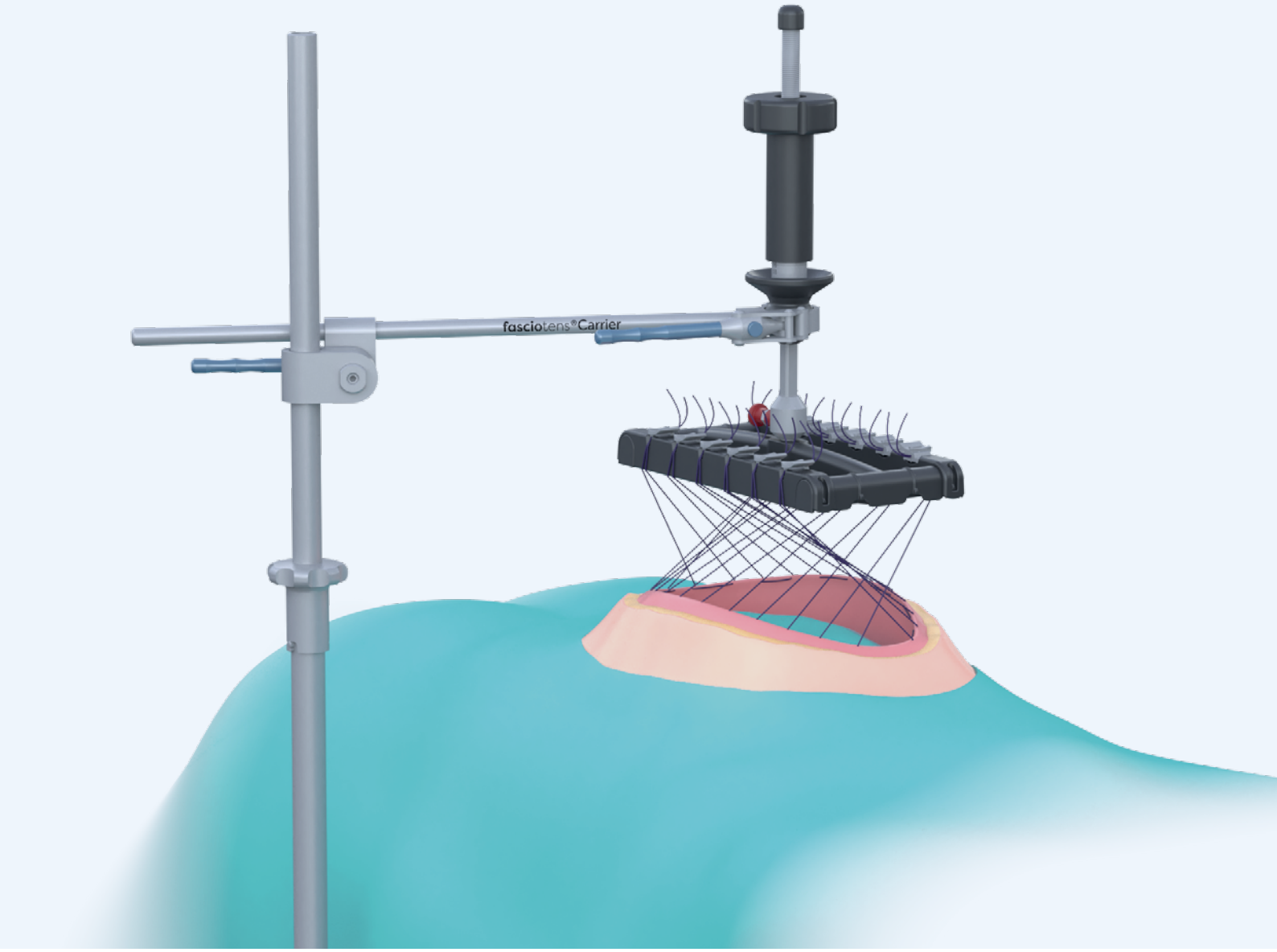
fasciotens®Hernia
elevated by fasciotens®Carrier

Instructions for use



fasciotens
ABDOMINAL WALL SOLUTIONS

www.fasciotens.de

Dear customer,

Thank you very much for choosing fasciotens®Hernia, the innovative therapy option in the treatment of large ventral abdominal wall hernias. 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 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.

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Video tutorial

https://www.fasciotens.de/wl-hernia-carrier-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®Hernia 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®Hernia is a medical device belonging to class Is (sterile) and is used in combination with fasciotens®Carrier.

The product is intended exclusively for human medical purposes and is used during surgery. The product can only be used in combination with fasciotens®Carrier.

The product is approved for use in combination with fasciotens®Carrier. Combination with other retractor systems is not permitted by the manufacturer.

Indications

Typical indications for the combined used of both products for stretching the abdominal wall are extensive and complex primary abdominal wall hernias and incisional hernias where, owing to lateralisation of the abdominal wall structures, a primary low-tension closure can only be achieved by using hybrid methods. These include:

- Laparostomahernias
- Primary hernias and incisional hernias
- Hernias with a loss of domain
- Florid mesh infections without adequate closure (to avoid the use of synthetic materials)

Contraindications

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

Local factors:

- Necrotic or mechanically unstable fascia tissue
- Adhesions between abdominal organs and the abdominal wall that cannot be removed

General factors:

- Insufficient clearance between patient and device due to obesity, for example
- Pregnancy
- Age ≤ 10

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 attributed to the product).

