USER INSTRUCTIONS

MKS® LUMBAGO VARIO

LUMBAR BANDAGE

WITH SILICONE PAD STIMULATING BLOOD CIRCULATION
1. Introduction

1.1. Introduction

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 this User Instructions carefully before using the brace. Proper use and operation of the brace will only be possible if you have carefully read and understood all instructions, notes and procedures. Should you have any doubts with regard to the User Instructions, or should any of the instructions, operations or safety notes be unclear, please contact your local dealer or the manufacturer albrecht GmbH directly before using the brace. This holds particularly true for the safety notes.

1.3. Mode of operation

Through building up circular pressure the lumbar vertebral column is supported. The firm fastener element provides the necessary abdominal pressure which can be enhanced through the additional tensioning straps. The inserted silicone pad in the integrated back pocket stimulates blood circulation.

The various possibilities of adjustment offered by the MKS® Lumbago Vario allow the construction of lumbar bandages of different girths and shapes.

Only two sizes are needed to cover a range of girths from 70cm to 125cm: Vario Standard (70-95cm) and Vario Extra (95-125cm).

1.4. Application

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

The MKS® Lumbago Vario assists treatment in the application area from the first to the fifth lumbar vertebral body in adults. It provides stabilization of the entire spine. The MKS® Lumbago Vario 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® Lumbago Vario 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 abdominal piece with hook and loop fastener
- Back pocket suitable for silicone pad stimulating blood circulation or MKS® Osteo back plate
- Circumference and shape can be adjusted
- Silicone pad stimulating blood circulation

1.8. Indications

Your physician will decide on the type of treatment to apply based on his diagnosis. Generally the use of the MKS® Lumbago Vario, i.e., the straightening and stabilization of the lumbar spine, is indicated in:

- Severe lower back pain
- Severe lumbago
- Relapsing lumbago
- Osteochondrosis
- Spondylolysis without displacement of vertebrae
- Mild lumbar deformity (with displacement of vertebrae)
- Spondylarthrosis
- Sacroiliac joint irritation
- 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 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® Lumbago Vario for the first time it is important to learn how to handle it.

Putting it on and taking it off should be practiced. Wear the MKS® Lumbago Vario 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® Lumbago Vario please follow the steps below. This will ensure reliable effectiveness. Always make sure that the MKS® Lumbago Vario is a smooth and tight fit. However, in order to prevent constrictions along the edges it shouldn’t be over-tightened.

The MKS® Lumbago Vario consists of the two lateral pieces 1 and 2, the center piece 3 with markings 4, the textile cover 5 and the supportive pad 6. Depending on the girth and shape required, the two lateral pieces are symmetrically attached through hook and loop connection to the center piece. The embroidered markings serve as orientation.

1. Insert the supportive pad into the slide-in back pocket specially designed for that purpose. The textile cover (5) will overlap the edges.
2. Put the MKS® Lumbago Vario around your waist from the back to the front making sure that the dark slide-in pocket rests inside against your back.
3. Press the band with the fleece on the front down on your stomach and pull the hook and loop fastener of the MKS® Lumbago Vario forward so that you can feel a slight pressure around your waist.
4. Now press the hook and loop fastener of the tightened MKS® Lumbago Vario on the fluffy end and flatten down the MKS® Lumbago Vario brace with 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® Lumbago Vario 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>
</tr>
</thead>
<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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5. Choice of size

The MKS® Lumbago Vario is available in two sizes as per the table below. The MKS® Lumbago Vario is supplied with a supportive pad in the slide-in back pocket stimulating the blood flow. If necessary, the pad can be removed.

6. Size chart and article numbers

<table>
<thead>
<tr>
<th>Name</th>
<th>Body circumference</th>
<th>Abdominal height</th>
<th>Height of back piece</th>
<th>Art.-No.</th>
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</thead>
<tbody>
<tr>
<td>Standard</td>
<td>70 - 95 cm</td>
<td>18 cm</td>
<td>25 cm</td>
<td>581-069-S</td>
</tr>
<tr>
<td>Extra</td>
<td>95 - 125 cm</td>
<td>18 cm</td>
<td>25 cm</td>
<td>581-070-S</td>
</tr>
</tbody>
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