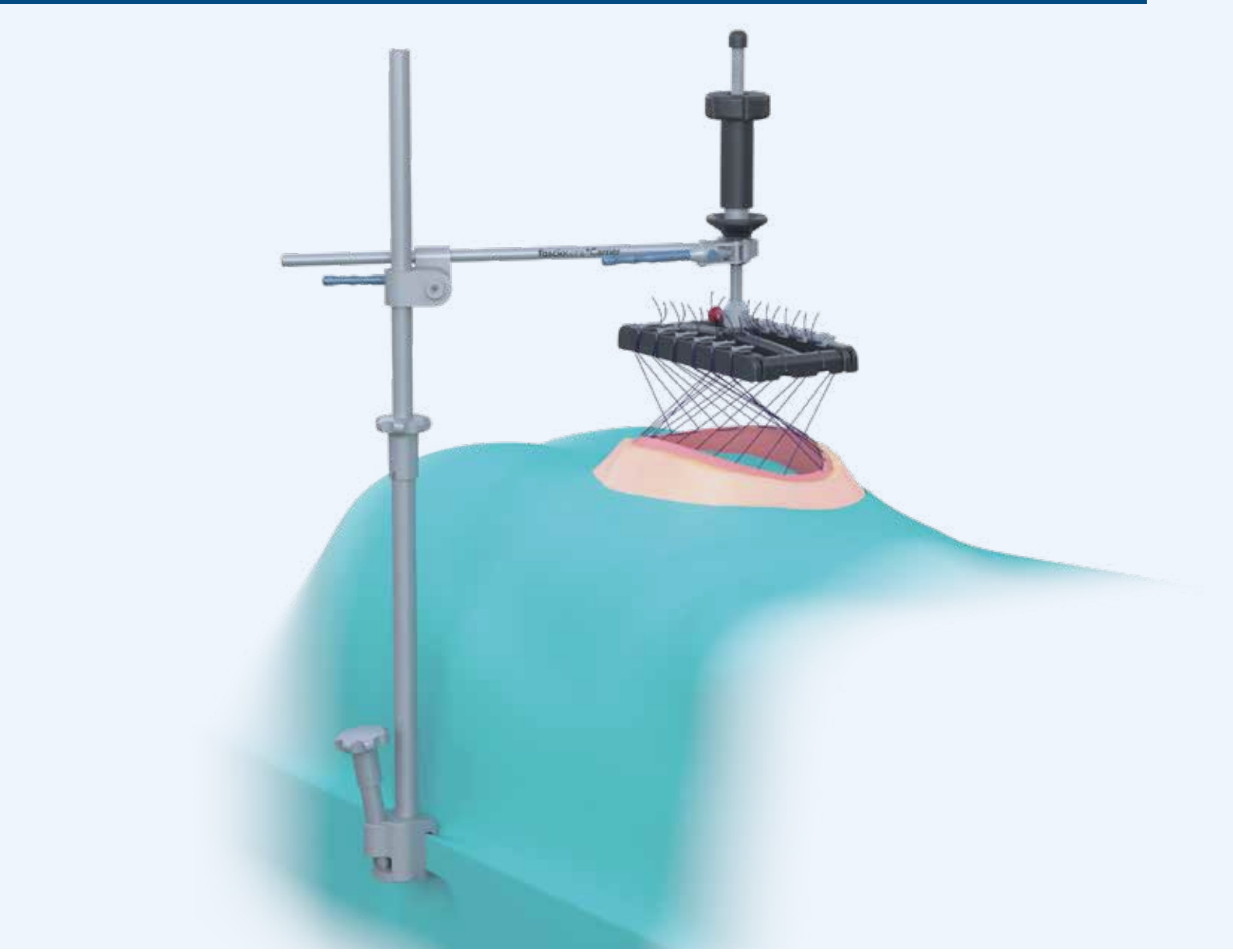
fasciotens®Carrier

Instructions for use



fasciotens
ABDOMINAL WALL SOLUTIONS

www.fasciotens.de

Dear customer

Thank you for choosing the fasciotens®Carrier. fasciotens® products provide the highest quality, safety and state-of-the-art technology. This product was developed in partnership with practising surgeons.

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. 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

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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.

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For your safety

Please observe the Instructions for Use

Any application or handling of the medical device 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 the fasciotens®Carrier is as a holding device for fasciotens products before, during and after surgical procedures. fasciotens®Carrier is a class I medical device. The product is intended exclusively for human medical purposes and is used during surgery. The product is approved for use in combination with fasciotens®Hernia.