Target patient groups

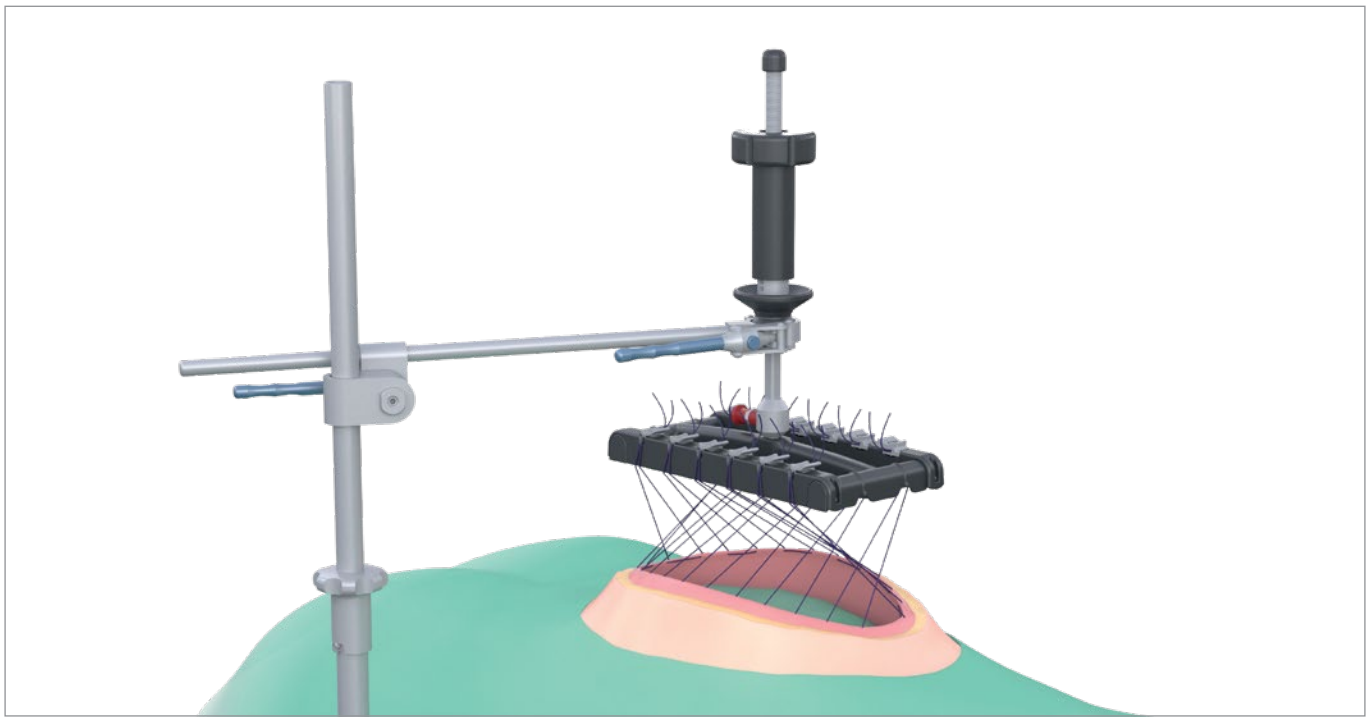
Adult patients diagnosed with a primary hernia of the abdominal wall that cannot be closed with low tension. Predominantly patients in a stable medical condition.

Intended users

Surgeons with experience in abdominal surgery (e.g. general, visceral, vascular and trauma surgery), nurses (trained to work in the operating theatre under sterile conditions).

Product design

fasciotens®Hernia can only be used in combination with fasciotens®Carrier. The figure below shows how the product fasciotens®Hernia is used in combination with fasciotens®Carrier.



Please refer to the Instructions for Use for fasciotens®Carrier.

fasciotens®Hernia consists of two modules:

Traction controller

Suture retention frame

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

fasciotens®Hernia and fasciotens®Carrier may only be used in a sterile condition. fasciotens®Hernia is delivered in a sterile condition and can be used during surgery without prior sterilisation.

Preparing the patient

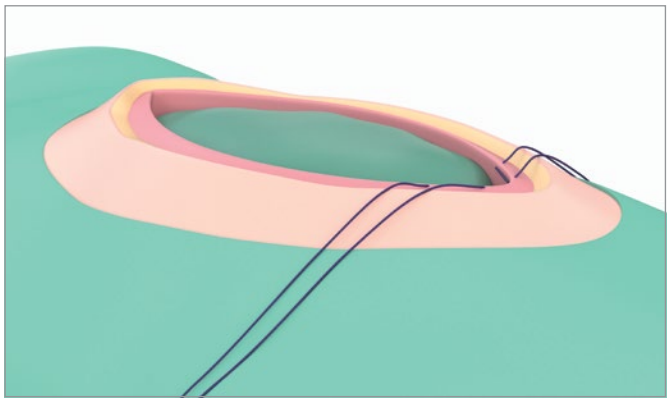
Surgical access to fascia

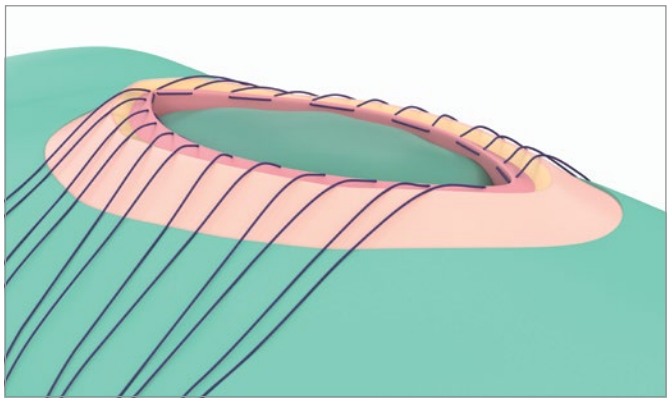
In view of the prevailing anatomical situation and the condition of the patient, extra caution and surgical experience are required when surgically opening the abdomen, and thus creating access to the fascia of the rectus abdominis muscle. Expose the sac and ensure the abdominal wall fascia is accessible prior to traction.

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 suture material

The fasciotens®Hernia uses 12 surgical sutures to apply ventral traction. These sutures are attached to the fascia at regular intervals and clamped into the suture retention frame of the device. The sutures should be stitched as a U-suture, so that using 6 sutures per fascia side results in 12 attachment points on each fascia side. This ensures sufficient distribution of the tensile force over a total of 24 points.





The following procedure is recommended for attaching the surgical sutures to the fascia. The process must be repeated twelve times.

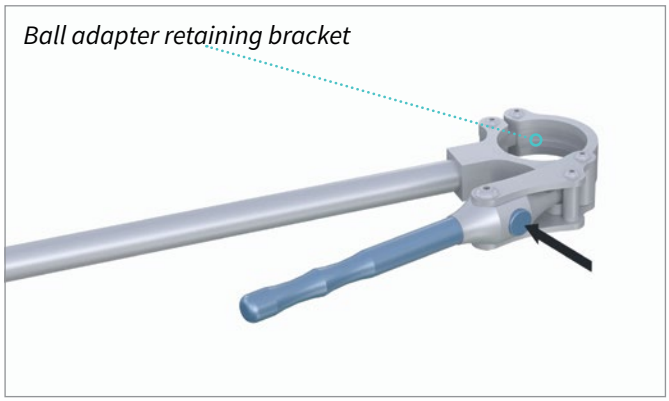
1. Pierce the suture through the fascia from the outside.
2. Pierce the suture again from the inside to the outside as a U-suture (distance approx. 2-3 cm).
3. Align the suture so that it is the same length on both sides (approx. 25 cm).

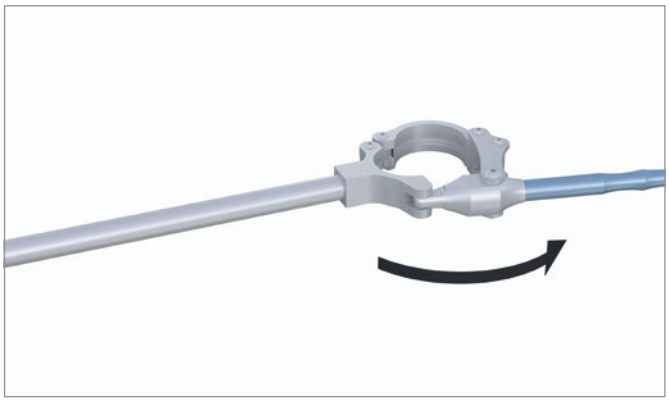
Braided suture material (USP 2) must be used to ensure that the sutures are securely retained.

