USER INSTRUCTIONS

MKS® THORECTA PLUS

THREE-POINT-FIXATION

albrecht©
FUNKTIONELLE REHABILITATION

MKS® Thorecta plus

User Instructions

Contents

1. Introduction

1.1. Foreword

Our MKS® Modular Corset System straightens and stabilizes defined areas of the vertebral column in order to achieve postural corrections which actively support rehabilitation in specific indications.

Our MKS® programme is comprised of a modular system which can be divided into an orthesis set consisting of rigid supportive elements and a set of partially elastic, smoothly-fitting back-and-body bandages which adapt comfortably to the body.

By combining the individual components of the two sets an exact adjustment to both the respective indication and the patient can be achieved.

1.2. Customer information

For your own safety please read through these User Instructions carefully and accurately before using the brace. The instructions, notes and procedures must be read and understood thoroughly in order to benefit from the correct operation and use of the device. If anything in the User Instructions is not clear, or any instructions, operating procedures or safety information is not fully understandable, please contact the appropriate specialist retailer or albrecht GmbH directly, before you use the brace. This particularly applies to the safety instructions.

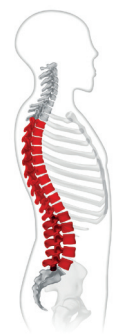
1.3. Mode of operation

The MKS® Thorecta plus functions according to the 3-Point-Principle. Front-and back piece straighten and hence relieve the vertebral column. The wide thorax support limits the lateral flexion of the spine to further immobilize and relieve the vertebral column. The reclination straps straighten the vertebral column further and minimize rotation. Focused compression between iliac crest and thorax relieves the lumbar vertebral column further.

1.4. Application

The brace must only be used for the orthotic treatment of the vertebral column.

The MKS® Thorecta plus assists treatment in the application area from the nineth thoracic vertebral body to the fifth lumbar vertebral body in adults. It provides stabilisation of the entire spine. The MKS® Thorecta plus is intended to help you achieve a lifestyle that is as independent as possible, while still meeting your needs and matching your personal capabilities.



T3 - L5

1.5. Scope of delivery

The MKS® Thorecta plus is delivered to you ready for use, in the size you ordered, with User Instructions and labeling on the product.

1.6. Declaration of conformity

The albrecht GmbH company, as the manufacturer solely responsible, declares that the MKS® Thorecta plus brace conforms to the Regulation (EU) 2017/745 concerning medical devices.

1.7. Features

- Adjustable, stable aluminium profiles
- Padded pelottes
- Individual strap course
- Compression padding for the waist
- Additional firm thorax support
- Reclination straps
- Clip fastener for easy handling

Optionally, a gluteal brace can be used for further limitation of the lateral flexion.

1.8. Indications

The physician will decide on the type of treatment to apply based on his diagnosis. Generally the use of the MKS® Thorecta plus, i.e., relief and/or correction of lumbar/thoracic spine in sagittal and frontal plane with functional mobilisation is indicated in:

All indications requiring a relief and/or correction of lumbar/thoracic spine as well as limitation of movement in sagittal and frontal plane with following functional mobilisation, such as:

- Stable vertebral body fractures
- Scheuermann's disease
- Postsurgical stabilisation
- Tumor
- Spondylitis

For all other indications a physician must be consulted.

1.9. Contra indications

The brace is only intended for use in contact with intact skin.

1.10. Safety Instructions

The optimal effect of the brace is only achieved when used correctly.

- The brace must only be used in the intact, complete and mechanically undamaged condition and with complete and intact cushioning and walers. This must be verified by the user before each usage.
- Opening or removing one or more belts, as well as excessive loosening of the waler when using the brace leads to a reduction of the therapeutic effect of the brace and may lead to injury.
- The brace must not be worn over open wounds.
- The skin should be free of oils, grease, gels or other debris, to prevent reactions with the skin or the structure of the material.
- The orthosis should fit firmly but not too tight, so as not to restrict the blood circulation and adversely affect nerve and lymph vessels. Excessive compression is therefore to be avoided.
- Combination with other products is currently not provided for or is to be agreed with the manufacturer in writing.
- The brace is not intended for single use, but is intended for multiple use by a single person.
- The product as delivered is not sterile.

- Contact your physician immediately in the event of an allergic reaction.
- Please note that cushioned sections can heat up under direct sunlight. Protect the orthosis from direct sunlight if necessary.
- Currently there is no test for flammability. Exercise caution when using the orthosis in the direct vicinity of open flames such as lighters and cigarettes.

1.11. Warranty

We assume the warranty for the brace for a period of 3 months. The brace is a medical rehabilitation device and must not be used for any purpose other than the intended, as described in the Instructions for Use. Changes to the brace or other applications require the written consent of the albrecht GmbH. If this is not obtained, the manufacturer may not honor the guarantee. If you are using single joints or other components, these should be used as intended. If changes or modifications (e.g. additional mounting holes) are made to the individual parts or components, the manufacturer's warranty no longer applies. The removal of or damage to the QM seal will also void the warranty.

1.12. Transfer of the brace

The brace is not intended for single use, but rather is intended for multiple use by a single person. We do not recommend transfer to other users. Should this be desired however, please ensure to pass on the care and cleaning instructions and have the brace checked by an authorized specialist dealer for safe and proper operation.

