fasciotens®Abdomen

Instructions for use

fasciotens
ABDOMINAL WALL SOLUTIONS

www.fasciotens.de

Dear customer,

Thank you very much for choosing fasciotens®Abdomen, the innovative therapy option in the treatment of the open abdomen. fasciotens® products provide the highest quality, safety and state-of-the-art technology. Medical necessity dictated the development of this product, and it was practising surgeons who accomplished this innovation.

The principle of fascia retraction is based on a combination of diagonal and vertical traction. For this reason, it follows that purely vertical traction provides the greatest possible pressure relief for the abdominal cavity. In the case of diagonal clamping of the sutures, the intra-abdominal volume is reduced and the fasciae are pulled towards each other.

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 or inappropriate use 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.

Company address:
fasciotens GmbH
Moltkeplatz 1
D-45138 Essen
Germany

Tel. +49 (0)201 99 999 630
Fax +49 (0)201 99 999 639
Email: info@fasciotens.de
Website: www.fasciotens.de

fasciotens
ABDOMINAL WALL SOLUTIONS

Video tutorial

https://www.fasciotens.de/wl-abdomen-ifu-video-en

The user must view the video tutorial in full before using the product.

Table of Contents

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, indications and contraindications

Intended purpose

The intended purpose of fasciotens®Abdomen is to prevent fascial retraction in the open abdomen and to stretch the abdominal wall/fascia in the case of current or previous loss of abdominal wall/fascial tissue. fasciotens®Abdomen is a medical device belonging to class Is (sterile) and is intended exclusively for human medical purposes.

Indications

Typically, all indications where applying external tensile force may be an option when a laparostoma was created due to elevated abdominal pressure or other causes. fasciotens®Abdomen is intended to prevent fascial retraction or – in cases where a loss of fascia/abdominal wall has already occurred – to stretch and recover tissue.

Any use of the product for other anatomical structures or other interventions is contrary to the intended purpose.

Contraindications

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

Local factors:

- Skin damage or infections in the areas where the support surfaces are to be placed
- Application to intact skin not possible
- Unstable thorax
- Unstable pelvis
- Other local impairments to stability in the areas of the support surfaces
- Insufficient clearance between patient and device due to obesity, for example
- Silicone implants in the area of the support surfaces, especially in the female breast
- Adhesions between abdominal organs and the abdominal wall that cannot be removed

General factors:

- High-grade heart failure from NYHA III or ejection fraction below 35%
- Pregnancy
- Acute impairment of lung function necessitating an 80% FiO2

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 from the support surfaces
- Damage to the fascia (a general therapy-specific side effect that is not specifically attributed to the product)

Intended patient population

Critically ill adult patients requiring open abdomen treatment due to underlying septic/non-septic abdominal conditions; critically ill primarily means ICU patients with a long duration of treatment.

Intended users

- Surgeons with experience in abdominal surgery (e.g. general, visceral, vascular and trauma surgery)
- Nurses

Product design

fasciotens®Abdomen

Preparing the patient

fasciotens®Abdomen should be ready for use when planning to create a laparostoma, e. g. in the case of confirmed abdominal compartment syndrome.Likewise, fasciotens®Abdomen should be available in the event of an intraoperative decision to create a laparostoma.

