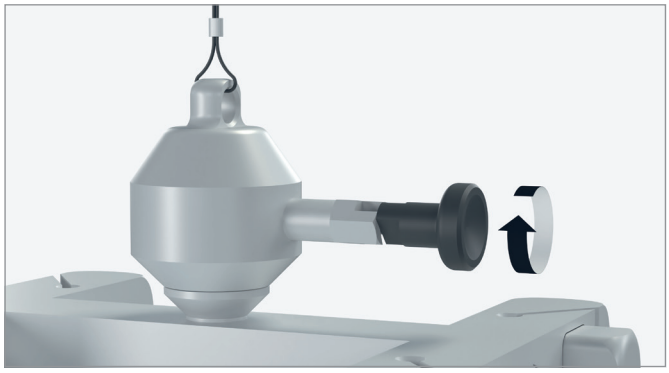


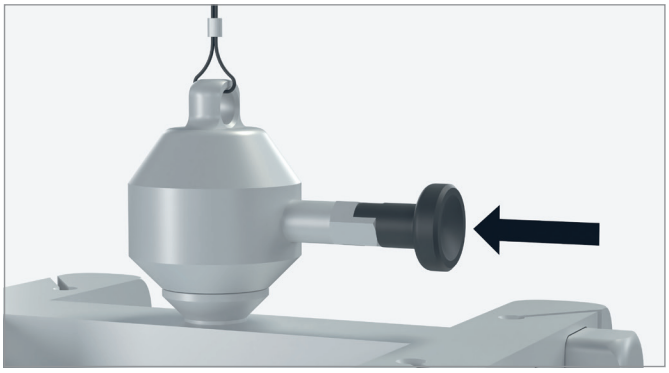
3. Guide the suture retention frame with the pin into the retaining bracket from below.





4. Turn the locking bolt 90° back to lock it in the retaining bracket.





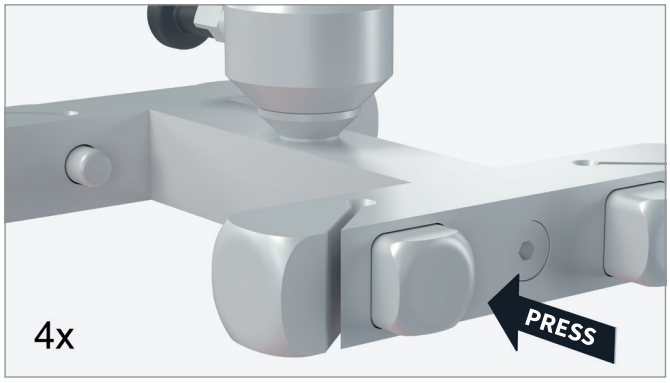
*Check that the suture retention frame is firmly seated by pulling it down with moderate force. The suture retention frame must not come loose from the retaining bracket.*

*Ensure that the traction device of the traction controller is in the uppermost position.*

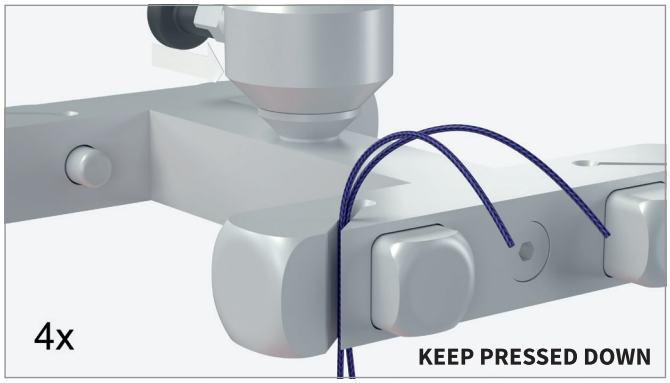
*Please refer to the Instructions for Use for fasciotens®Cradle regarding patient positioning.*

