

MALLEOFIX PLUS

Mobile ankle orthosis with elastic strap

Ref. SRT 312

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
Ankle circumference (cm)	20-22	22-24	24-26	26-28	28-30
Reference	SRT312M1	SRT312M2	SRT312M3	SRT312M4	SRT312M5

The circumference of the ankle is measured around the malleolus

The orthosis can be used on both the left and the right ankle.

Indications

It is used in cricks, luxations, ankle articulation instability.

Description

Orthosis made of textile, provided with:

- 2 side pads that frame the malleolus (polyethylene foam)
- 2 elastic straps crossed around the ankle for compression and fastening.

The heel area is open.

Hook and loop fastener on the front side.

Height: 21 cm.

Purpose

The orthosis is an ankle support, and the two elastic straps around the ankle exert additional compression, ensuring stability while wearing.

Composition

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

Positioning

The orthosis is placed on the foot and fastened in the front; the crossed straps are closed on the back side to the optimal compression.

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: 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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