Assembly and alignment

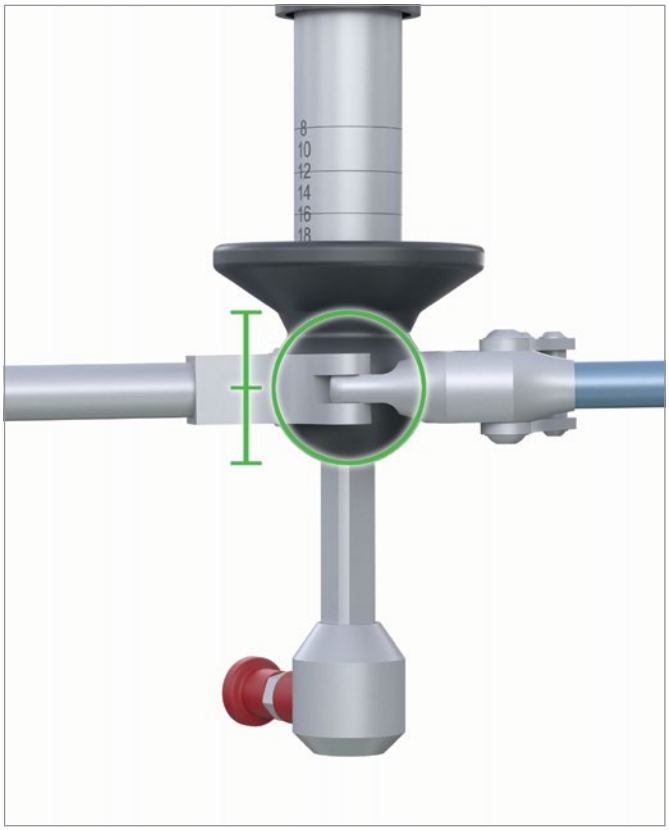
To attach fasciotens®Hernia to fasciotens®Carrier, perform the following steps:

1. **Release the lock on the ball adapter retaining bracket of the articulated arm** by holding down the pushbutton on the clamping lever and pulling the clamping lever at the same time.

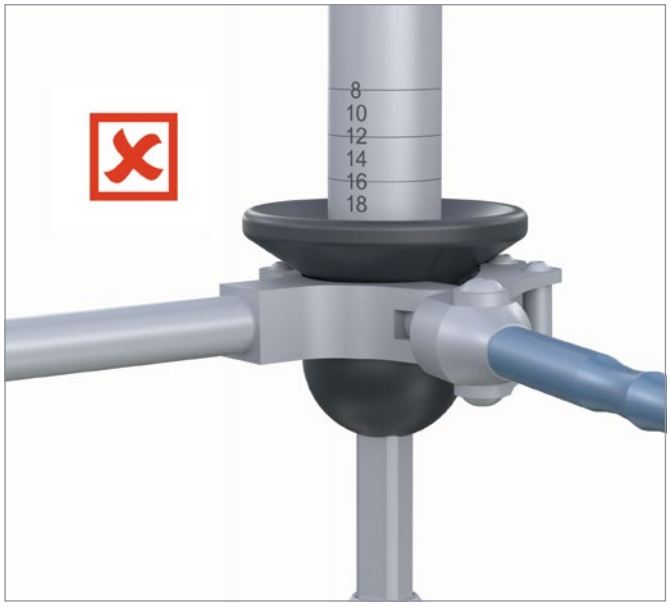


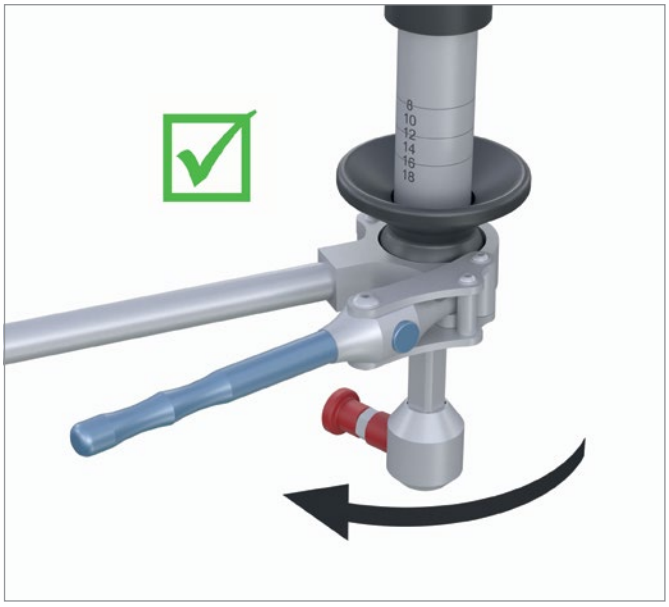


2. **Now insert the traction controller into the ball adapter retaining bracket from above using the red locking bolt.**
The ball adapter must be positioned **centrally** in the ball adapter retaining bracket.



3. Fasten the ball adapter by inserting it into the ball adapter retaining bracket and closing the clamping lever.



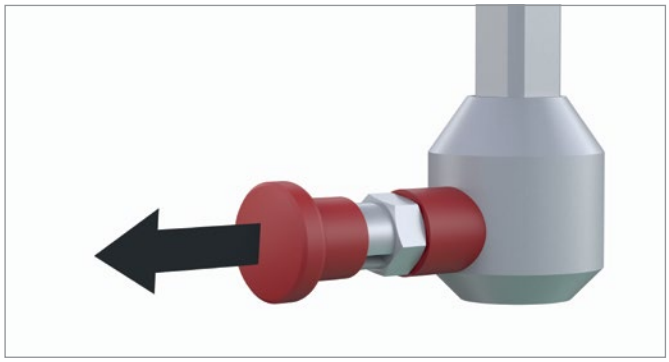


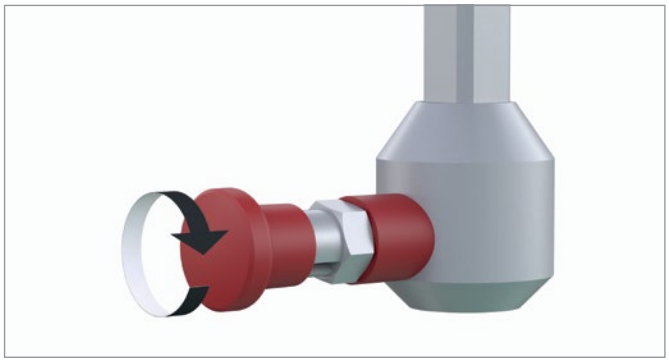
Check that the traction controller is firmly and securely in position.