Combination with any products other than fasciotens®Hernia has not been verified and validated by the manufacturer. The intended purpose does not include such a combination and is the responsibility of the user.

Indications

- Combination with fasciotens® products
- Combination with operating tables or standard rails

Contraindications

- No sufficiently stable fastening rail

Information about side effects and risks

No undesirable side effects are known when using the product.

Target patient groups

The target patient group is derived from combination with those receiving the product fasciotens®Hernia. Adult patients diagnosed with primary W3 and incisional hernias of the abdominal wall as defined by the European Hernia Society. Predominantly patients in a stable medical condition.

Intended users

- Surgeons with experience in abdominal surgery (e.g. general, visceral, vascular and trauma surgery)
- Nurses
- Employees of the Central Sterile Services Department (CSSD)

Components

Screw head post (P1)

Post base (P1)

Post extension (P2)

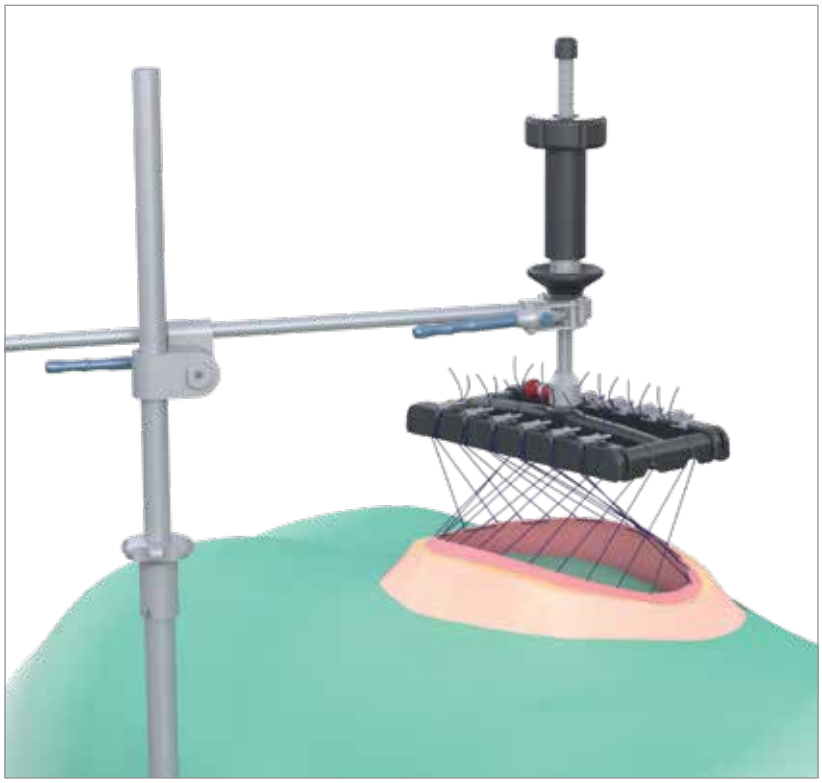
Screw head post extension (P3)

Eccentric handle (P4)

Articulated arm

Product design of fasciotens®Carrier

The figure below shows how the product fasciotens®Hernia is used in combination with fasciotens®Carrier:



fasciotens®Carrier consists of the following modules:

Post HC021

Articulated arm HC022

fasciotens®Carrier and fasciotens®Hernia may only be used in a sterile condition. fasciotens®Carrier is supplied in a non-sterile condition by the manufacturer and must be sterilised in the hospital before each use in the operating room. Please follow the processing instructions. Please follow the storage instructions for the product. Before each use, check that the product is intact.

Product assembly

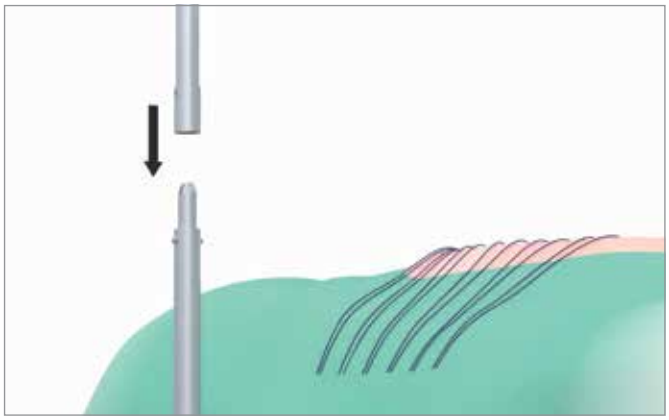
fasciotens®Carrier can be attached to all operating tables that have a standard rail. The post is mounted above the sterile cover on the operating table. The position of the post can be determined by the user but should not obstruct the surgeon. Make sure that the product has been sterilised beforehand according to the processing instructions.

