USER INSTRUCTIONS

MKS® PONTSANA® /-PLUS /-MOBIL

LUMBAR BANDAGE WITH BRIDGING RODS

MKS® PONTSANA® STABIL

LUMBAR BANDAGE WITH FIRM BRIDGING FRAME

albrecht©

FUNKTIONELLE REHABILITATION

Inhalt

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® functions according to the bridging principle.
The wide bandage with the additional lateral double straps straightens and hence relieves the lumbar vertebral column.

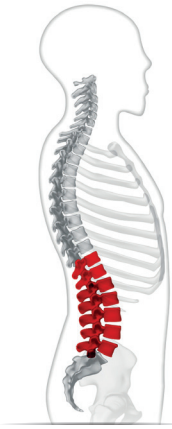
1.4. Application

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

The MKS® Pontsana® and the MKS® Pontsana® mobil assists treatment in the application area from the eleventh thoracic vertebral body to the fifth lumbar vertebral body in adults.

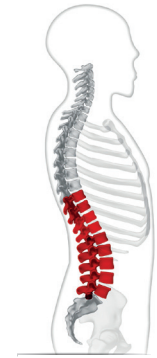
The MKS® Pontsana® plus and the MKS® Pontsana® stabil assists treatment in the application area from the nineth thoracic vertebral body to the fifth lumbar vertebral body in adults.

It provides stabilisation of the entire spine and is intended to help you achieve a lifestyle that is as independent as possible, while still meeting your needs and matching your personal capabilities.



T11 - L5

MKS® Pontsana® mobil



BWK 9 bis LWK 5

MKS® Pontsana® stabil

1.5. Scope of delivery

The MKS® Pontsana® is delivered to you ready to use in the size requested, 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® Pontsana® brace conforms to the Regulation (EU) 2017/745 concerning medical devices.

1.7. Features

MKS® Pontsana

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

MKS® Pontsana plus®

+ Circular high abdominal piece with split hook and loop fastener

+ Optionally also as Semi-Assembled

Product* available.

MKS® Pontsana® mobil

+ lateral double straps that can be in accordance with the treatment plan detachabled for the mobilisation of the patient.

MKS® Pontsana® stabil

+ firm contoured bridging frame integrated

1.8. Indications

The physician will decide on the type of treatment to apply based on his diagnosis.

Generally, the MKS® Pontsana® 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:

MKS® Pontsana®

- Sacroilliac joint irritation
- Lumbar muscle insufficiency

MKS® Pontsana® plus

- Pain in the area of the lumbar / thoracic spine
- Degenerative changes in the lumbar / thoracic spine
- Instabilities in the lumbar / thoracic spine
- Dorsolumbagia
- Abdominal and lumbar muscle insufficiency

MKS® Pontsana® mobil

- Condition after intervertebral disc surgery
- Sacroilliac joint irritation
- Lumbar muscle insufficiencywith small up to medium-sized prolapse

MKS® Pontsana® /-mobil

- Lower back pain and
- Spondylarthrosis

MKS® Pontsana® /- plus /-mobil

- Condition after intervertebral disc surgery with small up to medium-sized prolapse

(only MKS® Pontsana® and /-plus)

- Moderatley severe lumbar sciatica with slight failures in intervertebral disc protrusion / prolapse
- Moderatley severe radicular lumbar syndrome, pseudo-radicular lumbar syndrome
- Spondylolithesis, grade I with lumbago
- Moderatley severe lumbar deformity (relapsing treatment, complicated course)

MKS® Pontsana stabil

- 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 / athrosis
- 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 th 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 fammability. 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® is adjusted to the needs of patients and indications by adjusting the bridging rods by your orthopedic specialist.