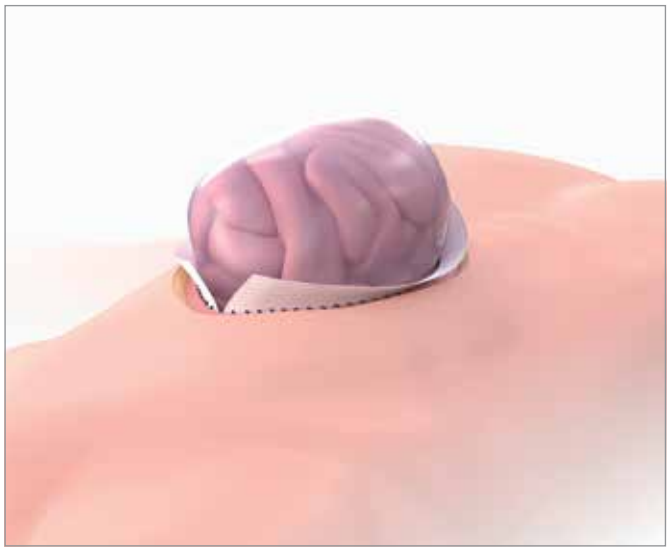
Surgical access to fascia

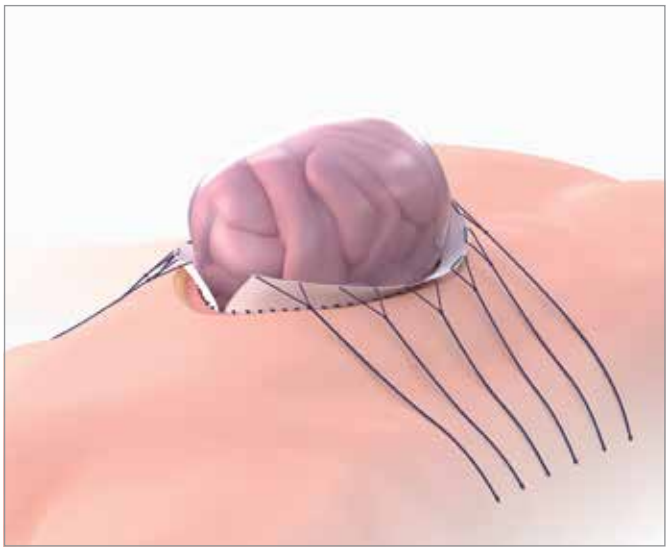
In view of the anatomical and pathological conditions, the surgeon requires surgical experience. Before applying fasciotens®Abdomen, the fascia of the rectus abdominis muscle must be sufficiently exposed on both sides (min. width 2-3 cm). The surgical site should be checked for adhesions of abdominal organs to the abdominal wall. Traction on the abdominal wall may cause tearing of adherent organs.

Placement of surgical mesh and suture materials

To conserve the structures of the abdominal wall, distribution of the ventrally applied traction by means of a sutured commercial surgical mesh is recommended. Ideally, a narrow doubled mesh border (approx. 1-2 cm wide) should be stitched in. We recommend short-spacing the sutures (small steps – small bites).

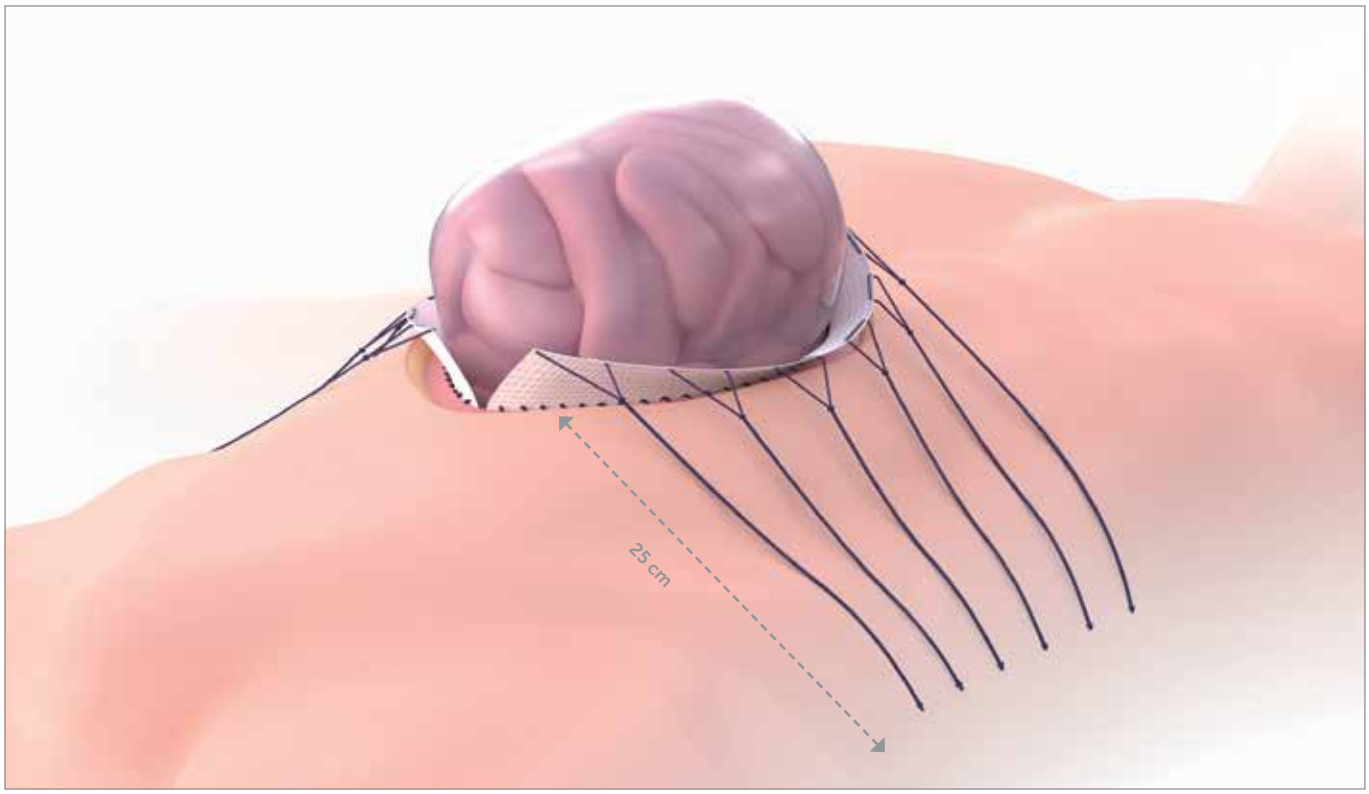
Braided suture material (USP 2) must be used to ensure that the sutures are securely retained in the suture retention frame.





The mesh should be stitched with a long suture, which is then guided upwards in a U-shape to be connected to the suture retention frame after surgery.

The visceral organs and the wound are covered according to the instructions of the treating physician.



After assembling the fasciotens®Abdomen, which is described in the following section, sutures should be introduced and fixated to the suture retention frame. We recommend leaving sutures about 25 cm in length at first and then shortening them after fixation in the side bar, as appropriate. Approx. 5 cm suture length should always be left over for any required slackening.