Attaching and removing the suture retention frame of fasciotens®Hernia

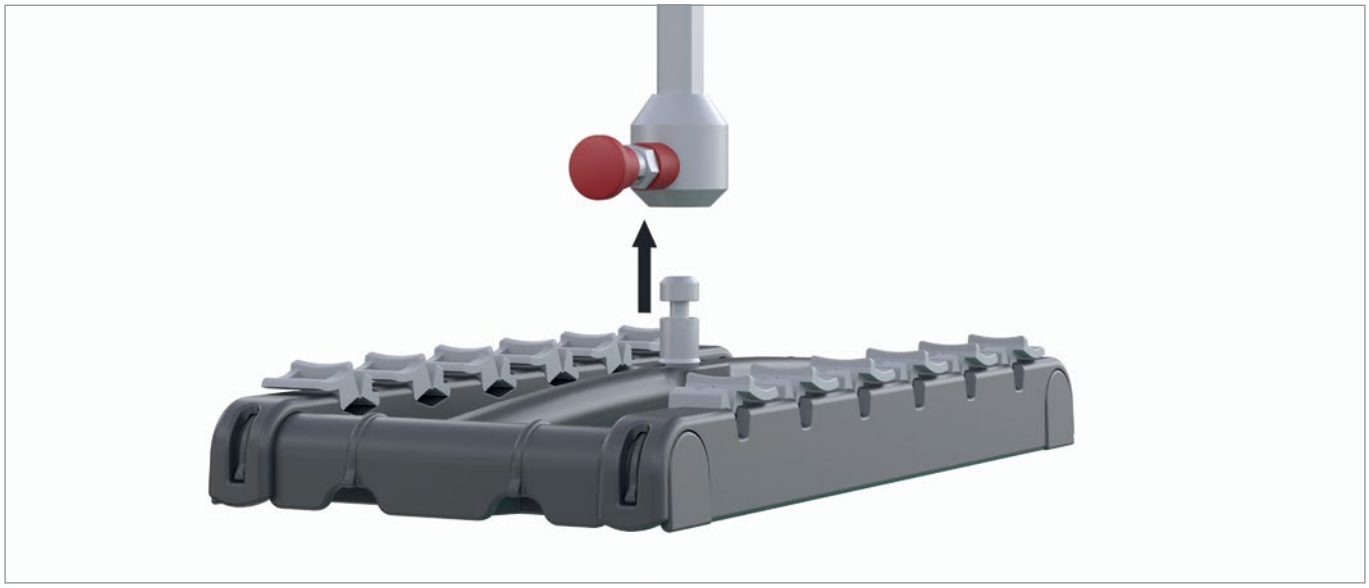
To attach the suture retention frame to the traction controller, perform the following steps:

1. **Pull out the red locking bolt** and turn it 90° (lock in open position).

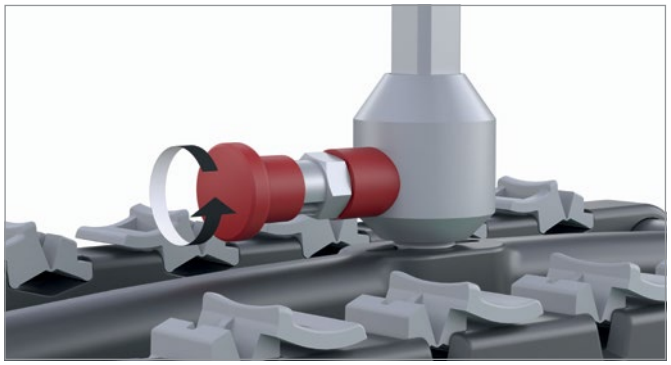


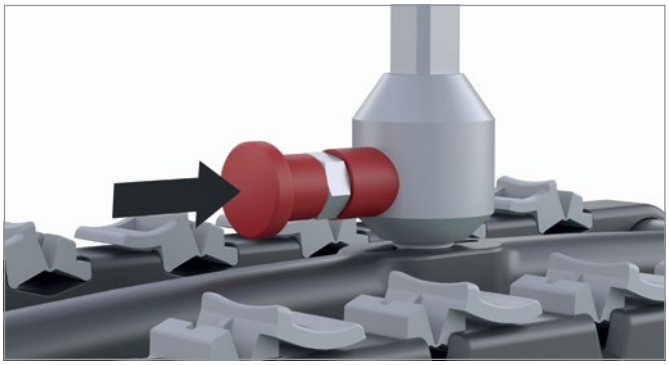


2. **Insert the suture retention frame** into the retaining bracket from below.



3. **Turn the locking bolt** back to the closed position to lock it in place.

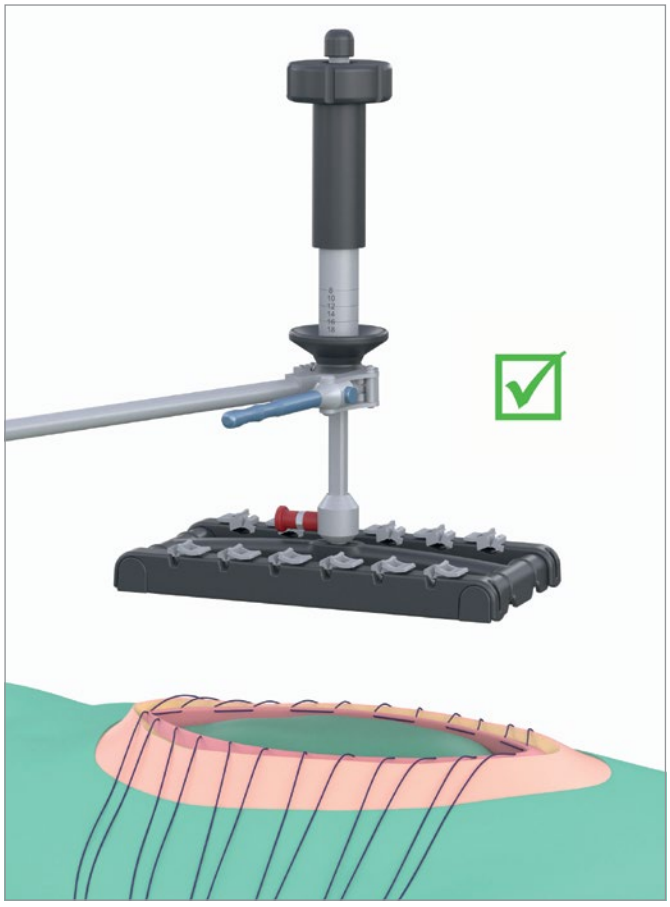




Ensure that the suture retention frame is fully inserted into the retaining bracket so that the locking bolt engages properly.

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

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



fasciotens®Hernia is now ready for use.

During the traction phase, make sure that the abdominal organs and subcutaneous tissues are protected with a number of moist abdominal cloths.

