USER INSTRUCTIONS

MKS® PONTSANA® STABIL

LUMBAR BANDAGE WITH FIRM BRIDGING FRAME

albrecht®
FUNKTIONELLE REHABILITATION
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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® Pontsana® stabil functions according to the bridging principle. The wide bandage with the additional lateral double straps and the firm bridging frame straightens and hence relieves the lumbar vertebral column.

1.4. Application

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

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

BWK 9 bis LWK 5
1.5. Scope of delivery

The MKS® Pontsana® stabil is delivered to you ready to use in the size requested, with User Instructions and labeling on the product.

1.6. Declaration of conformity


1.7. Features

- Semi-elastic bandaging material
- Firm abdominal piece with hook and loop fastener
- Lateral reinforcing stays
- Bridging rods (spring band steel)
- Additional lateral double divided straps
- Stable contour fitting bridging frame

1.8. Indications

The physician will decide on the type of treatment to apply based on his diagnosis. Generally the use of the MKS® Pontsana® stabil is indicated in all indications requiring a partial relief by delordozation of lumbar spine, such as:

- Severe lumbar sciatica with muscular failures in severe intervertebral disc protrusion/prolapse without absolute indication for surgery
- Severe radicular lumbar syndrome, pseudo-radicular lumbar syndrome
- Spondylolithesis with relapsing sciaticae
- Severe lumbar deformity caused by facet syndrome/arthrosis
- Condition after intervertebral disc surgery without residual paresis in cleared intervertebral disc, decompression of the spinal canal one-layer without defomity, intervertebral disc surgery one-layer
- Spinal stenosis without strong paresis after short walking distance

For all other indications a physician must be consulted.

1.9. Contraindications

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.
2. Individual Adjustments

The MKS® Pontsana® stabil is adjusted to the needs of patients and indications by adjusting the bridging rods by your orthopedic specialist.

1. The fastening strap must be adjusted in length and position with the measurements of the individual patient. For this, remove the Velcro end pieces, shorten the straps accordingly and attach the Velcro end pieces again.

3. Application

For those patients using the MKS® Pontsana® stabil 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® Pontsana® stabil 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® Pontsana® stabil please follow the instructions below. This will ensure reliable effectiveness.

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

Open the inner and the outer hook and loop fastener. Put the bandage around your waist so that the openings of the pockets for the stabilising rods point upwards.

1. Press the left-hand side fluffy band of the inner bandage belt flat on your stomach, and then pull the hook and loop end of the right-hand side inner strap forward and attach it.

2. Pull the outer strap ends forward to increase the stabilising pressure around your waist.

3. Press the tightened outer strap ends flat onto the closed inner strap and flatten it down with your flat hand.
4. 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.

4.1. 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® Pontsana® stabil 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.
5. Technical data

<table>
<thead>
<tr>
<th>Description</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Belt</td>
<td>elastic material 28% viscose, 48% perlon,</td>
</tr>
<tr>
<td></td>
<td>24% elastodiene</td>
</tr>
<tr>
<td></td>
<td>binding 83% viscose, 17% dorlastan</td>
</tr>
<tr>
<td></td>
<td>velours PA</td>
</tr>
</tbody>
</table>

6. Choice of size

The MKS® Pontsana® stabil is available in sizes according to the table below.

7. Sizes chart and article numbers

<table>
<thead>
<tr>
<th>Size</th>
<th>Body circumference</th>
<th>Abdominal height</th>
<th>Height of back piece</th>
<th>Art.-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60 - 70 cm</td>
<td>18 cm</td>
<td>32 cm</td>
<td>582-881-S</td>
</tr>
<tr>
<td>2</td>
<td>70 - 80 cm</td>
<td>18 cm</td>
<td>32 cm</td>
<td>582-882-S</td>
</tr>
<tr>
<td>3</td>
<td>80 - 90 cm</td>
<td>18 cm</td>
<td>34 cm</td>
<td>582-883-S</td>
</tr>
<tr>
<td>4</td>
<td>90 - 105 cm</td>
<td>18 cm</td>
<td>34 cm</td>
<td>582-884-S</td>
</tr>
<tr>
<td>5</td>
<td>105 - 120 cm</td>
<td>18 cm</td>
<td>38 cm</td>
<td>582-885-S</td>
</tr>
<tr>
<td>6</td>
<td>120 - 135 cm</td>
<td>18 cm</td>
<td>38 cm</td>
<td>582-886-S</td>
</tr>
<tr>
<td>51</td>
<td>105 - 120 cm</td>
<td>18 cm</td>
<td>34 cm (reduced)</td>
<td>582-8851-S</td>
</tr>
<tr>
<td>61</td>
<td>120 - 135 cm</td>
<td>18 cm</td>
<td>34 cm (reduced)</td>
<td>582-8861-S</td>
</tr>
</tbody>
</table>

MKS® Pontsana® stabil – reduced height:

<table>
<thead>
<tr>
<th>Size</th>
<th>Body circumference</th>
<th>Abdominal height</th>
<th>Height of back piece</th>
<th>Art.-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60 - 70 cm</td>
<td>16 cm</td>
<td>26 cm</td>
<td>582-881N-S</td>
</tr>
<tr>
<td>2</td>
<td>70 - 80 cm</td>
<td>16 cm</td>
<td>26 cm</td>
<td>582-882N-S</td>
</tr>
<tr>
<td>3</td>
<td>80 - 90 cm</td>
<td>16 cm</td>
<td>26 cm</td>
<td>582-883N-S</td>
</tr>
<tr>
<td>4</td>
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<td>16 cm</td>
<td>26 cm</td>
<td>582-884N-S</td>
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<td>6</td>
<td>120 - 135 cm</td>
<td>16 cm</td>
<td>26 cm</td>
<td>582-886N-S</td>
</tr>
</tbody>
</table>
MKS® Pontsana® stabil

User Instructions

8. 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 hinge checked by an authorized specialist dealer for safe and proper operation.

9. 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 hinge can be deposited in the normal waste disposal. To be sure, consult your specialist orthopedics dealer.