1.13. Disposal

The MKS® Thorecta plus contains recyclable materials and is free from toxic or otherwise polluting agents or substances. Provided that it is not contaminated with infectious germs, it can be disposed of by normal means. In order to be certain, please consult your orthopaedics store.

1.14. Individual adjustments

The overall height of the front and back parts depends on the length of the aluminium rails and the positioning of the individual plastic modules. Once the size has been determined using our table, the overall height can be precisely adjusted by moving the individual pads. The anatomically preformed aluminium rails of the front and back parts can be individually moulded to fit the patient and the indication. Once this has been done the actual mounting of the MKS® Thorecta plus starts.

Front part: Once the overall height has been adjusted by moving the sternal and symphyseal pad, the abdominal plate is positioned. Once all the modules are in the right position, they are fixed with the screws provided.

Back part: When sliding on or moving the individual modules of the back part, it is recommended that you first screw the bottom pad into position. This will prevent any offset between the two aluminium rails and will make the exact positioning of the individual modules easier.

Once all the elements have been fixed at the right height, you can start to adjust the girths. If the adjustable length of the hook and loop straps is insufficient, the lugs of the straps can be adjusted.

Should an ideal fit still not be possible despite the wide range of adjustment, all aluminium

and plastic parts can be shortened or otherwise reworked. It is also possible to add additional drill holes for screw connections. A combination with other products is currently not foreseen. Any such combination must be agreed with the manufacturer in writing.

Due to the individual adjustments, each MKS® Thorecta plus can only be used by one patient.

For those patients using the MKS® Thorecta plus for the first time it is important that they learn how to handle it. Putting it on and taking it off should be practiced.

Wear the MKS® Thorecta plus directly on the skin or over a tight-fitting singlet without any creases. It is recommended that an absorbent singlet be worn to avoid humidity caused by excessive sweating.

To put on the MKS® Thorecta plus please follow the attachment instructions. This will ensure reliable effectiveness.

Always make sure that the MKS® Thorecta plus is is a smooth and tight fit. However, in order to prevent constrictions along the edges it shouldn't be over-tightened.

1.15. Attachment instructions

During the acute phase, only put on your MKS® Thorecta plus with the help of your doctor or therapist. The MKS® Thorecta plus is put on in a lying position. Ideally, the patient should wear a T-shirt or a tight-fitting singlet. The patient is put in a stable lateral position. The parts that need to be slid underneath the patient can be sheathed in a sliding film. This will make it easier to pass them underneath the patient. Make sure that the entire back part is well positioned. The bulges on the pelvis-/ fastener element must sit on the waistline to make sure that the height is correct and that the MKS® Thorecta plus fits well. Now put the patient in a dorsal position, check the position of the MKS® Thorecta plus once again and attach the front part.

For standing up, the patient should follow the doctor's or therapist's instructions.

1.16. Downward conversion

A modification adjusted to the course of treatment is possible by changing the back rods. If the reclination rods 510 / 580 / 650mm are replaced by back rods 320 / 390 mm (Art. no. 221-006-S / 221-007-S) and the reclination straps are removed, the back orthosis MKS®-Thorecta Lumbar Spine / Thoracic Spine is created.

Hand wash at 30°C

Do not bleach

Do not iron

Do not dry-clean

Do not tumble dry

2. Cleaning, maintenance and disinfection

The orthosis is designed to be maintenance-free. To ensure proper operation over the period of treatment the orthosis should be cleaned regularly (at least every 3 months) or as required, according to the following instructions.

2.1. Care

- The product as delivered is not sterile and is not suitable for sterilization.
- Do not use harsh or abrasive cleaners.
- All fabrics can be washed by hand at 30 °C using water and a mild detergent and/or disinfectant.
- Not machine washable.
- The MKS® Thorecta plus can be dried in the open air.
- In the case of more severe soiling, a replacement set of textile parts is available.
- Wipe down surfaces with a cloth soaked with disinfectant.
- Wet completely, and do not wipe off.
- Spray inaccessible surfaces.
- When spraying ensure complete wetting.
- A mild alcohol-based disinfectant is recommended.

Ask your physician or pharmacist when selecting a disinfectant, and follow the instructions given by the disinfectant manufacturer. The Robert Koch list of approved disinfectants can be found at http://www.rki.de.

3. Technische Daten / Materialien

Description	Material
pads	velours PA
straps	velours PA

4. Choice of size

The MKS® Thorecta plus is available in different sizes as per the table below.

5. Size chart and article numbers

Size	Body circumference	Height of front piece	Height of back piece	Height of back piece
S	70 - 125 cm	40 - 47 cm	27 - 31 cm	711C
M	70 - 125 cm	48 - 53 cm	27 - 31 cm	711A
L	70 - 125 cm	54 - 59 cm	33 - 38 cm	711B

Opt. front rod 32 cm – Art.-No.: 221-014-S (for chest height 35-40 cm)
Opt. Reclination rod 46 cm – Art.-No.: 221-026-S (for height of back piece 48-51cm

Duty to report

Due to regional legal regulations, you are required to immediately report any serious incident involving the use of this medical device to the manufacturer and the responsible authorities. Please find our contact details on the back of this brochure.

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MD

Medical device

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