Product assembly and attachment

Prior to using fasciotens®Abdomen, if the sterile packaging is noticeably damaged, please ensure that the product is not used any further. Contact the manufacturer.

fasciotens®Abdomen consists of the following modules.

Module 1: *Support surfaces*

Module 2: *Suture retention frame*

Module 3: *Stand with anchor screws*

Pre-assembly of fasciotens®Abdomen

The pre-assembly of the product and the suture retention frame to the stand can be carried out on the sterile instrument table or in the ICU. It is important that the surgical precautions necessary for assembly have been carried out as described in the “Pre-operative planning” section.

A sterile procedure +is recommended for the initial application of the product during surgery.

First, Module 1 (support surfaces) and Module 3 (stand + anchor screws) are required.

1. Remove the anchor screw and insert it from below through the opening in the plate. The marking on the plate indicates the top.

Always secure the anchor screws so they are firmly fixed in the supporting foot.
Use the instrument table or a sterile surface created for this purpose.

2. Insert the anchor screw into the thread on the stand's supporting foot. To do this, place the stand on the sterile instrument table and turn the supporting feet upwards.

3. Screw the anchor screws into the supporting foot until these are secure. The plates are now securely connected with the supporting foot.

4. Erect the stand. You can now rotate the traction controller 180 degrees.

The emergency release with the red lever must now point downwards.

The screw head must be turned up to the end cap when starting the adjustment and before each reattachment.

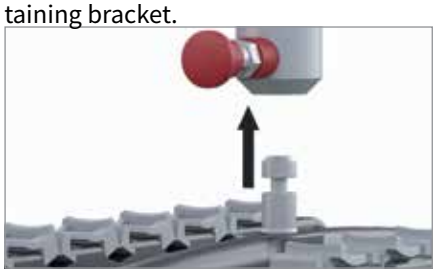
5. Place the stand on the support surfaces.

Secure the support pads so that they do not come off when transferring the assembly!

Secure the suture retention frame with one hand when engaging the red locking bolt.

6. The suture retention frame (Module 2) is fastened using the red locking bolt. The bolt is fixed in the open position by retracting it and rotating it by 90°.

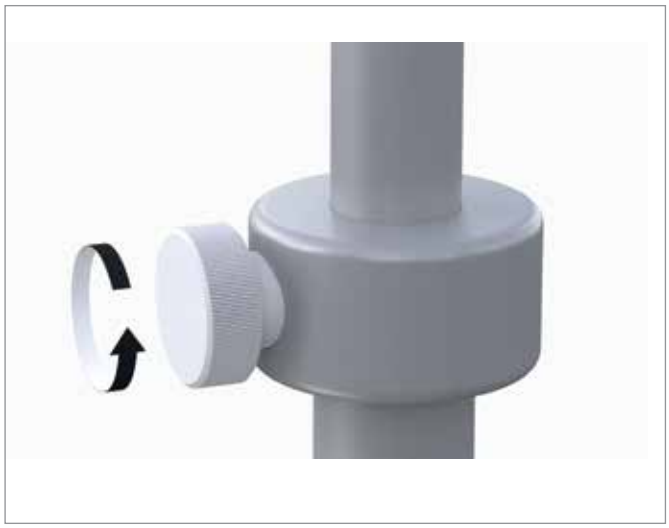
7. The suture retention frame may now be inserted from below. When turned back, the bolt will engage in the ‘locked’ position, and the suture retention frame is secured. Please check that the suture retention frame is securely fixed in the retaining bracket.



Ensure that the suture retention frame is fully inserted into the retaining bracket and that the locking bolt engages properly.

Optional length and height adjustment

Height adjustment is loosened or locked by turning the side thumb screws. Both supporting feet can be individually adjusted in terms of their height. When making a height adjustment, the corresponding side should be secured to the product with one hand.



The thumb screws at the top allow the length to be adjusted along the articulated arm. When making a length adjustment, the black screw head should be secured with one hand.

Do not loosen the thumb screws more than is necessary, to prevent them coming off.

Application of fasciotens®Abdomen

Please read the following safety instructions carefully before starting the treatment!

Before applying the product, the visceral organs and the wound must be covered according to the instructions of the treating physician.

Always cushion the support surfaces with large crease-free absorbent pads or similar crease-free materials.

Ensure that no foreign objects, e.g. cables, electrodes, feed or discharge lines are trapped under the support surfaces and pads.

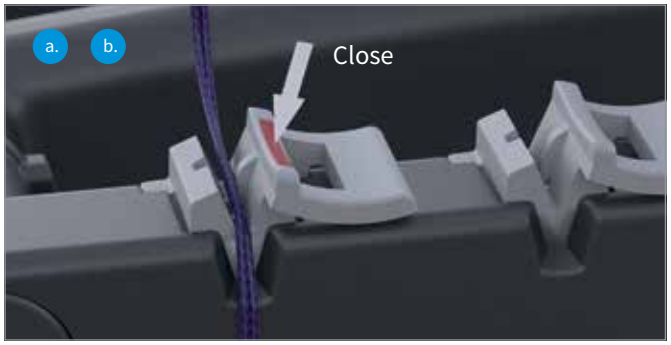
The product should never be placed on the genitals.