1. **Remove the components from the tray** and place them on the instrument table. Make sure that the clamp opening at the lower end of the post is fully open.
2. **Turn the screw head** into the hole provided for this purpose at the lower end of the post.
3. **Place the post on the standard rail** of the operating table**.**

Make sure that the post is properly attached and that there are no objects in the way which would prevent/impair proper attachment (e.g. patient blanket, catheter, ECG cable). The surgical table covering should have no more than 2 layers.

4. **Lock the post base (P1) on the standard rail** of the operating table by turning the screw head clockwise.

5. **Guide the post extension (P2)** onto the upper end of the part of the post attached to the operating table.

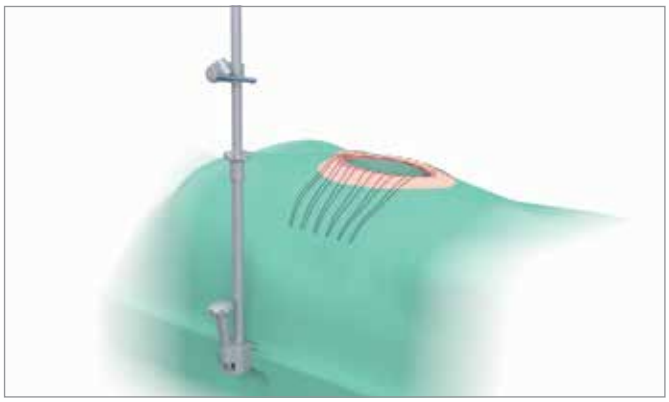


Check that it is firmly in place on the operating table.

6. **Guide the screw head extension (P3) with the opening onto the post extension** and connect both parts of the post by turning the screw head.

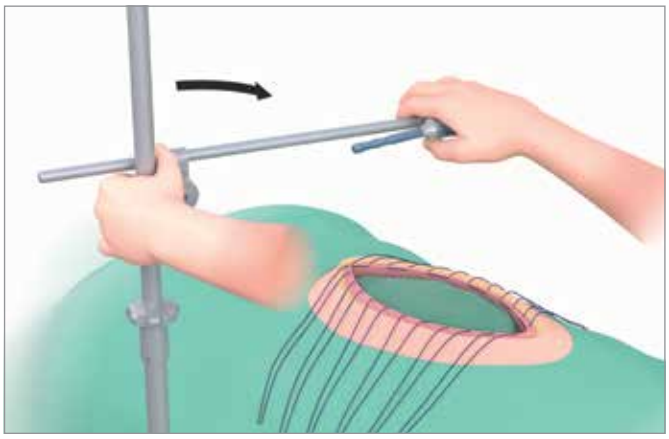
Check that both modules are firmly locked.

7. **Guide the eccentric handle (P4) onto the top of the post extension** and move it to the screw head extension (P3).



8. **Insert the articulated arm** into the open eccentric handle.

9. Align the articulated arm over the patient based on the defect and the abdominal circumference. The ball adapter retaining bracket of the articulated arm should be positioned centrally over the defect.



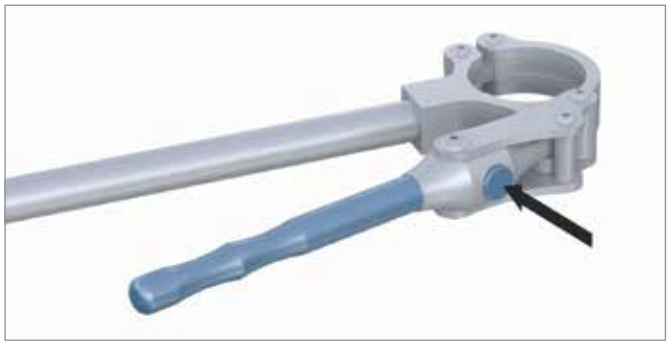
10. Secure the articulated arm in the eccentric handle by flipping the clamping lever.

The word "closed" will now be visible on the eccentric closure.

