

## HALLUFIX

Hallux valgus orthosis

Ref. SRT 301

### 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

Universal size, left and right versions, for forefoot with circumference between 20 - 29 cm.

#### Indications

It is used for the correction of hallux valgus and post surgery. To be worn during night.

#### Description

Orthosis with anatomical design, made of textile, provided with a mouldable metal splint designed to physiologically correct the position of the hallux.

Hook and loop fastener.

#### Purpose

The orthosis prevents deformation of the hallux in the early phase of Hallux Valgus, fixes and prevents deviation of the hallux after surgery

#### 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 so that the metal splint is parallel with the hallux and gives lateral support. It is fixed with the hook and loop straps 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.

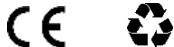
**Deadline for communication of the solution: 15 days.**

Please send notifications and complaints to the following email address: [suportclienti@triamed.ro](mailto:suportclienti@triamed.ro)

<b>WARRANTY COUPON</b> 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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