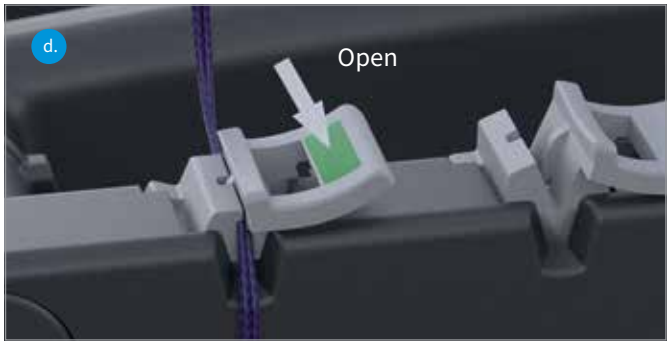
The suture retention frame must always be aligned parallel to the laparostoma.

1. Now place fasciotens®Abdomen on the thorax and the anterior pelvic ring.

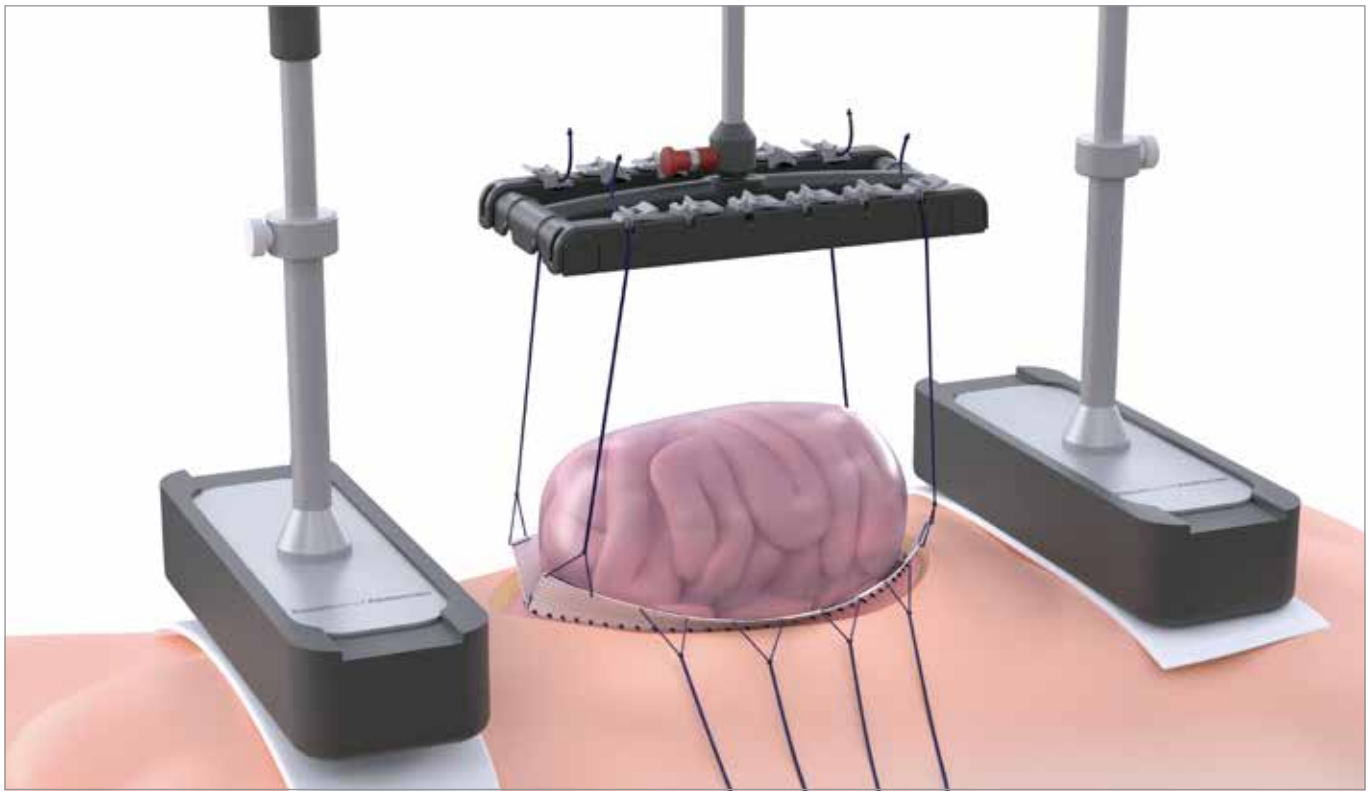
2. The traction sutures stitched into the meshes may now be fixed to the suture retention frame as follows:

a. Guide the doubled traction sutures upwards and insert them from the outside into the open slot of the fixing clip.
b. Close the fixing clip by pressing it in the middle.
c. Perform steps a and b a total of twelve times for all traction sutures previously applied.
d. To release or re-tension the traction sutures, press the side lever on the fixing clip.