## Attaching the traction sutures to fasciotens®Pediatric

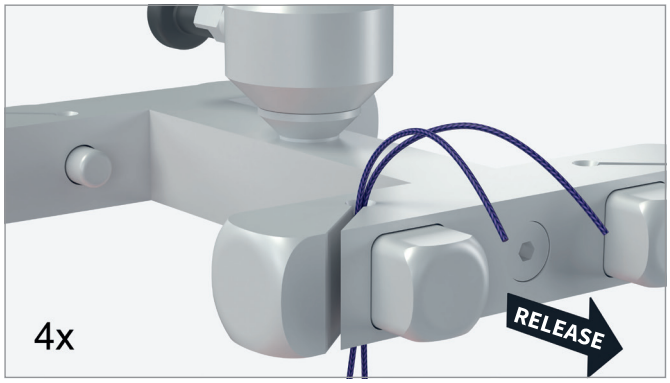
The sutures applied in the mesh are secured to the suture retention frame as follows. Perform the procedure four times.




1. Press the pushbutton on the side bar of the suture retention frame and keep it pressed down.

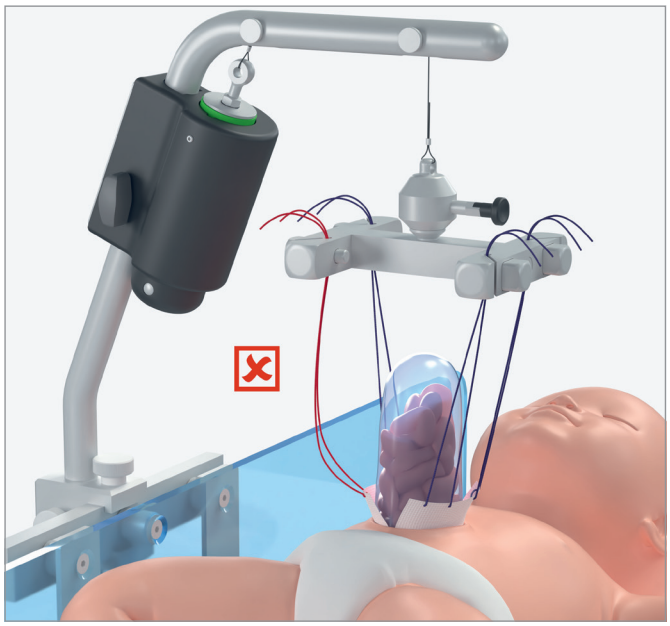


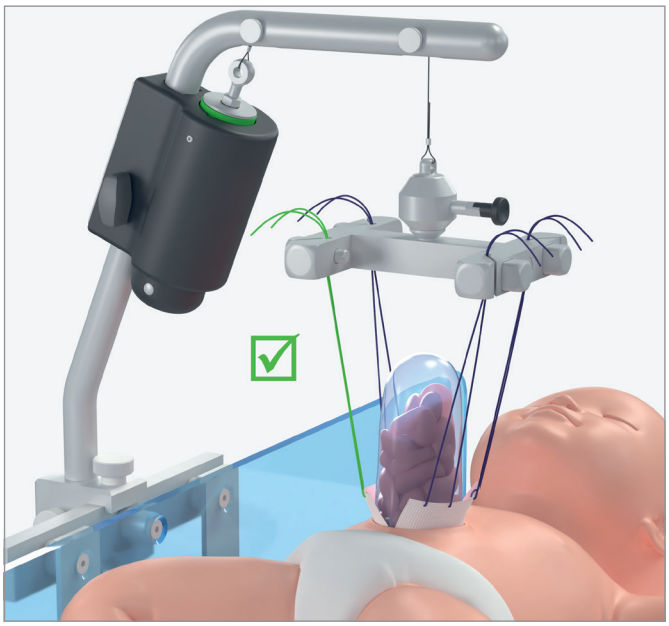

2. Guide each doubled suture through the nearest slit in the side bar of the suture retention frame.



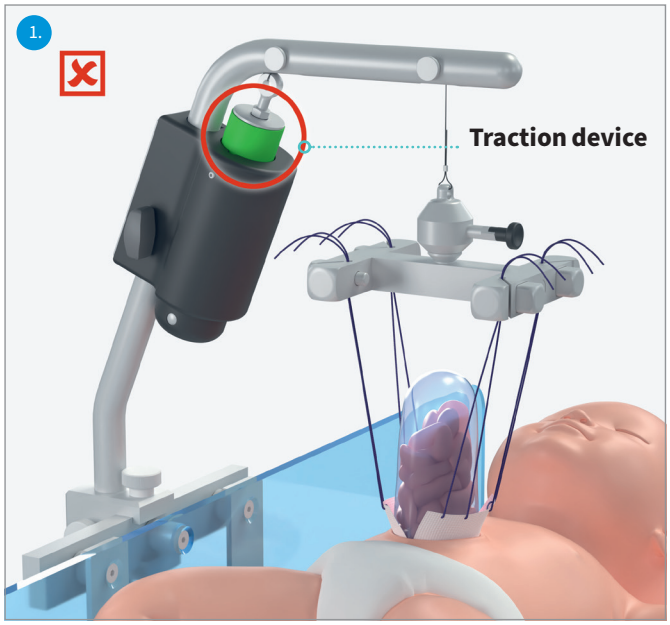

3. Release the pushbutton while keeping the sutures taut.