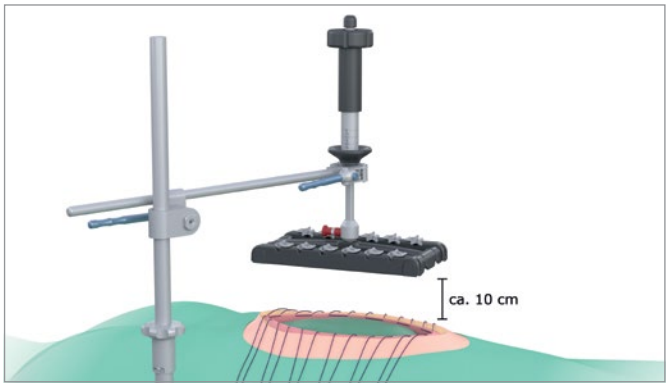
Pre-tensioning the traction controller

In preparation for the traction phase, it is recommended to align the traction sutures crosswise in order to be able to carry out a simplified, diagonal tensioning of the sutures.

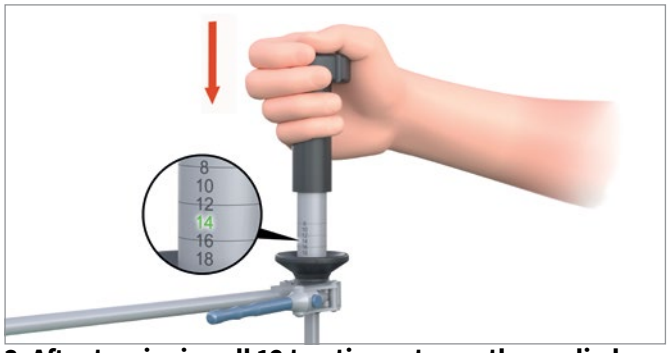
1. Evaluate the distance between the suture retention frame and the patient. The suture retention frame should be positioned as close to the patient as possible, avoiding direct contact with the wound. If necessary, adjust the height of the articulated arm on the fasciotens®Carrier. Please note the instructions for use of fasciotens®Carrier.

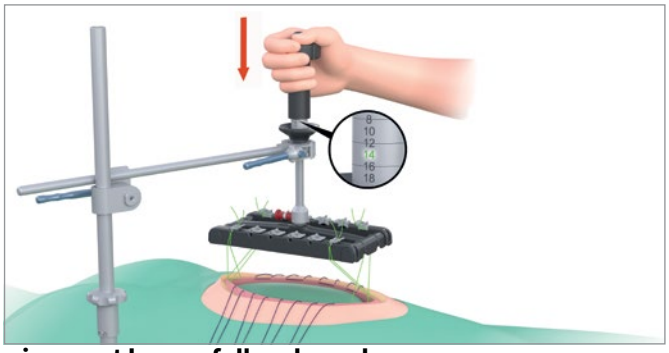
A distance of at least 10 cm from the wound is recommended.

A second person is required to apply the pre-tension.

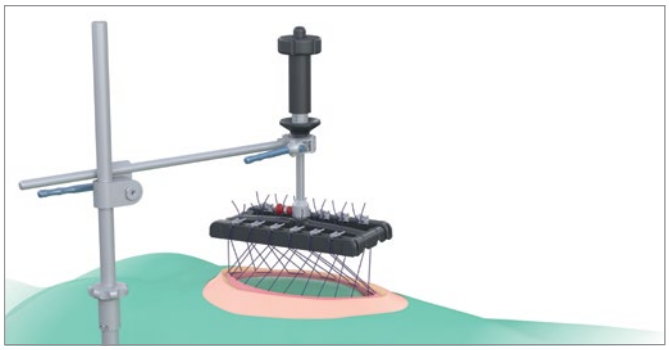


2. Now bring the traction controller to a pre-tension of approx. 14 kg by pressing the screw head down and keeping it pressed. Secure the four corner sutures in the suture retention frame. Then continue with the other traction sutures.





3. After tensioning all 12 traction sutures, the applied pre-tension must be carefully released.



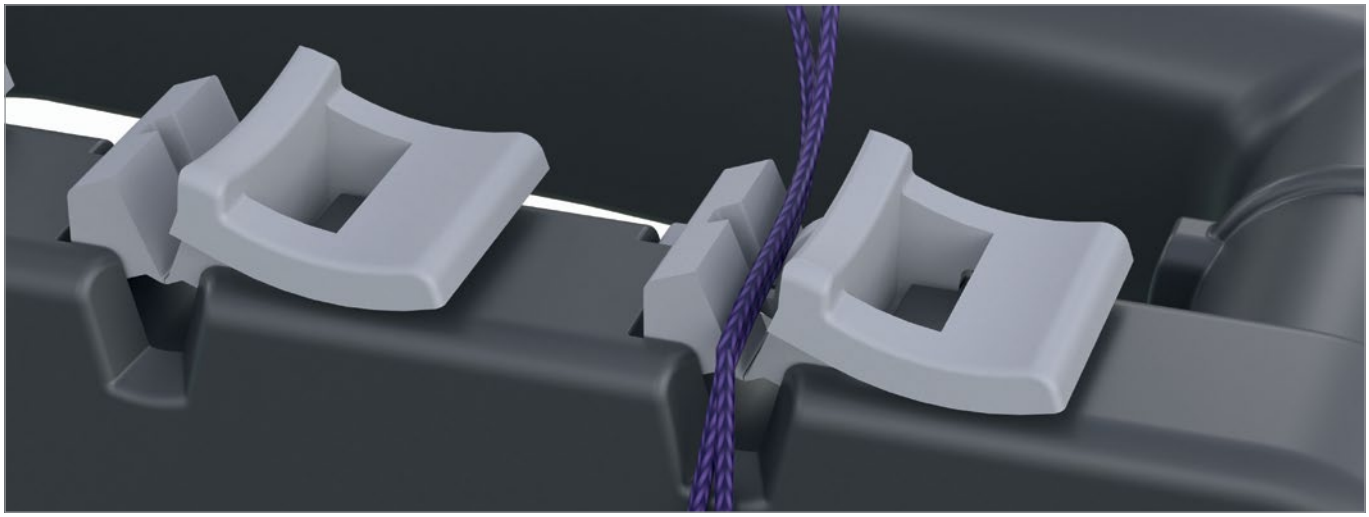
Until all sutures are tensioned in the suture retention frame, the pre-tension must not be released. It is important to release the pre-tension carefully after all the traction sutures have been attached.

The tensile force at the start should always be approximately 14 kg. If the tensile force is reduced after releasing the pre-tension, it is recommended to bring the pre-tension back up to 14 kg (by pressing down on the screw head) and re-tension the sutures.