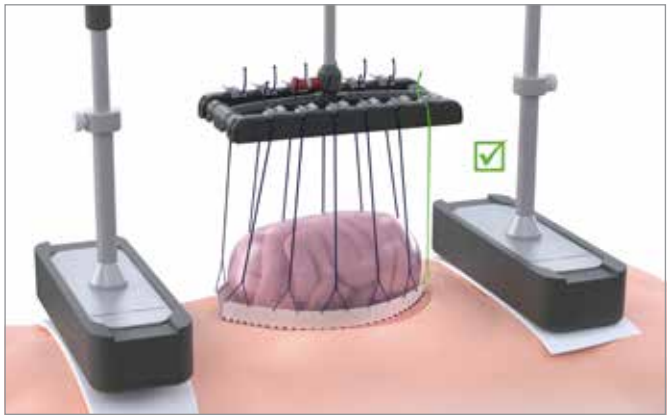


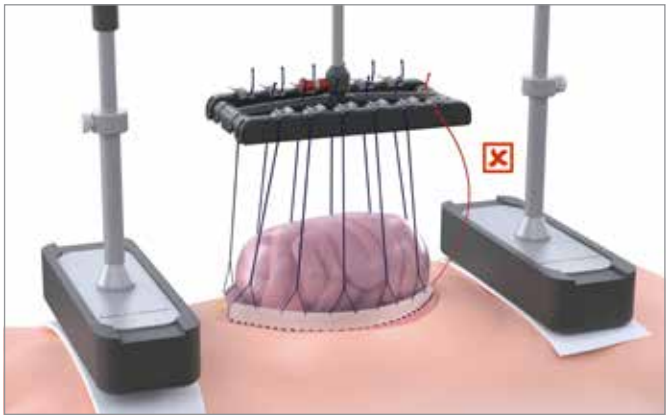


To simplify application, the product should be secured by an assistant until the four corner pull traction sutures are securely attached.

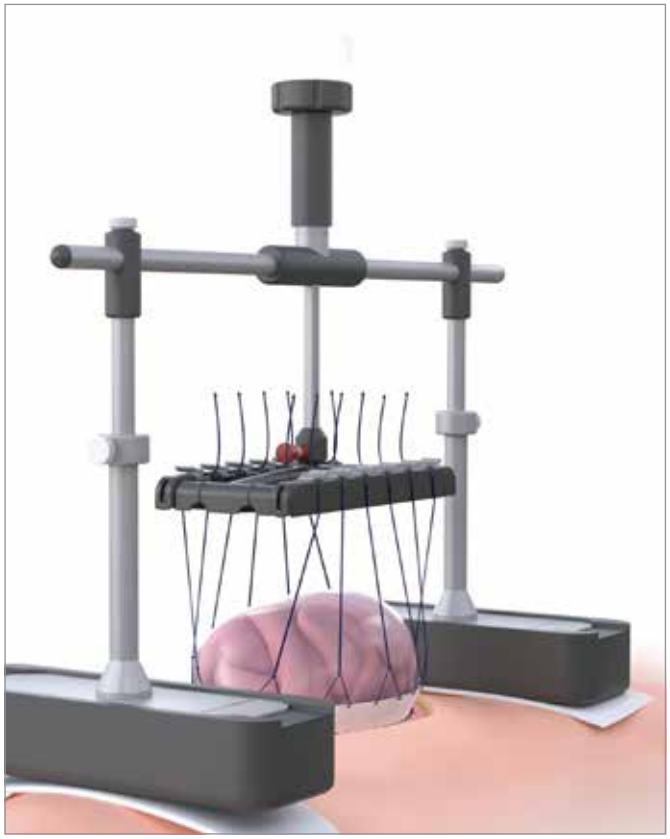


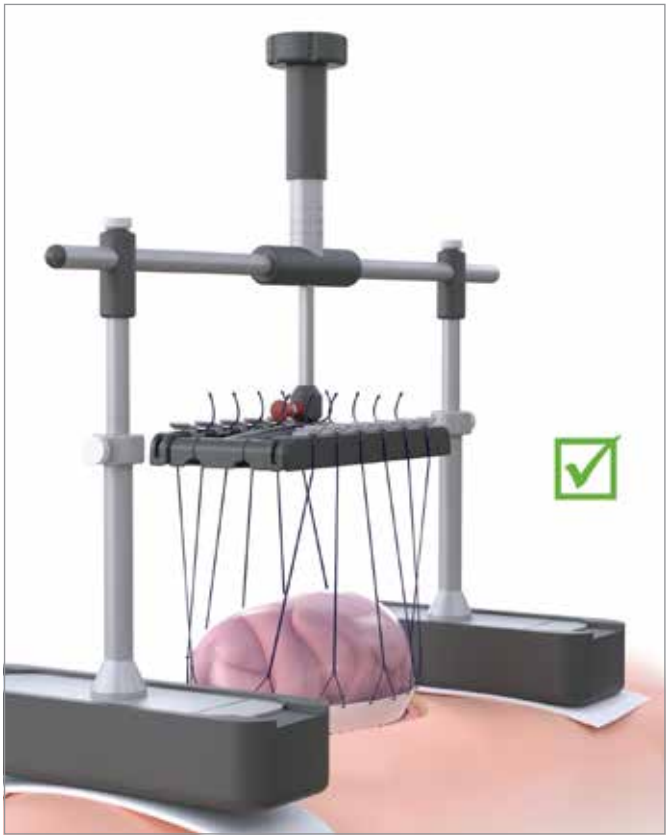
3. Then attach the remaining traction sutures and set them to roughly the same basic tension.





