USER INSTRUCTIONS

MKS® PONTSANA® PLUS

LUMBAR BANDAGE WITH BRIDGING RODS
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® Pontsana® plus functions according to the bridging principle. The circular high bandage with the additional lateral double straps 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® 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® Pontsana® 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.

1.5. Scope of delivery

The MKS® Pontsana® 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

1.7. Features
• Semi-elastic bandaging material
• Lateral reinforcing stays
• Firm, circular high abdominal piece with hook and loop fastener
• Bridging rods (spring band steel)
• Additional lateral double straps

Optionally also as Semi-Assembled Product* available.

1.8. Indications
The physician will decide on the type of treatment to apply based on his diagnosis. Generally, the MKS® Pontsana® plus is used to stabilize the lumbar/thoracic vertebral column by supporting the abdominal and back muscles. It is used for all indications in which a stabilisation of the lumbar/thoracic spine is required, such as:
• Pain in the area of the lumbar/thoracic spine
• Moderately severe lumbar sciatica with slight failures in intervertebral disc protrusion/prolapse
• Moderately severe radicular lumbar syndrome, pseudo-radicular lumbar syndrome
• Spondylolithesis, grade I with lumbago
• Moderately severe lumbar deformity (relapsing treatment, complicated course)
• Condition after intervertebral disc surgery with small up to medium-sized prolapse
• Degenerative changes in the lumbar/thoracic spine

• Instabilities in the lumbar/thoracic spine
• Dorsolumbagia
• Abdominal and lumbar muscle insufficiency

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® Pontsana® 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.
2. Individual adjustments

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

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

1. Put the orthosis around your waist with the care label pointing upwards. Press the left fluffy band at the lower end of the bandage strap flat on your stomach, pull the hook and loop fastener of the right lower end towards the front and fasten it.

2. Press the left fluffy band at the end of the upper bandage strap flat on your stomach, pull the hook and loop fastener of the right upper end towards the front and fasten it.

3. Then increase the stabilising pressure applied to the waist by strongly pulling the outer strap ends forward. Press the tensioned outer strap ends flat onto the closed inner strap and flatten it out with the palm of your hand.
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® Pontsana® 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.
4. Technical data

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

5. Choice of size

The MKS® Pontsana® plus is available in six sizes as shown in the table below.

6. Size chart and article numbers

<table>
<thead>
<tr>
<th>Size</th>
<th>Body circumference</th>
<th>Abdominal Height (1) / Height of back piece (2)</th>
<th>Semi-Assembled Product*</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>25 cm (1) / 32 cm (2) Art.-No.</td>
<td>30 cm (1) / 38 cm (2) Art.-No.</td>
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<tr>
<td>1</td>
<td>60 - 70 cm</td>
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<td>582-9012-S</td>
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<td>2</td>
<td>70 - 80 cm</td>
<td>582-9021-S</td>
<td>582-9022-S</td>
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<td>3</td>
<td>80 - 90 cm</td>
<td>582-9031-S</td>
<td>582-9032-S</td>
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<td>4</td>
<td>90 - 105 cm</td>
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<td>582-9042-S</td>
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<td>5</td>
<td>105 - 120 cm</td>
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<td>582-9052-S</td>
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<td>6</td>
<td>120 - 135 cm</td>
<td>582-9061-S</td>
<td>582-9062-S</td>
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