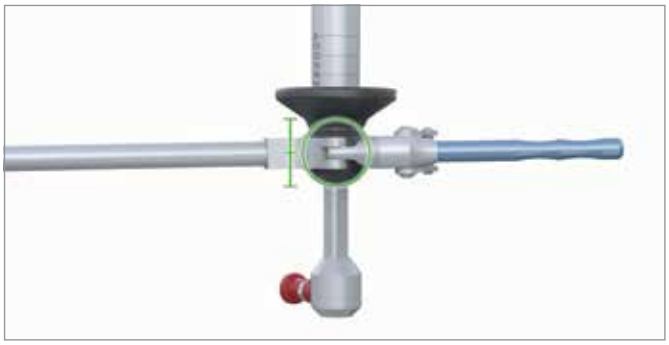
Make sure that there is always sufficient space between the patient and the articulated arm.

Combination with fasciotens®Hernia

To combine with fasciotens®Hernia, release the lock on the ball adapter retaining bracket of the articulated arm. To do this, press the pushbutton on the clamping lever and open the clamping lever at the same time.



Now insert the fasciotens®Hernia traction controller into the ball adapter retaining bracket from above.



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

Always check that the ball adapter is firmly and securely seated.

For more information, please refer to the fasciotens®Hernia instructions for use.

Processing fasciotens®Carrier

Service life

fasciotens®Carrier is a reusable medical device. Its service life depends on how much wear and damage it encounters. Frequent reprocessing has no effect on the performance of the product.

A passive coating forms on the instruments over time. This is influenced by factors such as material composition, surface condition and processing conditions. The passive coating on the instruments is neither a quality defect nor does it affect the function of the system. Experience has shown that the risk of corrosion tends to decrease as the passive coating becomes thicker.

In order to keep the product functional and safe for a significant period, we recommend observing the following instructions for preparing instruments supplied in non-sterile condition as well as for the reprocessing of contaminated instruments.

Preparation

We recommend reprocessing the contaminated instruments as soon as possible after they have been used. They should be transported in a sealed container. After using reprocessable instruments, care should be taken not to damage them during transport. The instruments must be disassembled into individual parts as much as possible before cleaning.

Due to the risk of corrosion and in order not to impair cleaning, long waiting times before reprocessing (e.g. overnight or over the weekend) should be avoided. The Instrument Processing Working Group (AKI) recommends dry disposal, i.e. taking the instruments for sterilisation without them being submerged in liquid when possible. Waiting times of up to 6 hours when the instruments are out of liquid, i.e. dry disposal, should be avoided.

Use a mechanical process for cleaning and disinfection. When selecting the detergent to be used, please pay attention to material compatibility, suitability and effectiveness for cleaning medical devices. The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent or detergent and disinfectant as well as the specifications for rinsing must be observed.

Disassembling the post
The post can be disassembled into individual parts for processing. All individual components are provided with corresponding serial numbers and can therefore be easily allocated. To disassemble the post, proceed as follows:

Disassembly

When reassembling the post, care must be taken to ensure that the components have the same serial numbers.

For both wet disposal and dry disposal, avoid long waiting times before processing (e.g. overnight or over the weekend) due to the risk of corrosion and other factors which may make it difficult to clean the instruments. The AKI recommends dry disposal, i.e. taking the instruments for sterilisation without them being submerged in liquid. Experience has shown that waiting times of up to 6 hours are not a problem in cases of dry disposal, i.e. when the instruments are out of liquid.

Cleaning

Cleaning consists of the following steps:

1. **Pre-cleaning**
   - **1.1 Manual pre-cleaning**
   - **1.2 Pre-cleaning in an ultrasonic cleaner**
2. **Machine cleaning according to DIN EN ISO 15883-1 and -2 (in a washer-disinfector)**

We recommend the use of cleaners with prion decontamination (see manufacturer's instructions). In recent studies on decontamination procedures against infectious prion proteins, the most effective methods have been successive treatment with an alkaline detergent (pH > 10) and subsequent disinfection or sterilisation. Please carry out the cleaning steps according to the cleaning agent manufacturer’s instructions. The following points refer to the alkaline cleaner Deconex 28 Alka One by Borer Chemie, which was used for the processing validation.

1. Pre-cleaning

1.1 Manual pre-cleaning

Soak dirty parts in cold water (at least drinking water quality) for at least 10 minutes. Please note: The instruments should not be left in water and/or cleaning agents/disinfectants for a long period of time, overnight or over the weekend.