Check all traction sutures have similar basic tension. If necessary, re-tension the individual traction sutures. To do so, please follow the above procedure.





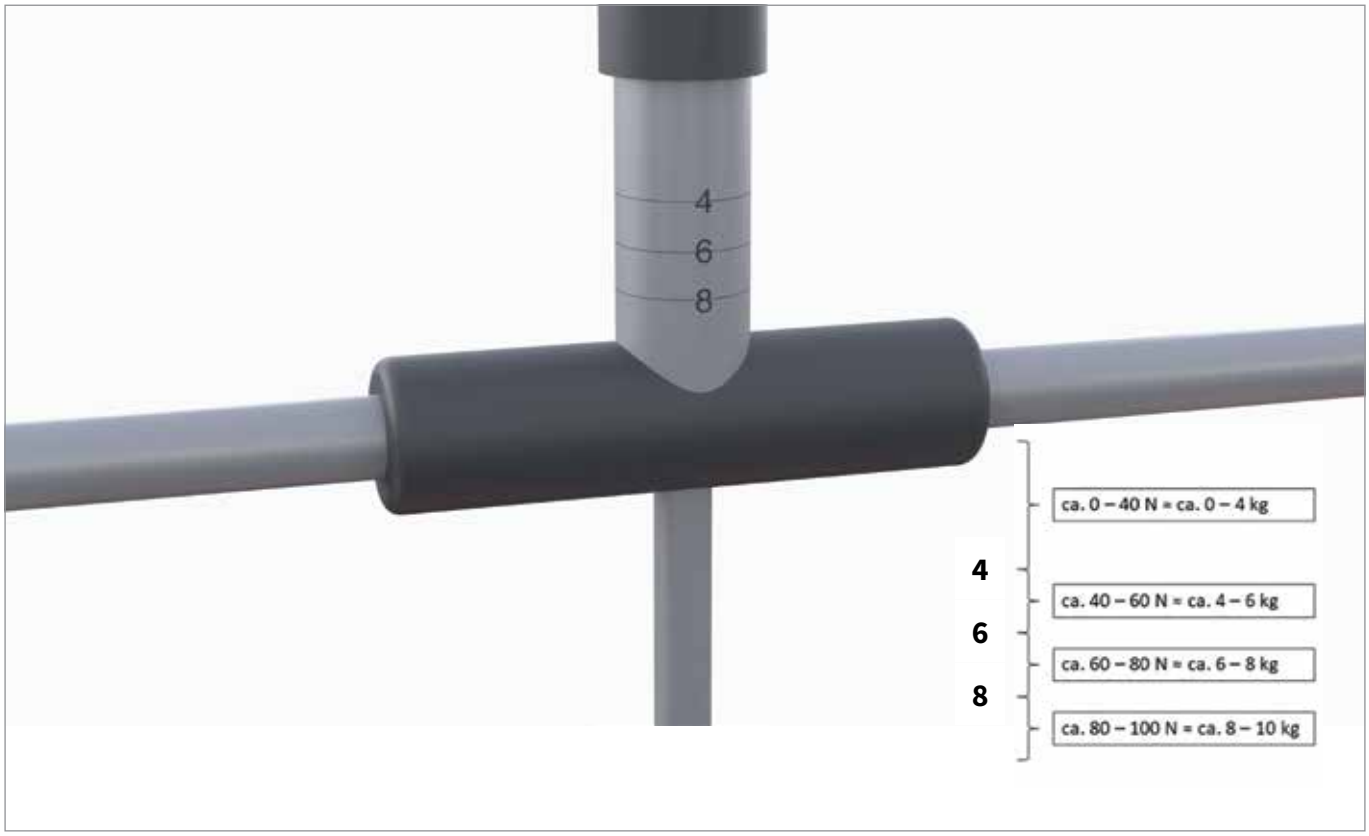
If too much tension (above 4 on the scale) is built up when tensioning the traction sutures, the tensile force cannot be readjusted using the black screw head.

Adjusting the tensile force

The tensile force applied to the abdominal wall/fascia is adjusted by turning the black screw head. It takes several turns of the black screw head to reach the recommended tensile force.

A scale serves as an adjustment aid for the tensile force. It is recommended to adjust the tensile force in the range between 6-8 (corresponds to approx. 6-8 kg).

When starting the adjustment, the black screw head must always be turned up to the end cap. At this stage, the black end cap should not protrude from the top of the screw head.



To avoid skin irritation, traction intervals of about 5 hours traction followed by a 1-hour break are required.

Once every traction break, examine the skin under the support surfaces for changes. If permanent reddening/ pressure sores are observed in the vicinity of the support surfaces, a medical assessment must be carried out.

During the ongoing therapy, it is recommended that the support surfaces are regularly positioned on other parts of the thorax or anterior pelvic ring by moving them longitudinally and/or rotating them.

The abdominal wall/fascia is now brought to tension ventrally.

Do a final check on the tension applied to each traction suture.

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

When positioning a patient, in particular changing the position of the thorax in relation to the pelvis, attention must be paid to possible changes in tensile force and direction of pull.