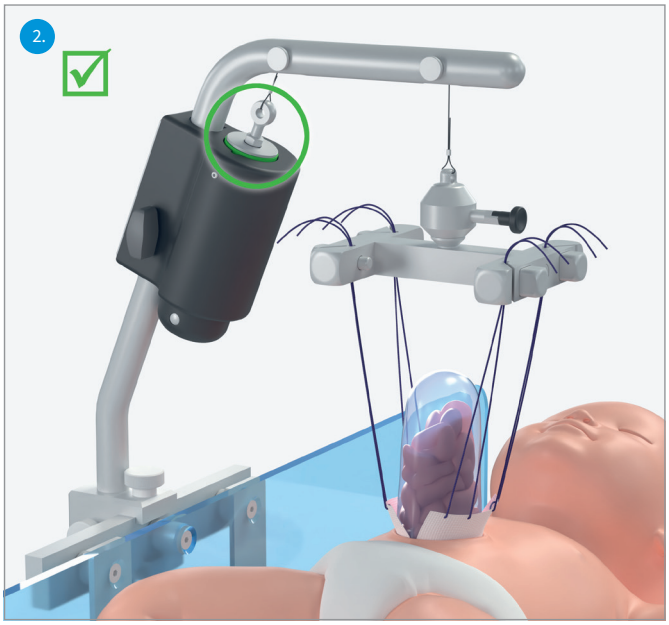
*All sutures should have equal basic tension. If necessary, retighten individual sutures.*





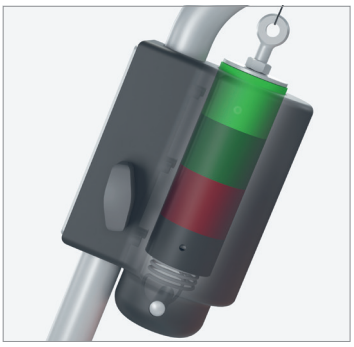
*Please ensure that the basic tension is not too high in the beginning. Ideally, the traction device remains in the starting position/zero position after initially applying the traction sutures (see pictures 1 and 2). This means that, if necessary, you can adjust and increase the tension via the traction device on the traction controller during the treatment with fasciotens®Pediatric.*