Immerse the parts and clean them with a soft brush for at least 1 minute. In case of heavy contamination, the duration of pre-cleaning may differ. Make sure that you reach all of the surfaces. You should use a suitable brush for cannulations and blind holes.

Rinse the parts thoroughly under running water (at least drinking water quality) for 1 minute. The water must flow through the cannulations and blind holes must be repeatedly filled and emptied.

1.2 Pre-cleaning in an ultrasonic cleaner

Place the pre-cleaned parts in an ultrasonic cleaner heated to 40°C (frequency: 35 to 40 kHz) with an alkaline cleaner (e.g. Deconex 28 Alka One, Borer Chemie) according to the manufacturer's instructions for use. Then treat the instruments with ultrasound for 10 minutes. After cleaning in the ultrasonic cleaner, rinse the instruments for 1 minute under cold running water (at least drinking water quality).

2. Machine cleaning (in a washer-disinfector according to DIN EN ISO 15883-1 and -2)

Before you start with the machine cleaning, you should have carried out a pre-cleaning according to Item 1. For machine cleaning, place the instruments on sieve baskets or racks suitable for cleaning purposes. Ensure that the water jet can reach all areas.

Connect hollow-body instruments to the hollow-body rinsing systems of the washer-disinfectors. An alkaline cleaner (pH > 10) should be used according to the manufacturer's instructions for use. Pay attention to the correct dosage! The products are approved for alkaline cleaning. Acidic cleaning agents and disinfectants must not be used.

The device manufacturer's instructions must be followed. A typical cycle should include the following steps and be carried out according to the cleaning agent manufacturer’s instructions.

Example of a cleaning cycle, including disinfection:
(Please note the cleaning agent manufacturer's instructions)

- Pre-wash with cold water for at least 2 minutes (at least drinking water quality and at max. 45°C)
- Treatment with alkaline cleaner for appropriate exposure time, according to the manufacturer's concentration and temperature specifications (e.g. at least 5 minutes with Deconex 28 Alka Onevon/Borer Chemie at 70°C)
- Carry out intermediate flushing according to the cleaning agent manufacturer's instructions (e.g. 1 minute, with 40-45°C warm drinking water, then 1 minute with deionised water (DI water))
- Thermal disinfection with DI water and max. 93°C – A0 value ≥ 3000 (e.g. 5 minutes at 90°C)
- Dry cycle (max. 120°C)

The above parameters may vary.

The instruments should be removed from the machine immediately after the end of the program and cooled to room temperature. They should not be left in the washing machine or the washer-disinfector after the washing process.

After cleaning, check all parts for visible dirt (especially in cannulations and blind holes). If necessary, repeat the cycle or clean manually.

All parts, especially joints, must be dried with clean compressed air after cleaning.

Insufficient drying can lead to corrosion of the instruments. Therefore, please make sure that the instruments are completely dry after disinfection.

After disinfection, store the product in the following conditions: Completely dry, protected from dust, in a closed container, in low-germ conditions (see Storage section).

When storing for several days, disinfect the product again before sterilisation.

For processing, the medical devices must be sterilised after disinfection (see Sterilisation). Inspect parts for damage that could impair their functionality. Damaged and defective instruments must be identified and replaced. Repairs are to be carried out exclusively by the manufacturer. In this case, the corresponding instruments must be sterilised beforehand (individual packaging, see Sterilisation section). Please use our returns form at the end of these instructions for use. After each cleaning and cooling cycle, areas such as joints, threads, etc. must be treated with suitable care products (medicinal white oil) depending on the manufacturer's area of application.

Sterilisation

Instruments can be sterilised individually wrapped (in a standard sterilisation pouch) in appropriate container systems or general purpose sterilisation containers. The containers should not be overloaded. Please pay attention to the manufacturer's instructions.

Sterilisation must be carried out in accordance with a validated procedure using steam with fractionated pre-vacuum (steriliser at least according to EN 285 and validated according to DIN EN ISO 17665-1). An exposure time of at least 5 minutes must be maintained at a temperature of 134 °C. All joints and eccentric closures must be open during sterilisation. After sterilisation, store the product in sterile packaging protected from moisture, temperature fluctuations, direct sunlight and dust.

Improper storage can lead to loss of sterility - the manufacturer accepts no liability on this point.