Procedure for surgical revision

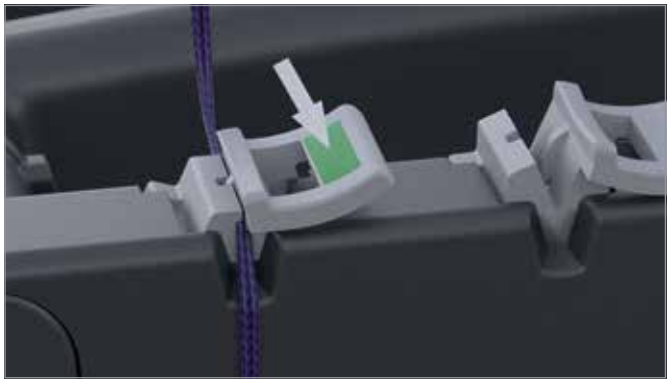
Depending on the course of therapy, follow-up operations and revisions may be necessary. In this case, disassembling fasciotens®Abdomen is simple and fast.

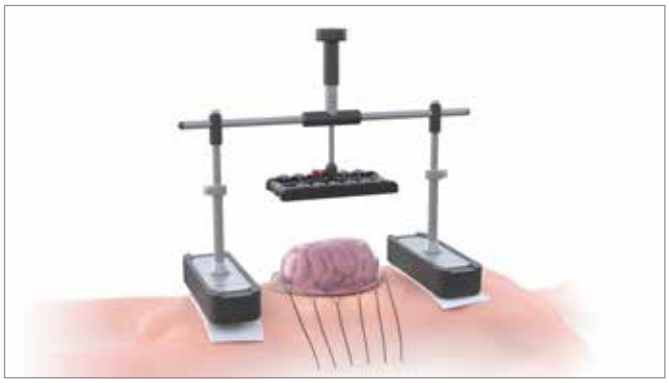
Please always remember that the product is no longer sterile during surgical revision procedures and must be removed from the patient before starting the sterile procedure.

Disassembly in case of surgical revision

1. Always release the overall traction by turning the black screw head until it is flush with the end cap.

2. Loosen all sutures from the fixing clips. You can then remove the product from the patient.





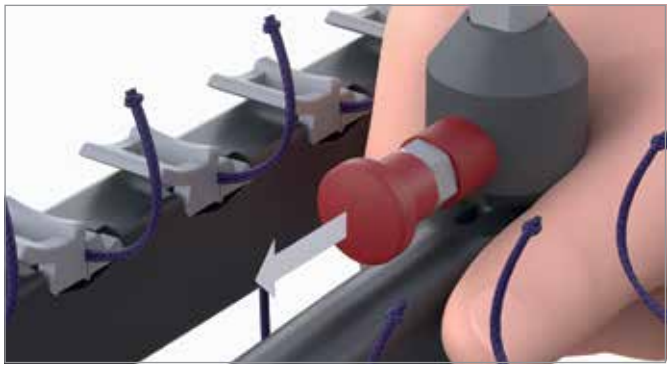
If the edema of the abdominal organs decreases and the attending physician decides to close the abdominal wall promptly, the tension sutures can be pulled in a diagonal direction. For this purpose, the traction sutures are tensioned crosswise in the suture retention frame.

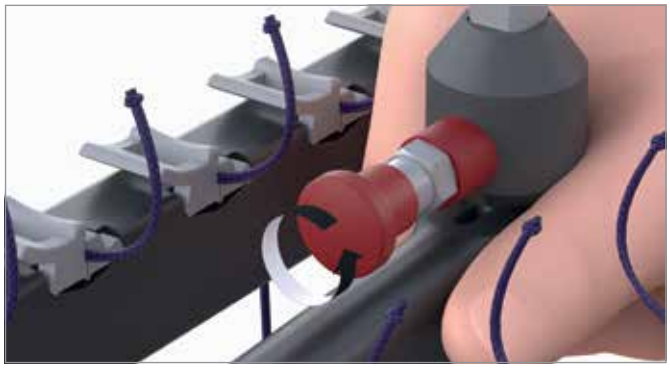
A diagonally-directed pull too early can lead to damage of the abdominal organs if the traction sutures are cut or due to an increase in the intra-abdominal pressure.

Disassembly in daily care and emergencies

The product can be disassembled quickly as part of daily care or in emergency situations.

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





2. Retract the red locking bolt and rotate it 90°.

3. This disengages the suture retention frame which now can be pulled downward and removed.

4. Remove the stand and its support surfaces from the patient.

5. Carefully place the suture retention frame on the wound dressing.

Secure the suture retention frame with one hand when engaging the red locking bolt.

In the event of routine care measures involving removal of the product, the tensile force should be reduced by turning the black screw head anti-clockwise before engaging the red locking bolt.

Reattaching the product

1. Place large crease-free absorbent pads on the thorax and anterior pelvic ring.
2. Place the stand and support surfaces on the pads.
3. Rotate the black screw head to the initial position until the screw head is flush with the end cap
4. From below, insert the suture retention frame into its recess
5. Lock the red locking bolt.
6. Adjust the tensile force once more.

