USER INSTRUCTIONS

MKS® EXTENSA

ORTHESIS TO RELIEVE THE LWS/BWS

DUE TO MOVEMENT RESTRICTION IN SAGITTAL PLANE WITH UP AND DOWN OPTION

albrecht©

FUNKTIONELLE REHABILITATION

MKS® Extensa

User Instructions

Contents

1. Introduction

1.1. Foreword

Our modular corset system is used to straighten and stabilise defined areas of the spine. This helps to achieve postural corrections that actively support rehabilitation in certain indications. The MKS programme consists of a modular system, which is divided into an orthotics programme with rigid supports and a bandage program with partially elastic, supple back and/or body bandages. The individual components of the programmes can be combined with each other in some cases and thus enable an exact, individual adjustment to the respective indication and the patient.

1.2. Customer information

For your own safety, please read these instructions slowly and carefully before using the brace. Only if all instructions and procedures have been thoroughly read and understood can proper use and operation for the purpose intended be possible. If something is not clear in the instructions for use or if directions, operations or safety information are not completely clear, please contact the responsible specialist dealer or go directly to albrecht GmbH before using the brace. This applies in particular to the safety instructions.

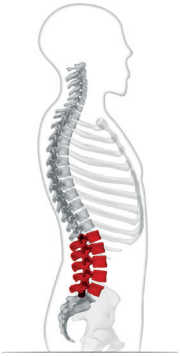
1.3. Mode of operation

The function of the MKS® and Extensa is based on the 3-point principle. The front and back parts straighten the spine and thus relieve the strain on it. Additional relief of the lumbar spine is achieved through targeted compression between the iliac crest and the thorax (cherry pit effect)

1.4. Intended use

The orthosis must be used exclusively for the orthotic treatment of the spine.

The MKS® Extensa supports treatment in the LWK 1 to LWK 5 care area of adults. With your MKS® Extensa you should achieve a lifestyle that is as independent as possible, which corresponds to your personal needs and performance.



LWK 1 to LWK 5

1.5. Scope of supply

The MKS® Extensa will be delivered to you in the ordered size with instructions for use and labelling on the product ready for use.

1.6. Declaration of conformity

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

1.7. Features

- Adjustable, stable aluminium profiles
- Padded plastic pads
- Individual strap routing
- Compression pads above the pelvic crests
- Easy to attach and place with clip closure

1.8. Indications

The doctor decides on the treatment based on his diagnosis. In general, the MKS®Extensa is suitable to treat all indications in which partial relief by correction of the LWS/BWS is necessary, such as:

- stable vertebral fracture
- post-operative stabilisation
- osteoporosis

For all other indications, the doctor must be consulted.

1.9. Contra-indications

The orthosis is only intended for contact with intact skin

1.10. Safety instructions

The optimal effect of the orthosis is only achieved with correct application.

- The orthosis may only be used if it is intact, complete, in mechanically perfect condition as well as having complete and undamaged pads and straps. This must be checked by the user before each application.
- Leaving undone or removing one or more straps, as well as excessively loosening the strap while using the orthosis, will reduce the therapeutic effect of the orthosis and may cause injury.
- The orthosis must not be worn on open wounds.
- The skin should be free of oils, fats, gels or other residues to avoid skin or material structure reactions.
- The orthosis should be tight, but not too tight, in order not to restrict blood circulation and to prevent damage to the nervous system and lymphatic vessels. Excessive compression should therefore be avoided.
- Combination with other products is currently not planned or should be agreed with the manufacturer in writing.
- The orthosis is not intended for single use, but for multiple use by only one person.
- The product is not supplied sterile.
- If you experience an allergic reaction, contact your doctor immediately.
- Keep in mind that parts of the pads that are exposed to direct sunlight may heat up. If necessary, protect the orthosis from direct sunlight.

- Currently, there is no flammability test. Use caution when handling open flames such as lighters and cigarettes in the immediate vicinity of the orthosis.

1.11. Warranty

We guarantee the orthosis for the application period of 3 months. The orthosis is a medical rehabilitation device and must not be used for any purpose other than that described in the Instructions for Use. Changes to the orthosis or other applications require the written consent of albrecht GmbH. If this is not obtained, the manufacturer cannot provide any guarantee. If individual joints or assemblies are used, they must be used in accordance with their intended purpose. The manufacturer can no longer assume any guarantee for changes or modifications (e.g. additional mounting holes) of the individual parts or components. The removal of or damage to the quality management seal will invalidate the warranty.