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

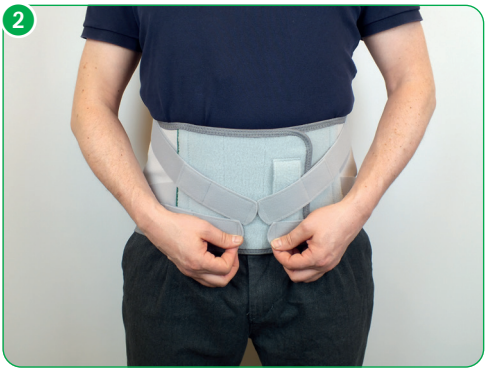
Wear the MKS® Pontsana® directly on the skin or over a tight-fitting singlet without any creases. It is recommended that an absorbent singlet be worn to avoid humidity caused by excessive sweating.

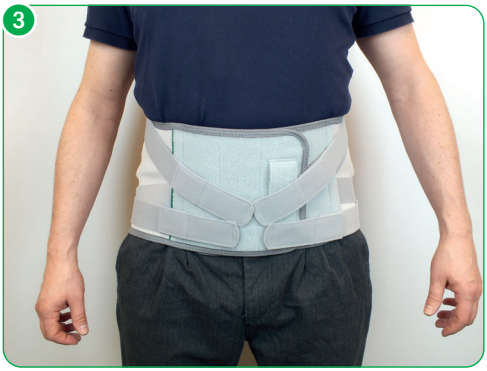
To put it on, please follow the instructions below. This will ensure reliable effectiveness. Always make sure it is smooth and tight fit. However, in order to prevent constrictions along the edges it shouldn't be over-tightened.

2.1. MKS® Pontsana® /-mobil and /-stabil

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.

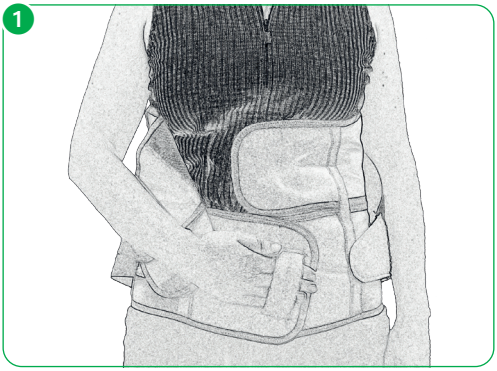
1. Press the left-hand side fluffy band of the inner bandage belt flat on your stomach, and then pull the hook and loop end of the right-hand side inner strap forward and attach it.
2. Pull the outer strap ends forward to increase the stabilising pressure around your waist.
3. Press the tightened outer strap ends flat onto the closed inner strap and flatten it down with your flat hand.

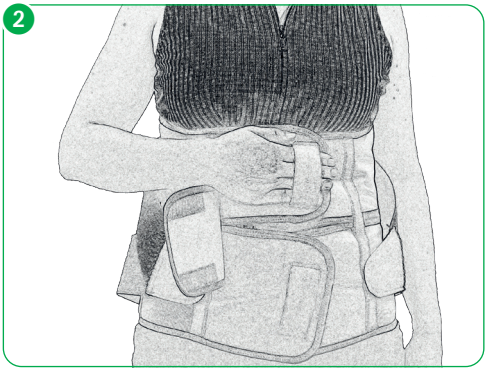


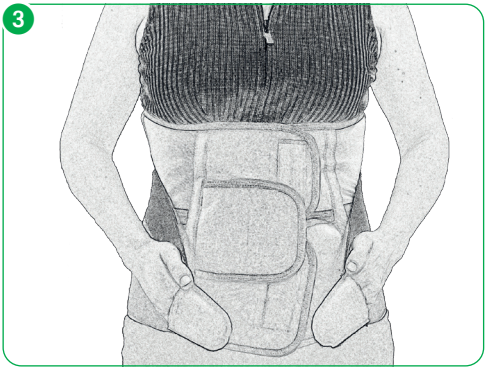


2.2. MKS® Pontsana® plus

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.







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.