Final instructions

These instructions have been determined by fasciotens GmbH to be suitable in order to prepare fasciotens®Carrier for reuse. The processor is responsible for ensuring that the processing carried out with the equipment, materials and personnel in the processing facility achieves the desired results. This normally requires validation and routine monitoring of the process. Similarly, the processor should carefully evaluate any deviation from the instructions for effectiveness and adverse consequences.

We hereby confirm that all products leave our facility only after an appropriate quality control. Nevertheless, issues are possible. Please check the goods are complete and functional and inform us immediately if you have any complaints. Please do not use rejected goods!

Repairs and returns of purchased equipment will only be accepted in a cleaned and sterilised condition. Please use the template (form) provided at the end of the instructions for use and attach it to the return documents or the return shipment.

fasciotens GmbH has determined that the above instructions are suitable for preparing the instruments for reprocessing.

Additional reference material:

- DIN Pocket Book 100/1 “Medical Instruments 1” (DIN Taschenbuch 100/1 “Medizinische Instrumente 1“), Beuth Verlag GmbH Berlin, Vienna, Zurich, ISBN-13: 978-3-410-20746-7
- DIN Pocket Book 100/2 “Medical Instruments 2” (DIN Taschenbuch 100/2 “Medizinische Instrumente 2“), Beuth Verlag GmbH Berlin, Vienna, Zurich, ISBN-13: 978-3-410-20749-8
- RKI recommendations: Hygiene requirements for the processing of medical devices Bundesgesundheitsblatt 2012 - 55:1244-1310 DOI 10.1007/s00103-012-1548-6
- Processing AKI instruments to preserve their condition, Issue 11

Storage instructions

fasciotens®Carrier may only be used if sterile. For storage, reprocessing and sterilisation of the system, follow the instructions for use and processing.

fasciotens®Carrier must

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

The generally applicable regulations and recommendations apply; these include:

- DIN EN ISO 17664:2018-04
- RKI recommendations
- AKI - Instrument processing done right - storage of re-sterilisable instruments.

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.

Maintenance must be carried out exclusively by fasciotens GmbH.

Maintenance improves reliability. It plays a vital role in keeping the instruments functional and safe. We therefore recommend that maintenance be carried out at regular intervals. fasciotens GmbH offers a refurbishment of its systems after the warranty has expired.

Repairs

If you encounter any problems with the functionality of the instruments, contact our customer support team by email **(support@fasciotens.de)** or **phone(+49 (0)221 17738 500)**.

All repairs must be carried out by fasciotens GmbH.

Disposal

You can dispose of the packaging in paper and household waste. In the design of the product, care was taken to avoid the use of composite materials as much 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 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, 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**.

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Template

For returns: Please note!

☐ **fasciotens®Carrier return**

☐ **fasciotens®Carrier return for repair**

This confirmation must be enclosed with the return shipment of fasciotens®Carrier.

We hereby confirm that the enclosed (leased) instrument set has been correctly disinfected, cleaned and sterilised.

Instrument set	*Proof/Adhesive label*
Hospital (address)	
Department	
Responsible Person	
Date, stamp, signature	

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 “Serial number”
	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 “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	Combination with any products other than fasciotens®Hernia has not been verified and validated by the manufacturer. The intended purpose does not include such a combination and is the responsibility of the user.	6
Product design of fasciotens®Carrier	fasciotens®Carrier and fasciotens®Hernia may only be used in a sterile condition. fasciotens®Carrier is supplied in a non-sterile condition by the manufacturer and must be sterilised in the hospital before each use in the operating room. Please follow the processing instructions. Please follow the storage instructions for the product. Before each use, check that the product is intact.	7
Product assembly	Make sure that the post is properly attached and that there are no objects in the way which would prevent/impair proper attachment (e.g. patient blanket, catheter, ECG cable). The surgical table covering should have no more than 2 layers.	8
	Check that it is firmly in place on the operating table.	8
	Check that both modules are firmly locked.	9
	Make sure that there is always sufficient space between the patient and the articulated arm.	10
Combination with fasciotens®Hernia	Always check that the ball adapter is firmly and securely seated.	11
Processing fasciotens®Carrier	Insufficient drying can lead to corrosion of the instruments. Therefore, please make sure that the instruments are completely dry after disinfection.	14
	When storing for several days, disinfect the product again before sterilisation.	14
	Improper storage can lead to loss of sterility - the manufacturer accepts no liability on this point.	15
Warranty	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.	16
	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.	16

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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

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