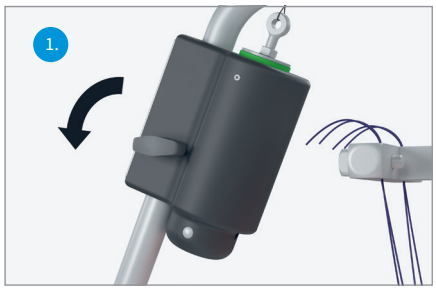
# Adjusting the tensile force

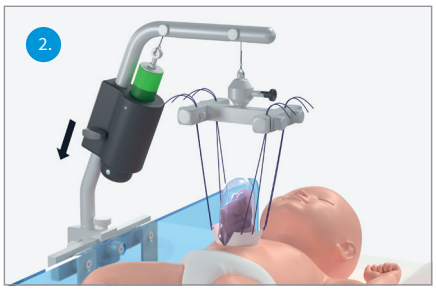
The tensile force is adjusted using the traction device on the traction controller. Traction forces of up to 3000 g can be applied. The treating physician decides the amount of tensile force to be applied. fasciotens recommends a tensile force of no more than half the patient's body weight. The adjusted tensile force can be monitored with the coloured rings on the plunger in the traction device. The coloured rings can be used to differentiate between three traction ranges: low traction range (light green, divided into approximately 0 – 500 g and 500 – 1000 g), medium traction range (dark green, divided into approximately 1000 – 1500 g and 1500 – 2000 g) and high traction range (red, divided into approximately 2000 – 2500 g and 2500 – 3000 g).

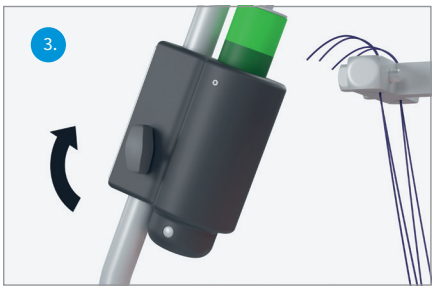


Proceed as follows to adjust the tensile force:

1. **Loosen the wing screw** on the side of the traction device.
2. **Lower the traction device** to achieve the desired tensile force according to the traction ranges given above.
3. **Lock the wing screw** to secure the traction device in the desired traction range.




*It is possible to reduce the tensile force of the individual sutures (e.g. at the desired expansion of the abdominal wall) and this should be checked at regular intervals. The tensile force may need to be readjusted.*

*Perform a final check to ensure there is equal tension of the individual sutures. The tension should be equally distributed.*

*The suture retention frame must not be in contact with the wound area or the abdominal organs!*

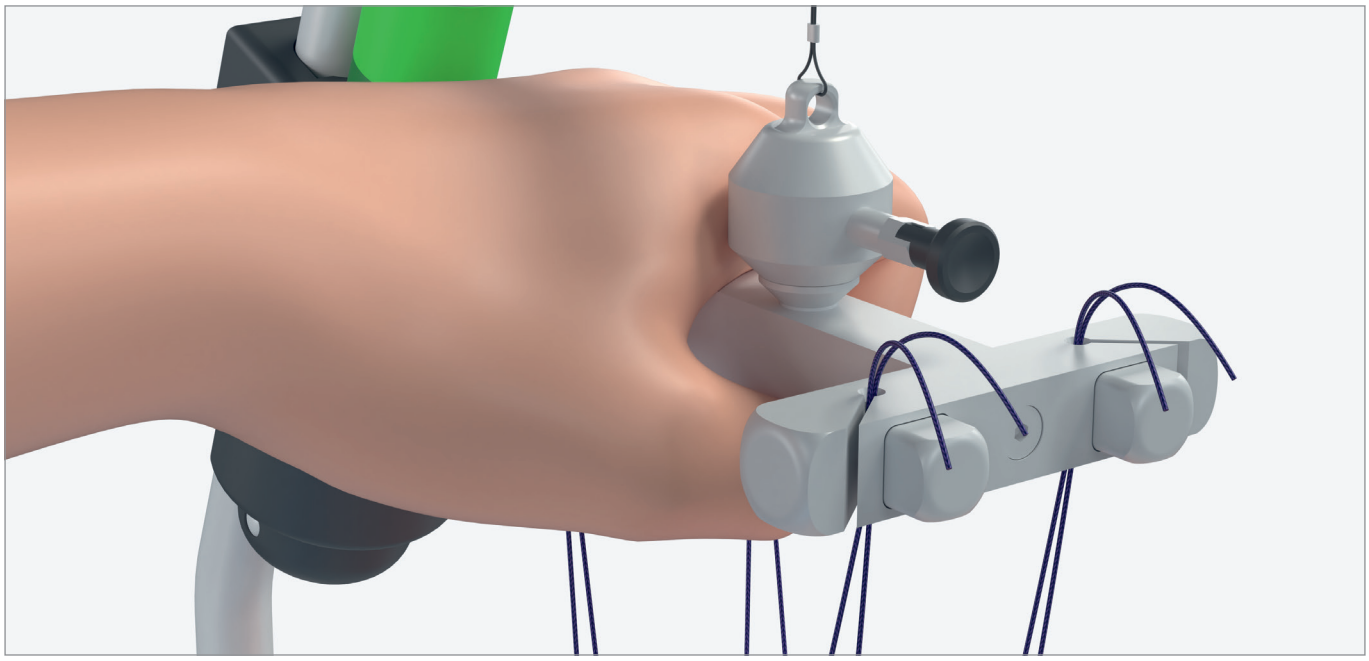
*Direct contact between the traction sutures and the abdominal organs must be avoided at all costs. Regular visual inspection of the viscera and sutures is required throughout the use of fasciotens®Pediatric. It may be necessary to adjust or replace the sutures to prevent injury to the prolapsed organs (e.g. by cutting the suture material).*