- 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® 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 / material

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

5. Size chart and article numbers

MKS® Pontsana® :

Size	Body circumference	Abdominal height	Height of back piece	Art.-No.
1	60 - 70 cm	18 cm	32 cm	582-801-S
2	70 - 80 cm	18 cm	32 cm	582-802-S
3	80 - 90 cm	18 cm	34 cm	582-803-S
4	90 - 105 cm	18 cm	34 cm	582-804-S
5	105 - 120 cm	18 cm	38 cm	582-805-S
6	120 - 135 cm	18 cm	38 cm	582-806-S
51	105 - 120 cm	18 cm	34 cm (reduced)	582-8051-S
61	120 - 135 cm	18 cm	34 cm (reduced))	582-8061-S

MKS® Pontsana® – reduced height:

Size	Body circumference	Abdominal height	Height of back piece	Art.-Nr.:
1	60 - 70 cm	16 cm	26 cm	582-801N-S
2	70 - 80 cm	16 cm	26 cm	582-802N-S
3	80 - 90 cm	16 cm	26 cm	582-803N-S
4	90 - 105 cm	16 cm	26 cm	582-804N-S
5	105 - 120 cm	16 cm	26 cm	582-805N-S
6	120 - 135 cm	16 cm	26 cm	582-806N-S

User Instructions

MKS® Pontsana® Plus :

		Semi-Assembled Product			
Size	Body circumference	Art.-No. Abdominal height Height of Backpiece	Art.-No. Abdominal height Height of Backpiece	Art.-No. Abdominal height Height of Backpiece	Art.-No. Abdominal height Height of Backpiece
		25 cm / 32 cm	30 cm / 38 cm	25 cm / 32 cm	30 cm / 38 cm
1	60 - 70 cm	582-9011-S	582-9012-S	582-9011-H	582-9012-H
2	70 - 80 cm	582-9021-S	582-9022-S	582-9021-H	582-9022-H
3	80 - 90 cm	582-9031-S	582-9032-S	582-9031-H	582-9032-H
4	90 - 105 cm	582-9041-S	582-9042-S	582-9041-H	582-9042-H
5	105 - 120 cm	582-9051-S	582-9052-S	582-9051-H	582-9052-H
6	120 - 135 cm	582-9061-S	582-9062-S	582-9061-H	582-9062-H

MKS® Pontsana® mobil:

Size	Body circumference	Abdominal height	Height of Backpiece	Art.-Nr.:
1	60 - 70 cm	18 cm	32 cm	582-811-S
2	70 - 80 cm	18 cm	32 cm	582-812-S
3	80 - 90 cm	18 cm	34 cm	582-813-S
4	90 - 105 cm	18 cm	34 cm	582-814-S
5	105 - 120 cm	18 cm	38 cm	582-815-S
6	120 - 135 cm	18 cm	38 cm	582-816-S
51	105 - 120 cm	18 cm	34 cm (reduced)	582-8151-S
61	120 - 135 cm	18 cm	34 cm (reduced)	582-8161-S

MKS® Pontsana® Stabil :

					Semi-Assembled Product		
Size	Body circumference	Abdominal height	Height of Backpiece	Art.-No.	Abdominal height	Height of Backpiece.	Art.-No.
1	60 - 70 cm	18 cm	32 cm	582-881-S	16 cm	26 cm	582-881N-S
2	70 - 80 cm	18 cm	32 cm	582-882-S	16 cm	26 cm	582-882N-S
3	80 - 90 cm	18 cm	34 cm	582-883-S	16 cm	26 cm	582-883N-S
4	90 - 105 cm	18 cm	34 cm	582-884-S	16 cm	26 cm	582-884N-S
5	105 - 120 cm	18 cm	38 cm	582-885-S	16 cm	26 cm	582-885N-S
6	120 - 135 cm	18 cm	38 cm	582-886-S	16 cm	26 cm	582-886N-S
51	105 - 120 cm	18 cm	34 cm (reduced)	582-8851-S	16 cm		
61	120 - 135 cm	18 cm	34 cm (reduced)	582-8861-S	16 cm		

6. 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.

7. 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.

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

Manufacturer

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TÜVRheinland ZERTIFIZIERT
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