

OSTEO TLS FIX

Thoraco lumbo sacral orthosis for osteoporosis

Ref. SRT 139

INSTRUCTIONS FOR USE

Dear Customer!

Thank you for the confidence you have shown in purchasing Triamed products! We would like to inform you that Triamed products are made of the best performing materials, all having quality certificates and biocompatibility tests. These orthoses comply with the Technical Specification and the requirements of Regulation (EU) MDR 2017/745 of the European Parliament on medical devices and comply with the requirements set out in Annex I - General Requirements for safety and performance- and Annex VIII - Classification rules. Conformity is declared on the basis of Article 52 (7), Annex II and Annex III of MDR 2017/745.

Important information

The orthosis is used according to the recommendations of the specialized physician.

Choosing the size - For optimal results, the appropriate size will be selected based on the measurements table of the product. A size too small may lead to intolerance to wearing or the damage of the product! A size too large significantly diminishes the efficacy of the orthosis.

This orthosis should only be applied in accordance with the instructions mentioned here. The product is intended for single patient use.

No liability is accepted for incorrect product use. Guarantee is bound to statutory regulations.

Available sizes

Sizes	1	2	3	4	5	6
Waist circumference (cm)	65-75	75-85	85-95	95-105	105-115	115-125
Height of orthosis on the back (cm)	49-58	49-58	49-58	49-58	49-58	49-58
Reference	SRT139M1	SRT139M2	SRT139M3	SRT139M4	SRT139M5	SRT139M6

The circumference of the waist is measured

Indications

It is used in case of intervertebral disc herniation, back pain, postoperative, osteoporosis, for stabilization of the thoracolumbosacral spine in chronic conditions.

The hyperextension of the spine can be achieved by modeling the metal ensemble.

Description

It is made of rigid fabric, provided with:

- one metal ensemble, made of 2 S-FORM metal splints, with adjustable length between 45-55 cm, on the rear component, to support the thoracolumbosacral area.

The length is adjusted with the help of 4 Inbus type screws. Inbus key is included.

- 2 plastic splints on the front component, to support the abdominal area

- 2 straps which surround the shoulders and the chest, achieving a good upright posture by traction. The straps have one elastic and one rigid component, positioned over the head of the humerus and are adjustable by cutting. They are inserted in 2 buckles and brought back to the front, on the abdomen. Those 2 buckles are fixed on a movable support, provided with hook and loop fastener. They can be fixed on the entire length of the column, as needed. The lower it is positioned, the lower the pressure in the subaxillary area.

The 2 bands are adjustable. To shorten the straps, remove the "crocodile" type fastening from the edges, cut the bands to the optimal length and reposition the "crocodile" type fastening. Hook and loop fastener on the front side.

Width: front 16 cm, back height between 49 – 58 cm, for each size.

For an easy application it is provided with helping strips.

The metal ensemble and the 2 plastic splints stabilize the thoracolumbosacral region, slightly reducing lordosis and kyphosis.

Purpose

The orthosis stabilizes the thoracolumbosacral region, slightly reducing lordosis and kyphosis.

Composition

Laminated textile. The laminated textile ensemble behaves like a moisture regulator, ensuring a quick transfer of the moisture to outward.

Elastic fabric with a structure that allows high air permeability in both directions.

The rigid fabric with a structure that allows high air permeability in both directions.

Positioning

The lumbar support is applied from the back to front, the wider part is fixed on the lumbar region, the narrow part is closed in the front, on the abdomen. The 2 long straps surround the shoulders, they are inserted at the back in the 2 buckles, bring back to the chest and cut to the desired length. The "crocodile" type fastening is repositioned on each strip and closed on the front. If necessary, the length of the metal assembly is adjusted using 4 Inbus screws. The Hex key is included in the product box. The lumbar part is perfectly stretched, without creases, at a correct application.

If it is necessary to adjust the position of the orthosis, the adjustment is made by fully opening the hook and loop fastener and repositioning the orthosis higher or lower on the body segment, depending on the need. **To avoid the damage of the material, do not pull the orthosis while is fixed.**



Cleaning

To be washed by hand with warm water, no bleaching, no spinning, no ironing, no chemical cleaning!

Storage

At room temperature, in a dry space with good ventilation.

Commercial warranty of the product: 30 days.

Date of production: see packaging label.

Validity date: no expiry date.

To validate the warranty, the seller must indicate the date of purchase. The buyer is obliged to keep and present the warranty coupon.

In order to solve the problems that appeared in the warranty, the following data must be notified: Article reference, batch and date of manufacture, indicated on the packaging box of the product.

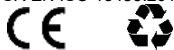
Deadline for communication of the solution: 15 days.

Please send notifications and complaints to the following email address: supportclienti@triamed.ro

WARRANTY COUPON 30 days from the date of purchase	Batch and date of manufacture
Product reference	Date of purchase
The reason of complaint	Seller name and signature

SR EN ISO 9001:2015

SR EN ISO 13485:2016



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