

TLS FIX

Thoraco lumbo sacral orthosis

Ref. SRT 138

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)	48	49	50	51	52	53
Reference	SRT138M1	SRT138M2	SRT138M3	SRT138M4	SRT138M5	SRT138M6

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.

Description

It is made of elastic fabric, provided with:

- 2 lateral plastic splints located on the posterior component, to support the lumbar area
- 2 S-FORM metal, paravertebral splints located on the posterior component, to support the thoracolumbosacral area
- 2 plastic splints located on the anterior component, to support the abdominal area
- 2 elastic bands of 5 cm, around the waist, providing stability and compression. The elastic straps continue on the front with rigid strips.
- 2 straps that surround the shoulders and are fixed on the chest. The straps are provided with sleeves for armpit protection.

Hook and loop fastener on the front side.

Width: front 16 cm, back height between 48 – 53 cm, depending on size.

For an easy application it is provided with helping strips.

The 4 metal splints and the 2 plastic splints stabilize the thoracolumbar region, slightly reducing lordosis and kyphosis, and the compression exerted by the elastic bands stimulates local metabolism, reducing muscle tension and pain. The 2 elastic bands that surround the shoulders and are fixed on the chest, correct by traction the position of the torso.

Purpose

The orthosis stabilizes the thoracolumbosacral region, slightly reducing lordosis and kyphosis, the compression exerted by the elastic bands stimulates local metabolism, reducing muscle tension and pain.

Composition

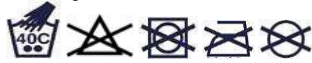
Elastic fabric with a structure that allows high air permeability in both directions.

Positioning

The orthosis is placed from 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 bands are passed around the shoulders, crossed at the back and are fixed in the front, on the orthosis. 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 it 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.

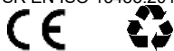
In order to solve the problems that appeared in the warranty, the following data must be notified: Article reference, batch and date of manufacture, indicated on the packaging box of the product.

Deadline for communication of the solution: 15 days.

Please send notifications and complaints to the following email address: suportclienti@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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