



Technical Data Sheet

Spinomed

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medi GmbH & Co. KG
Medicusstrasse 1
95448 Bayreuth
Germany
www.medi.de

Product Management
phone +49 921 912 -
fax +49 921 912 -

1 Product description

Spinomed is a brace designed to actively relieve load and correct the lumbar spine/ thoracic spine in the sagittal plane.

Presentations

USA version: (basic product identical to global version comes with back panel and textile covers; frontal panel and cover are optional spare parts due to reimbursement in the US)

Var. 008: French version comes with additional item no. 56S9309 „Sangle d'appui“ („extra chest belt“); item no 56S9319 “Sous-cuisses élastiques” (=elastic bottom belts) and E014044 IFU bottom belt

Var. 005: direct sale in Italy

Indications:

All indications requiring a relief and/or correction of the lumbar/thoracic spine as well as movement restriction in sagittal plane, such as: • Osteoporotic collapse of thoracic and/or lumbar vertebrae • Juvenile Scheuermann's disease • Kyphosis with chronic back pain

Contraindications: None known to date

Risks / Side Effects

If the aids are too tight, this can cause local pressure sores or constriction of blood vessels or nerves. Therefore you should consult the doctor treating you before you use it if the following circumstances apply to you:

- Condition or injury of the skin in the area of application, particularly with infectious indications (excessive heat, swelling or reddening)
- Paraesthesia and circulatory disorders (e.g. as seen in diabetes, varicose veins)
- Lymph drainage disorders – equally, swelling of soft tissue adjacent to the area of application which is not related to a condition

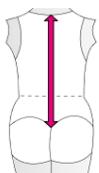
When wearing snug-fitting aids, this can result in localised skin inflammation or irritation that is due to mechanical irritation of the skin (particularly in conjunction with sweating) or due to the composition of the material.

1.1 Material composition

Aluminum, polyamide, polyester, elastane, elastomer

1.2 Presentations and Measurements

size	article number	length splint	length of back (pocket)	max. circumference of pelvis	weight
x-small	5.669.081	39 cm	40 cm	162 cm	560 g
small	5.669.082	42 cm	43 cm	166 cm	570 g
medium	5.669.083	47 cm	50 cm	196 cm	605 g
large	5.669.084	52 cm	54 cm	196 cm	650 g
x-large	5.669.085	57 cm	58 cm	196 cm	670 g
xx-large	5.669.086	62 cm	63 cm	198 cm	680 g



Rückenlänge / back length (cm)	bis / up to 42	41 – 48	47 – 54	53 – 60	59 – 66	65 – 72
Größe / size	XS	S	M	L	XL	XXL
Art.-Nr. / Art. No.	5.669.081	5.669.082	5.669.083	5.669.084	5.669.085	5.669.086

1.3 Features

- Pivot joint for optimum freedom of movement, secure fit and high wearing comfort
- Belt system for straightening and pain relief in accordance with therapeutic needs
- Effortless donning and doffing thanks to preformed shoulder straps
- External hand fastener and grips on both sides make it easy and effortless to put on
- Back padding with inset holes and ventilation channels for optimal thermoregulation is noticeably soft and comfortable to wear

- Tool free adjustment of the aluminium back splint
- Effectiveness has been proved by clinical studies

2 Safety instructions

This medical device  is made for single patient use only . If it is used for treating more than one patient, the manufacturer's product liability will become invalid. If undue pain or an unpleasant sensation develops while you are wearing the product, please consult your doctor or orthotist immediately. Do not wear the product over open wounds and use it only as instructed by your doctor or orthotist.

Note on wearing

Wear the orthosis over your clothes.

The Spinomed should only be worn for 1 to 2 hours per day in the habituation phase and in order to gradually restore the muscle activity. The length of time that the brace is worn can be increased in stages over the course of the therapy. The brace should be taken off during longer periods of sitting or lying down. If required, the brace must be realigned by your orthopaedic technician. Your acceptance and cooperation play an important role in this form of therapy. Therefore, should any issues occur, please discuss them with your doctor or therapeutic technician. They may be able to make any potentially required changes to your Spinomed brace. To ensure that this therapy is successful, you must follow your doctor's instructions at all times.

3 Storing conditions

Keep the product in a dry place and do not expose to direct sunlight.



4 Chemical substances

Contact with chemicals (e. g. benzole, methanol, salicylic acid in high concentrations) may have adverse actions on the effect of the product. Do not apply ointments or oils before putting on the product.

5 Care instructions

The straps, shoulder pad and the large hook-and-loop fastening can be washed by hand in water with a mild detergent. The back support and pads can be cleaned using a moistened cloth. Hook and loop fasteners should be closed for washing. Soap residues, lotions and ointments can cause skin irritation and material wear.

- Wash the product by hand, preferably using medi clean washing agent.
- Do not bleach.
- Leave to dry naturally.
- Do not iron.
- Do not dry clean.

6 Packaging/Labeling

Product will be sent out in folded box.

Label on the back brace: product name, size, care symbols, CE, medi GmbH & Co. KG, Medicusstr. 1, 95448 Bayreuth, Germany, LOT number (xxxx xx /year month)
back splint marked with size and serial number
Fitting instructions included.

Label on the box: Spinomed, Back orthosis for osteoporosis, size LOT, Ref., CE, EAN, UDI-Code, MD, medi GmbH & Co. KG, Medicusstr. 1, 95448 Bayreuth, Germany

7 Disposal

The product can be disposed of in the domestic waste.