1.12. Disclosure

The orthosis is not intended for single use, but for multiple use by only one person. We advise against passing the brace on. If, however, this is desired, please observe the care and cleaning instructions before passing on and have the brace checked for safe and perfect operation by an authorised specialist dealer.

1.13. Disposal

The brace contains recyclable materials without toxic or other harmful materials and substances. Provided it is not contaminated with infectious germs, it can be disposed of normally. To be sure, consult your orthopaedic specialist.

1.14. Adjustment / assembly

The height of the front and rear parts is determined by the length of the aluminium rods and the positioning of the individual plastic modules. If the size was determined using our table, the total height can be adjusted precisely by moving the individual pads. The anatomically preformed aluminium rod of the front part can be shaped individually according to the patient and indication. Once this has been done, the actual installation of the MKS® Extensa begins.

Front: Once the overall height is adjusted by moving the sternal and symphic pads, the abdominal plate is positioned. Once all modules are in the correct position, they are fixed with the screws provided.

Back: The circumference can now be adjusted on the back plate. If the adjustment range of the Velcro straps is not sufficient, the straps can be moved to another position by wrapping them around.

If, despite our wide range of adjustment, an optimal adjustment is not possible, all aluminium and plastic parts can be shortened or reworked in other ways. It is also possible to drill additional holes for the screw connection.

A combination with other products is currently not planned. It must be agreed in writing with the manufacturer.

Due to the individual adjustment, the use of the orthosis is only possible for the patient concerned.

1.15. Putting it on

In particular, it is necessary to learn how to use the MKS® Extensa when ordering new supplies It is necessary to practice putting the brace on and taking it off.

The MKS® Extensa can be worn directly on the skin or on a fold-free, tight-fitting vest. The wearing of an absorbent vest is recommended to avoid moisture from excessive sweating.

To tighten the MKS® Extensa proceed as described in the tightening instructions. They thus ensure reliable effectiveness. Always make sure that the MKS® Extensa is firmly seated. However, it must not be tightened so tightly that the edges become entangled!

If the patient is in an acute phase, apply the corset only when doctor or therapist is present. The corset is put on when lying down. Ideally, the patient should wear a T-shirt or a tight-fitting vest under the corset.

The patient should be placed in a stable position on his/her side. The parts to be pushed under the patient can be coated with a sliding foil. This makes it easier to push them through. Make sure that the entire back panel is positioned correctly. The beads applied to the pelvic/closure element must lie exactly in the waist to ensure that the height is correct and the corset fits well. Then put the patient in a supine position, balance again and attach the front part.

Get up as directed by your doctor or therapist!

Hand wash 30°C.

Do not bleach

Do not iron

Do not dry clean

Not suitable for dryer

2. Cleaning, servicing and disinfecting

The orthosis is designed to be maintenance-free. To ensure proper functioning during the treatment period, the orthosis should be cleaned regularly (at least every 3 months) or, if necessary, according to the following instructions.

2.1. Care

- The product is not supplied sterile and is not suitable for sterilization.
- Do not use harsh or abrasive cleaning agents.
- All materials can be hand washed at 30°C with water and a mild detergent and / or disinfectant.
- Do not wash in a machine.
- The MKS® Extensa can be air-dried.
- A replacement set of textile parts is available for heavy soiling.
- Wipe surfaces with a cloth soaked in disinfectant.
- Wet completely, do not wipe. Spray inaccessible surfaces.
- When spraying, make sure that it is completely wet.
- A mild disinfectant based on alcohol is recommended.

When selecting the disinfectant, ask your doctor or pharmacist and follow the instructions of the disinfectant manufacturer. The Robert Koch list of approved disinfectants can be found at http://www.rki.de.

3. Technical data / materials

Designation	Material
Pads	Velcro PA
Straps	Velcro PA

4. Select the size

The MKS® Extensa is available in different sizes according to the table below.

5. Size table and item part numbers overview

Size	Body circumfer-ence	Height of front part	Back height	Part number
S	70 - 125 cm	40 - 47 cm	28 cm	706C
M	70 - 125 cm	48 - 53 cm	28 cm	706A
L	70 - 125 cm	54 - 59 cm	28 cm	706B
Optional 32 cm front bar – Part No.: 221-014-S (for front height 35- 40 cm)				

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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