Attaching and detaching the suture material to/from the suture retention frame

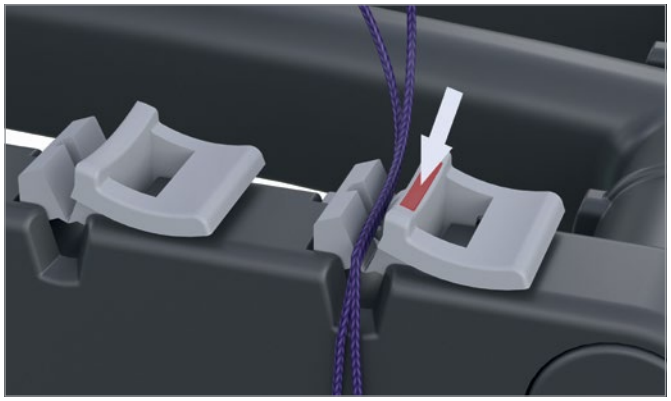
The sutures applied to the abdominal wall/fascia are fixed in the suture retention frame as follows.

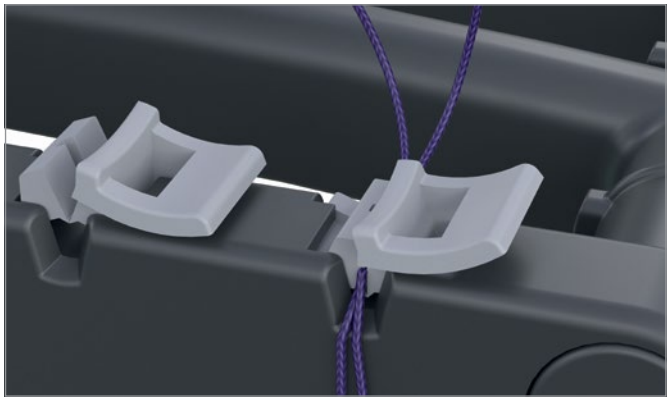
1. **Guide the crossed traction sutures upwards** with tension and insert them into the open slot of the fixing clip.



Make sure that the sutures are always inserted into the fixing clips from the outside over the fulcrum.

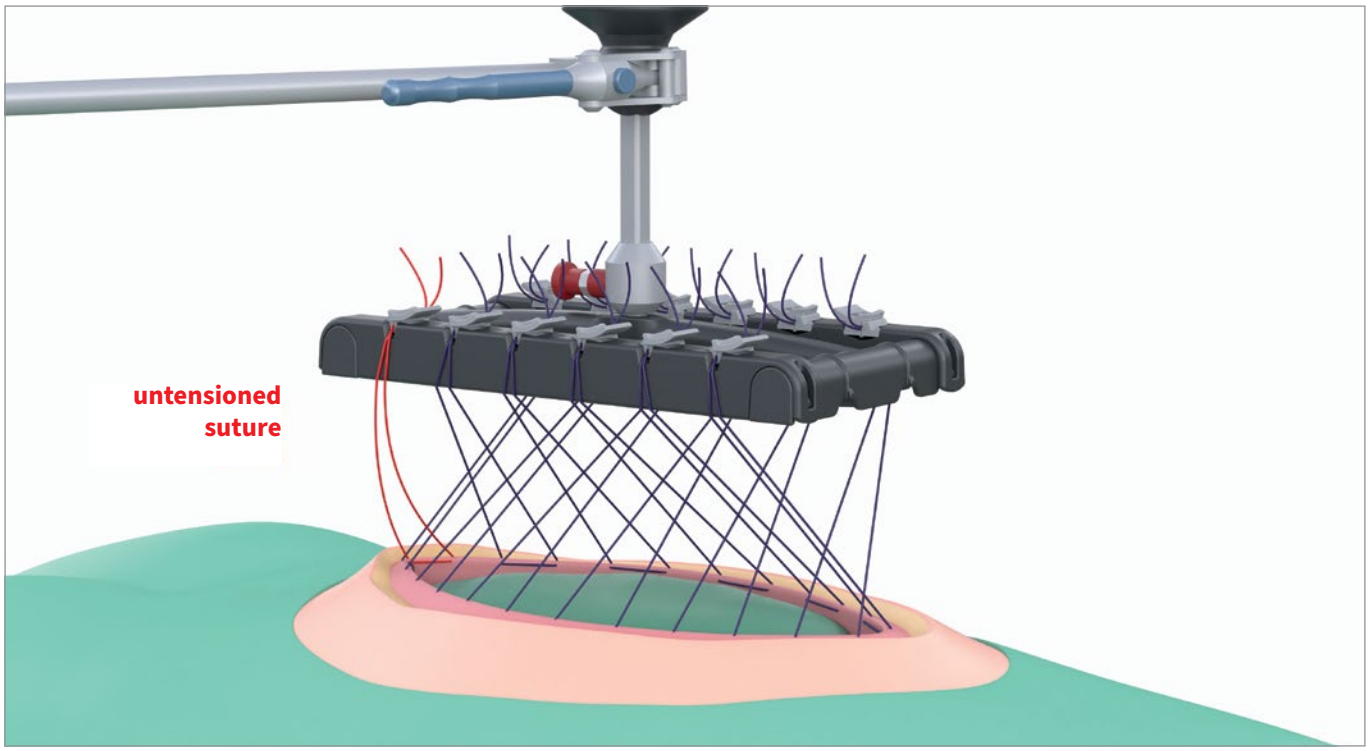
2. **Close the fixing clip** by pressing it in the middle.