# Removal for care measures, parent-child contact, surgical revision or in an emergency

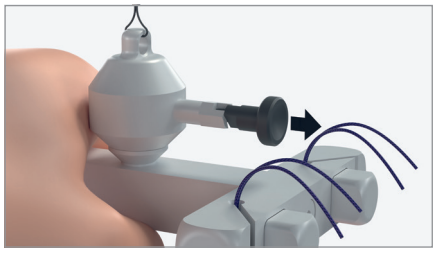
The following options are available for separating the product from the patient.

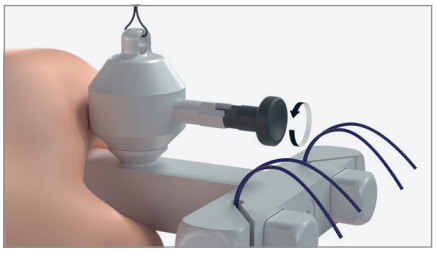
### Releasing the suture retention frame via the emergency release

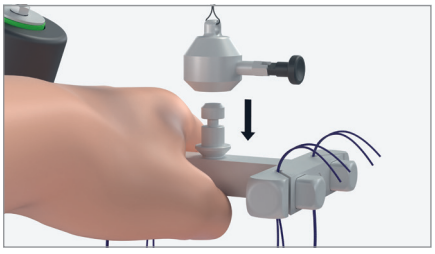
1. Hold the suture retention frame firmly with one hand.



2. Pull out the black locking bolt and turn it 90°.







The suture retention frame releases downwards and must be placed next to the patient.

