

USER INSTRUCTION

MKS® OSTEO

SPINAL ORTHOSIS



albrecht®
FUNKTIONELLE REHABILITATION

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User Instructions

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 orthosis 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[®] Osteo Spinal orthosis functions according to the reclination principle. The two shoulder straps attached to the back plate straighten the vertebral column to relieve the thoracic spine.

The wide lumbar bandage straightens and hence relieves the lumbar vertebral column.

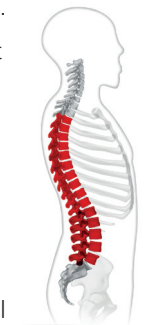
The reclination straps are attached to the lumbar bandage through additional lateral straps.

Hereby rotation is limited and stabilisation is ensured.

1.4. Application

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

The MKS[®] Osteo assists treatment in the application area from the third thoracic vertebral body to the fifth lumbar vertebral body in adults. It provides stabilisation of the entire spine. The MKS[®] Osteo 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[®] Osteo is delivered to you ready to use in the size requested, with User Instructions and labeling on the product.

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1.6. Declaration of conformity

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

1.7. Features

- Semi-elastic bandaging material
- Lateral reinforcing stays
- Firm abdominal piece with hook and loop fastener
- Adjustable back plate with incorporated aluminium profile
- Reclination straps
- Individual strap course

1.8. Indications

The physician will decide on the type of treatment to apply based on his diagnosis. Generally the use of the MKS® Osteo is indicated in all indications requiring an active straightening for relief and correction of lumbar/thoracic spine as well as limitation of movement in sagittal plane, such as:

- Osteoporosis
- Stable, osteoporotic and traumatic vertebral fractures
- Sintered vertebral fractures in osteoporosis
- Pain caused by poor posture, e.g. rounded shoulders
- Poor posture

- Hollow round back
- Chronic lumbago caused by hyperlordosis
- Spondylodiscitis
- Facet syndrome
- Degenerative changes in the lumbar spine
- Tumor
- Condition after intervertebral disc surgery
- Muscle insufficiency
- Abdominal muscle insufficiency
- 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.

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- 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 brace contains recyclable materials without toxic or other harmful substances or other environmentally hazardous substances. Provided it is not contaminated with infectious germs, the brace can be deposited in the normal waste disposal. To be sure, consult your specialist orthopedics dealer.

2. Individual adjustments

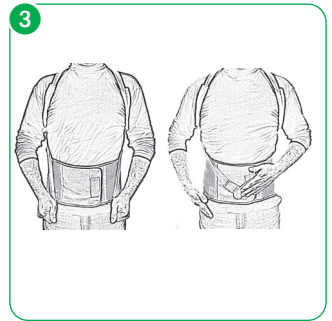
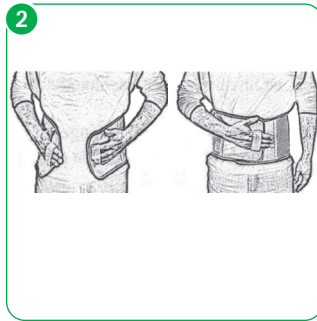
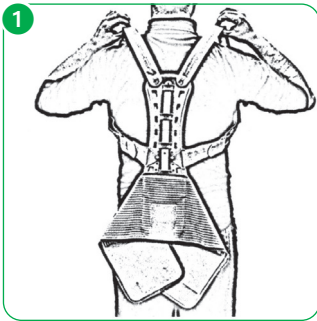
For those patients using the MKS® Osteo for the first time it is important that they learn how to handle it. Putting it on and taking it off should be practiced.

Wear the MKS® Osteo 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® Osteo please follow the steps below. This will ensure reliable effectiveness.

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

- 1 Take the ready for use MKS® Osteo, previously adjusted by your orthopaedist, out of the packaging and put it on like a backpack.
- 2 Close the body belt using the hand loops. Make sure that the belt fits correctly, i.e., flat and without any creases.
- 3 Tighten the reclination straps by pulling them downwards and attach them flat onto the body belt through hook and loop connections.



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Hand wash at 30°C



Do not bleach



Do not iron



Do not dry-clean



Do not tumble dry

3. 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.

3.1. 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[®] Osteo 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>.

4. Technical data

Description	Material
Body Belt	elastic material 28% viskose, 48% perlon, 24% elastodiene binding 83% viscose, 17% dorlastan velours PA
Pads	velours PA
Straps	velours PA

5. Choice of size

The MKS® Osteo is available in three sizes as per the table below.

Back piece = length from the sacrum to about 2 to 3 cm below the cervical vertebra C 7.

6. Size chart and article numbers

Size	Body circumference	Abdominal height	Height of back piece		
			S (46 cm) Art.-No.:	M (50 cm) Art.-No.:	L (56 cm) Art.-No.:
1	60 - 70 cm	18 cm	782C-1	782A-1	782B-1
2	70 - 80 cm	18 cm	782C-2	782A-2	782B-2
3	80 - 90 cm	18 cm	782C-3	782A-3	782B-3
4	90 - 105 cm	18 cm	782C-4	782A-4	782B-4
5	105 - 120 cm	18 cm	782C-5	782A-5	782B-5
6	120 - 135 cm	18 cm	782C-6	782A-6	782B-6

MKS® Osteo – reduced height

Size	Body circumference	Abdominal height	Height of back piece			
			XS (43 cm) Art.-No.:	S (46 cm) Art.-No.:	M (50 cm) Art.-No.:	L (56 cm) Art.-No.:
1	60 - 70 cm	14 cm	782D-1N	782C-1N	782A-1N	782B-1N
2	70 - 80 cm	14 cm	782D-2N	782C-2N	782A-2N	782B-2N
3	80 - 90 cm	14 cm	782D-3N	782C-3N	782A-3N	782B-3N
4	90 - 105 cm	14 cm	782D-4N	782C-4N	782A-4N	782B-4N
5	105 - 120 cm	14 cm	782D-5N	782C-5N	782A-5N	782B-5N
6	120 - 135 cm	14 cm	782D-6N	782C-6N	782A-6N	782B-6N

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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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Medical device



Manufacturer



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