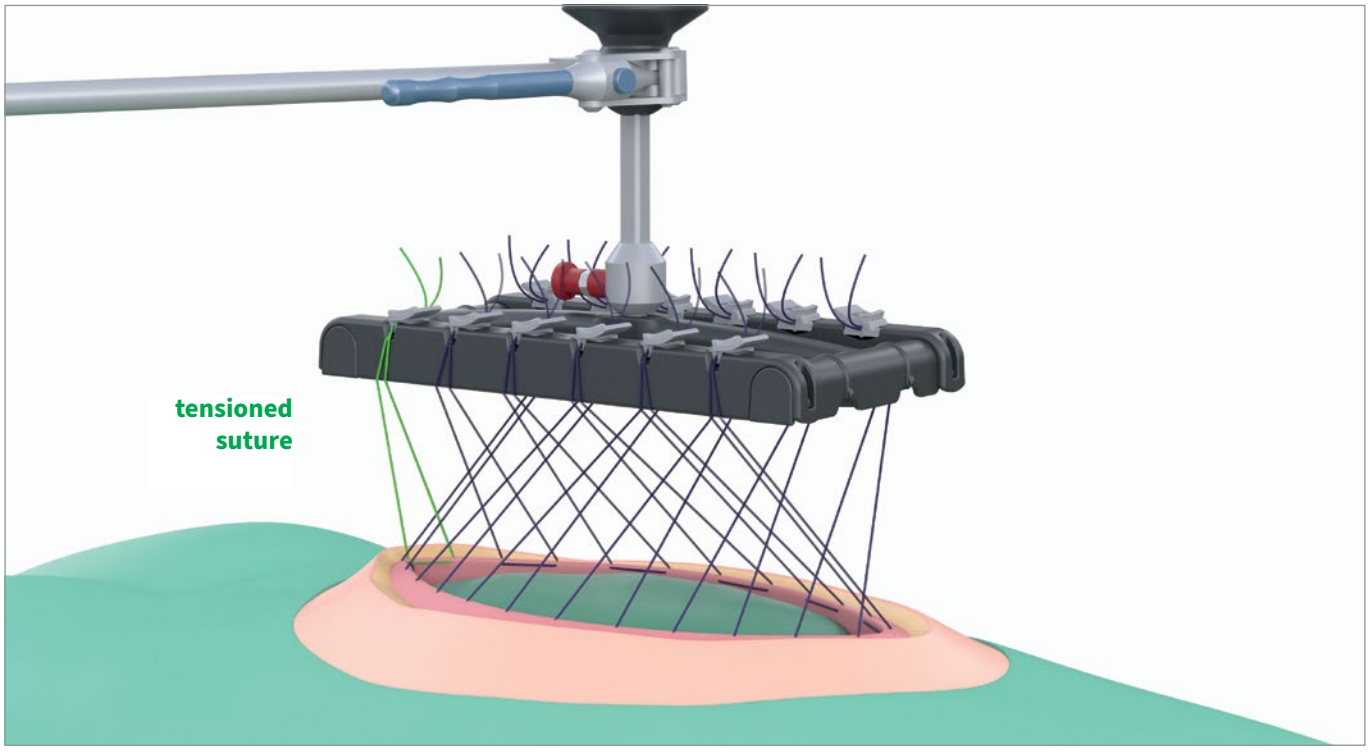




3. **Perform steps 1 and 2 a total of twelve times** for all sutures previously applied to the fascia.

4. Bring all sutures to a similar level of basic tension by re-tensioning individual sutures if necessary.





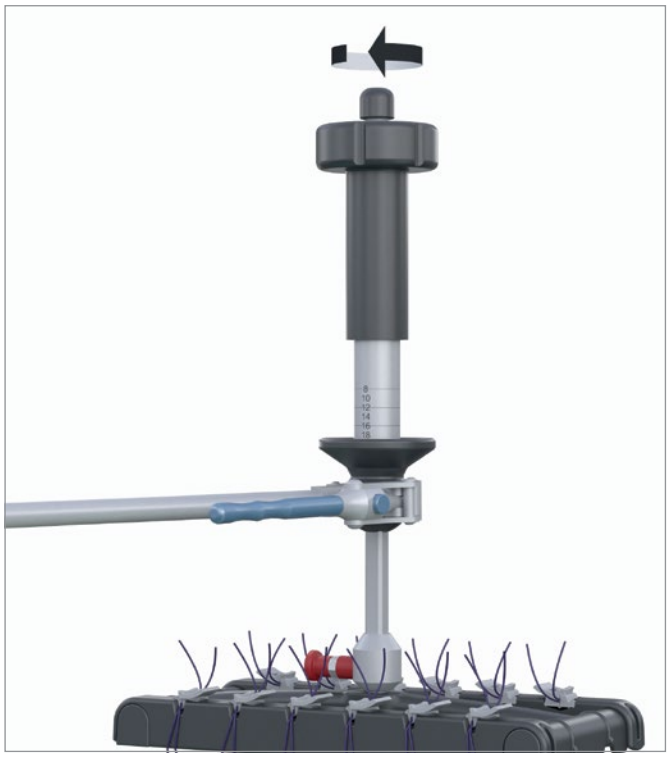
The fascial length gained during traction can be visualised by making an initial marking on the sutures, e.g. by using clamps.

Adjusting the tensile force

The tensile force is set with the black screw head. To increase the tensile force, turn the screw head clockwise. Tensile forces of up to 20 kg can be applied. The set tensile force can be monitored by means of an embedded scale.

The adjustment of the applied tensile force after setting the pretension depends on the anatomical conditions of the patient and is therefore carried out according to the instructions of the attending physician.

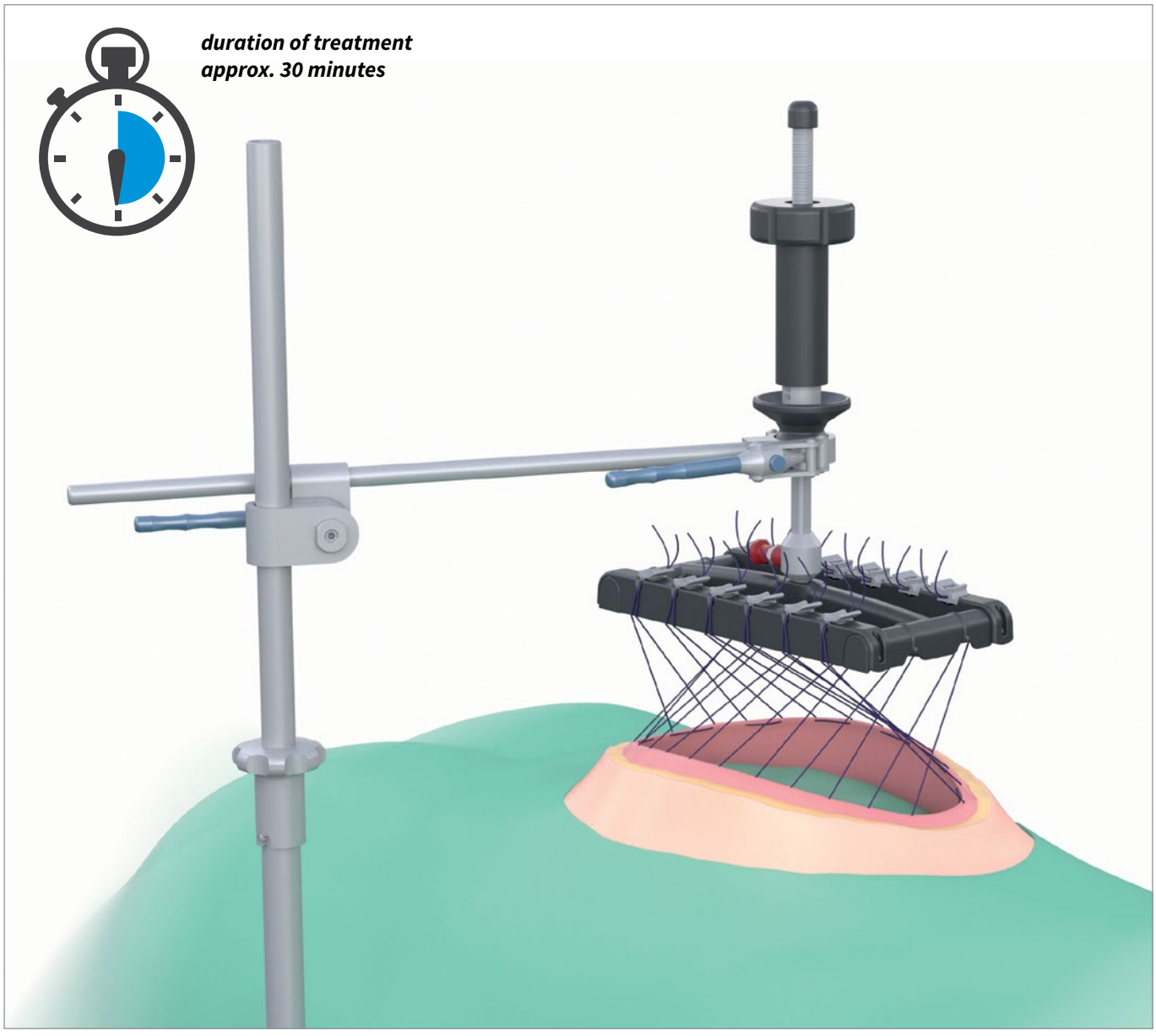
To decrease the tensile force, turn the screw head anticlockwise.