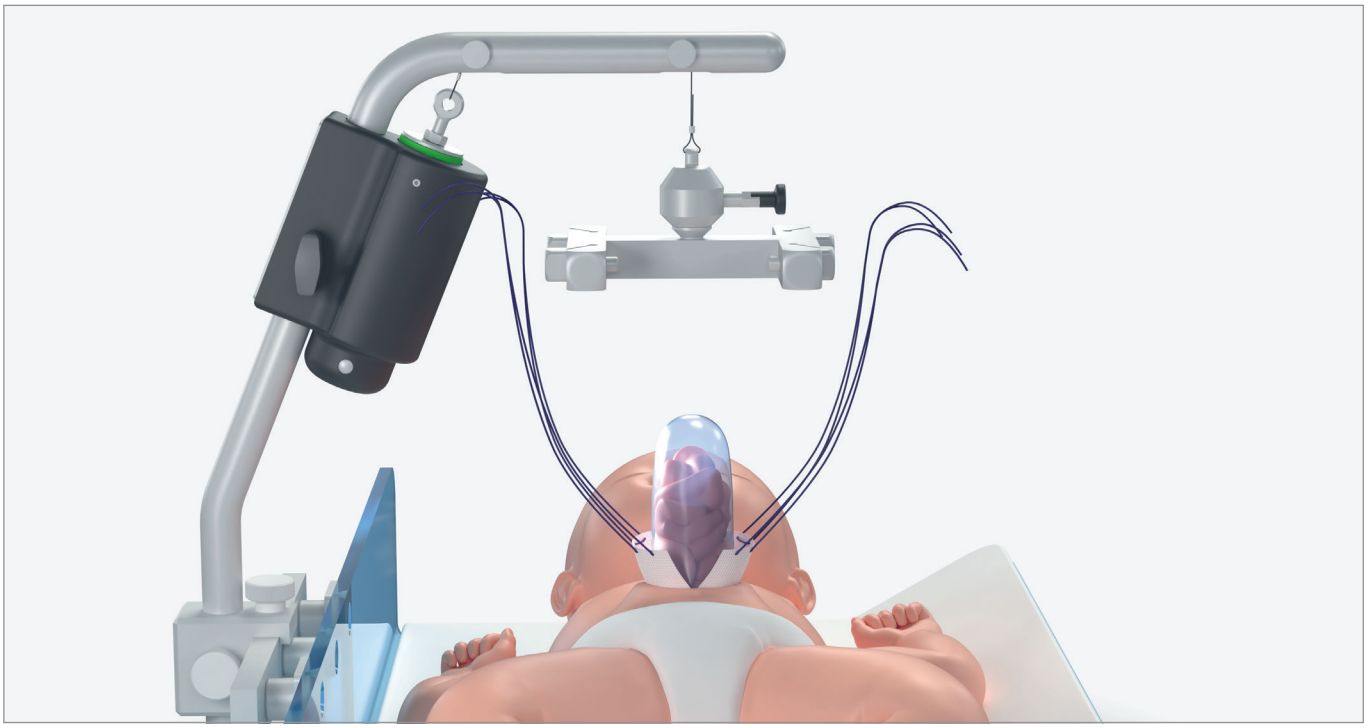
*The suture retention frame must be secured with one hand when using the emergency release to prevent it from suddenly falling onto the patient! To do this, grip the suture retention frame from below or at the centre bar of the suture retention frame!*

## Releasing the suture material from the clamps

*When releasing individual sutures, it is important to ensure that the tensile force is reduced beforehand, as after releasing individual sutures, the applied tensile force will be distributed over the few remaining individual sutures. This can cause the individual sutures to be overtensioned, which can lead to tissue damage.*

1. Hold the suture with your hand.
2. Press the pushbutton and release the suture from the clamp.
3. Repeat the procedure for all clamps.

After the treatment has been carried out, the product can be used again as described in the section on assembly.



# Cleaning and disposal

## Cleaning

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

- Before each re-application during surgical revisions on the same patient
- In the case of heavy soiling during use on the 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 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 therapy unit 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 the product

**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<br>• Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle |
| Bacillol® / 30 tissues | • Suitable for product materials of fasciotens®Pediatric and fasciotens®Cradle |
| Bacillol® AF / tissues | • Approval according to the manufacturer's data sheet from Hartmann for fasciotens®Pediatric |
| 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 |

### Re-conditioning / sterilisation

Repeat sterilisation and re-conditioning of the medical product is not permitted. Re-conditioning procedures cannot preclude potential adhesion of infectious material and damage to the product (e.g. material breakage) and consequently a hazard to the patient. The manufacturer is not able to guarantee the performance and safety of the medical device if used repeatedly.

### Disposal

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.

*Any re-conditioning or re-sterilisation and subsequent re-use of the product fasciotens®Pediatric is considered improper use. In such cases, the warranty and liability of fasciotens GmbH will be deemed to be null and void.*

*If there are any deficiencies that may result in a hazard for patients, staff or third parties, the device may no longer be used and must 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.<br>Symbol for “Product number” |
|   | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Batch code, lot” |
|  | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Name and address of the manufacturer” |
|  | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Please observe the Instructions for Use” |
|   | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Sterilised with ethylene oxide” |
|   | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Do not re-sterilise” |
|  | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Do not re-use” |
|  | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Do not use if the package is damaged” |
|  | Labelling of products placed on the market in accordance with the relevant European legal requirements. |
|  | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Protect from sunlight” |
|  | Labelling in accordance with the standard ISO 15223-1.<br>Symbol for “Keep dry” |

# Notes

fasciotens

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