Cleaning and disposal

Cleaning

fasciotens®Abdomen must be cleaned and disinfected in the following cases:
- Before each re-attachment during surgical revisions
- In the case of heavy soiling during use on a patient

fasciotens recommends for cleaning and disinfecting fasciotens®Abdomen:
- Scrubbing/wipe disinfection with soft cloths or compresses
- Removal of all product parts from the patient during the cleaning process
- Wear personal protective equipment according to hospital standards
- Product parts must not be soaked or immersed in liquid

Always follow standard safety precautions, your specific SOPs and all relevant regulatory requirements.

Reprocessing/sterilisation

The product is intended for single use only, therefore it is not suitable for resterilisation or reprocessing. Reprocessing procedures cannot preclude the potential adhesion of infectious material or damage to the product (e.g. material breakage) and consequently a hazard to the patient. For this reason the manufacturer is not able to guarantee the performance and safety of the medical device if used repeatedly.

Disposal

At the end of the therapy, please dispose of the product properly or send it to a recycling system. You can dispose of the packaging as paper and household waste. 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.

The product is for single use only and is labelled accordingly. Any reprocessing or resterilisation and subsequent re-use is considered inappropriate, and in this case all and any guarantee rights, the warranty and liability of fasciotens GmbH are deemed to be null and void.

In the event of any defects that may pose a risk to patients, staff or third parties, the device must 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 non-authorised persons is not covered by this warranty, nor is it 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 “Sterilised with ethylene oxide”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Do not re-sterilise”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Do not re-use”
	Labelling in accordance with the standard ISO 15223-1. 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. Symbol for “Keep dry”
	Labelling in accordance with the standard ISO 15223-1. Symbol for “Protect from sunlight”

Glossary of warnings

Section	Warning	Page
Intended purpose, indications and contraindications	Any use of the product for other anatomical structures or other interventions is contrary to the intended purpose.	6
	Usage may be limited by local factors in the area of application and the general condition of the patient!	6
Preparing the patient	Braided suture material (USP 2) must be used to ensure that the sutures are securely retained in the suture retention frame.	8
Product assembly and attachment	Prior to using fasciotens®Abdomen, if the sterile packaging is noticeably damaged, please ensure that the product is not used any further. Contact the manufacturer.	9
Adjusting the tensile force	Always secure the anchor screws so they are firmly fixed in the supporting foot. Use the instrument table or a sterile surface created for this purpose.	11
	The screw head must be turned up to the end cap when starting the adjustment and before each reattachment.	12
	Secure the support pads so that they do not come off when transferring the assembly!	13
	Secure the suture retention frame with one hand when engaging the red locking bolt.	13
	Ensure that the suture retention frame is fully inserted into the retaining bracket and that the locking bolt engages properly.	13
Optional length and height adjustment	Do not loosen the thumb screws more than is necessary, to prevent them coming off.	15
Application of fasciotens®Abdomen	Before applying the product, the visceral organs and the wound must be covered according to the instructions of the treating physician.	15
	Always cushion the support surfaces with large crease-free absorbent pads or similar crease-free materials.	15
	Ensure that no foreign objects, e.g. cables, electrodes, feed or discharge lines are trapped under the support surfaces and pads.	15
	The product should never be placed on the genitals.	15
	The suture retention frame must always be aligned parallel to the laparostoma.	15
	Check all traction sutures have similar basic tension. If necessary, re-tension the individual traction sutures. To do so, please follow the above procedure.	17
Adjusting the tensile force	When starting the adjustment, the black screw head must always be turned up to the end cap at the top of the traction controller. At this stage, the black screw head should be flush with the top of the traction controller at the end cap.	18
	To avoid skin irritation, traction intervals of about 5 hours traction followed by a 1-hour break are required.	18
	Once every traction break, examine the skin under the support surfaces for changes. If permanent reddening/pressure sores are observed in the vicinity of the support surfaces, a medical assessment must be carried out.	18
	Do a final check on the tension applied to each traction suture.	19
	The suture retention frame must not be in contact with the wound area or the abdominal organs!	19
	When positioning a patient, in particular changing the position of the thorax in relation to the pelvis, attention must be paid to possible changes in tensile force and direction of pull.	19

Section	Warning	Page
Procedure for surgical revision	Please always remember that the product is no longer sterile during surgical revision procedures and must be removed from the patient before starting the sterile procedure.	20
	A diagonally-directed pull too early can lead to damage of the abdominal organs if the traction sutures are cut or due to an increase in the intra-abdominal pressure.	21
Disassembly in daily care and emergencies	Secure the suture retention frame with one hand when engaging the red locking bolt.	22
Warranty	The product is for single use only and is labelled accordingly. Any reprocessing or resterilisation and subsequent re-use is considered improper use, and in this case all and any guarantee rights, the warranty and liability of fasciotens GmbH are deemed to be null and void.	24
	In the event of any defects that may pose a risk to patients, staff or third parties, the device must no longer be used and must be replaced.	24
	Damage resulting from improper use, external mechanical impacts, transport damage, applications that do not comply with the intended purpose, or applications carried out by non-authorised persons is not covered by this warranty, nor is it covered by the liability of fasciotens GmbH.	24

fasciotens

Company address: fasciotens GmbH, Moltkeplatz 1, D-45138 Essen, Germany
Tel. +49 (0)201 99 999 630, Fax +49 (0)201 99 999 639, Email: info@fasciotens.de

CE 0044