The abdominal wall/fascia is brought to tension by vertical-diagonal traction. With fasciotens®Hernia, the tension is distributed evenly and in a controlled manner over the fascia or abdominal wall via the sutures and should be maintained for approx. 30 min.

The tension of the traction controller should be checked regularly and readjusted if necessary.

Individual sutures may stretch more quickly than others. This may make it necessary to re-tension individual sutures. The individual sutures should be checked for sufficient tension every 2 minutes and retightened if necessary.



The stretching of the abdominal wall/fascia can lead to a reduction in tensile force over the course of the treatment. This will be indicated on the scale. Use the screw head as described above to readjust the tensile force.

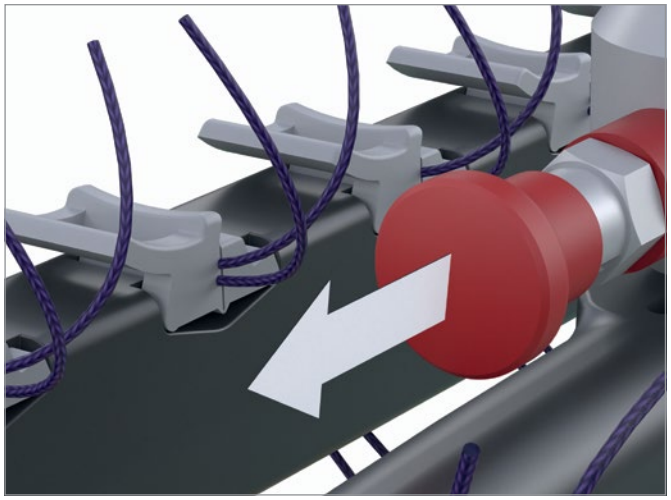
Dismantling the product

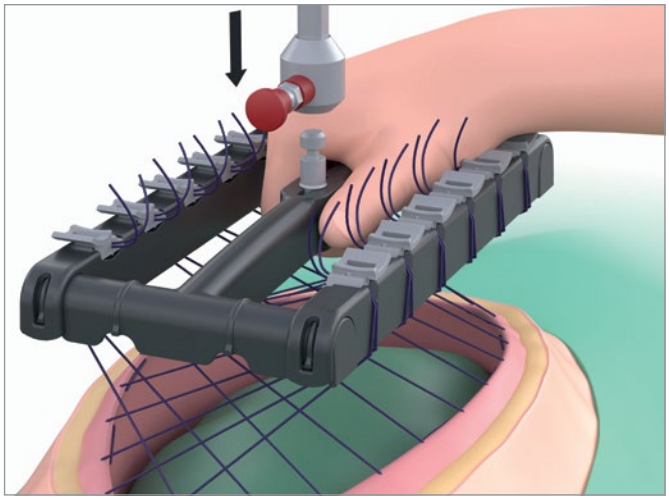
Please note that when releasing the suture retention frame, there may be high forces in the direction of the surgical site. For this reason, it is important to comply with the following dismantling procedure for patient safety.

1. Reduce the tensile force as much as possible by turning the screw head anticlockwise.

2. Hold the suture retention frame firmly with one hand to prevent it falling when released.

3. Retract the red locking bolt. The suture retention frame can be removed by pulling downwards.





Make sure that the suture retention frame does not fall onto the surgical site and is never in contact with the wound.

4. After releasing, continue to hold the suture retention frame tension-free over the surgical site with one hand.

5. Remove the traction sutures from the fixing clips.

6. Fix the traction controller with one hand and open the ball adapter retaining bracket on the fasciotens®Carrier. The traction controller can be guided out upwards.

7. Now remove the fasciotens®Carrier from the operating table.

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.

Any reprocessing or resterilisation and subsequent re-use of the product fasciotens®Hernia is considered inappropriate, In such cases, the warranty and liability of fasciotens GmbH will be 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 may no longer be used and must be replaced.

Damage resulting from improper use, external mechanical impacts, transport damage, inappropriate use 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 “Please observe the Instructions for Use”
	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	The product is approved for use in combination with fasciotens®Carrier. Combination with other retractor systems is not permitted by the manufacturer.	6
	Usage may be limited by local factors in the area of application and the general condition of the patient!	6
Product design	Prior to using fasciotens®Hernia, if the sterile packaging is noticeably damaged, please ensure that the product is not used any further. Contact the manufacturer.	8
Preparing the patient	Braided suture material (USP 2) must be used to ensure that the sutures are securely retained.	9
Assembly and alignment	Check that the traction controller is firmly and securely in position.	11
Attaching and removing the suture retention frame of fasciotens®Hernia	Ensure that the suture retention frame is fully inserted into the retaining bracket so that the locking bolt engages properly.	13
	Check that the suture retention frame is firmly seated in the retaining bracket on the emergency release by pulling it down with moderate force. The suture retention frame must not come loose from the retaining bracket.	13
	The suture retention frame must always be aligned parallel to the surgical site.	13
	During the traction phase, make sure that the abdominal organs and subcutaneous tissues are protected with a number of moist abdominal cloths.	13
Pre-tensioning the traction controller	The suture retention frame must never be in contact with the wound area or organs of the patient. A distance of at least 10 cm from the wound is recommended.	14
	Until all sutures are tensioned in the suture retention frame, the pre-tension must not be released. It is important to release the pre-tension carefully after all the traction sutures have been attached.	14
Dismantling the product	Check all traction sutures have similar basic tension. If necessary, re-tension the individual traction sutures. To do so, please follow the above procedure.	19
	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.	19
Warranty	Any reprocessing or resterilisation and subsequent re-use of the product fasciotens®Hernia is considered inappropriate, In such cases, the warranty and liability of fasciotens GmbH will be deemed to be null and void.	21
	In the event of any defects that may pose a risk to patients, staff or third parties, the device may no longer be used and must be replaced.	21
	Damage resulting from improper use, external mechanical impacts, transport damage, inappropriate use or applications carried out by non-authorised persons is not covered by this warranty, nor is it covered by the liability of fasciotens GmbH.	21

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