

## 深圳简单医疗科技有限公司

### 产品说明书

#### 踝部固定器

产品型号：62007 产品规格：S, M, L



感谢您购买本公司产品！请在操作前仔细阅读本使用说明书！以充分了解本产品，以保证本产品的安全性及有效性，并请妥当保存说明书以备将来查阅。

#### 一. 产品概述

1.1 产品名称：踝部固定器

1.2 产品型号：62007

1.3 产品规格：S, M, L

1.4 产品结构：

由尼龙、氨纶纤维、聚丙烯等材料制成。穿戴于肢体体表，通过限制肢体活动，达到保持肢体稳定的目的。不具备矫形功能。无源产品。

1.5 工作原理

产品采用轻量化的设计，使用方便，佩戴舒适。所述产品采用自压式双气囊联动设计，按摩式压缩，有两处设有支撑器，大身采用透气柔软的面料来提高患者的佩戴舒适度。帮助缓解患者的疼痛。

1.6 预期用途

用于对人体踝部部位的外固定或支撑。

1.7 适用范围

用于跟腱炎，急性和慢性足底筋膜疼痛，脚后跟刺痛，脚跟骨刺和发炎患者的辅助治疗。

#### 二. 产品特点及性能描述

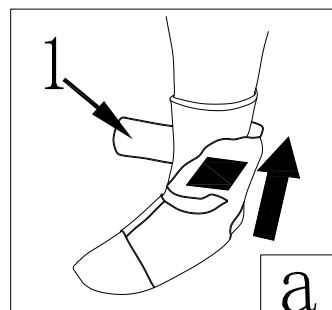
2.1 产品特点及贮存条件

【产品特点】产品简单，采用自压式双气囊联动设计，佩戴舒适且透气。

【贮存条件】本产品应贮存在相对湿度不大于 80%、无腐蚀性气体和通风良好的室内，避免高温。

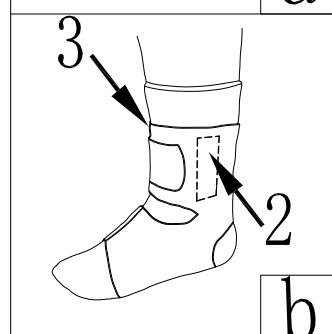
2.2 使用操作

#### 【使用方法】

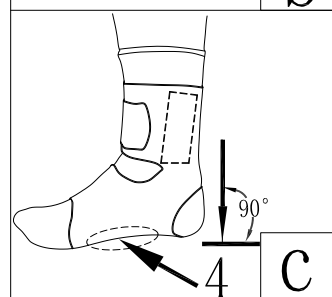


**使用说明**  
注意：1：穿戴踝关节固定器前请先穿好袜子！！

步骤 1：解开绑带 #1，绑带朝上将脚放入固定器里面（图 a）



步骤 2：调整固定器的踝气囊 #2 和 #3，使得踝气囊位于踝的内侧和外侧（图 b）。



步骤 3：脚直立于地板上，调整足弓气囊 4，使其位于足弓底下，再系上绑带#1（图 c）。

注意 2：绑带不要过紧，请根据需要调整绑带长度

#### 保养与维护

产品可以用中性洗涤剂和 30℃ 水手洗，并自然风干。切勿放入干衣机或使用其他热源进行干燥。盐水、沙子、污垢等元素会造成伤害。暴露于这些条件后，用清水彻底冲洗，毛巾擦干或风干（不要机器干燥）。如需洗涤剂请使用温和洗涤剂，切勿使用柔软剂和漂白剂。

#### 警告：

如果您使用此产品时感到疼痛，肿胀，过敏，或有不适的反应，请停止使用并咨询医生。

\*此产品仅为支撑装置，不用于预防伤害或者防止再次发生伤害

2.3 产品基本环境

1) 环境温度：-15~60℃

2) 相对湿度：≤80%

2.4 产品材料

1) 大身材料：氨纶纤维

2) 支撑器：聚丙烯

3) 气囊：TPU

4) 绑带：尼龙

2.5 禁忌症

⚠ 出现过敏者请勿用；

⚠ 皮肤出现不明肿块者禁用；

⚠ 皮肤肿破溃疡者禁用；

#### 三. 产品的保管，运输及有效期

3.1 产品有效期：5 年。

3.2 产品的保管：

未使用前请放置在干燥、清洁的室内，保证室内通风。

3.3 运输：本产品储存及运输的过程，应防尘、防潮、防污染。

#### 四. 废弃物处理

包装纸（包装袋）的处理：本产品的包装请根据所属地区法例进行弃置处理，对垃圾进行分类。

#### 五. 标记符号及图片说明

⚠ 注意，警告

🚫 禁止机洗

☀ 避免日晒

🚫 包装破损时切勿使用

🕒 有效期为 5 年

📖 参考使用说明

#### 六. 配件清单

说明书----- 1 份

#### 七. 售后承诺

产品出现材料或工艺方面的缺陷，请直接联系你的销售商，深圳简单医疗科技有限公司将对产品进行维修或更换。

#### 八. 厂家信息

【产品名称】踝部固定器

【医疗器械备案凭证编号】

粤深械备 20180572 号

【生产备案凭证编号】

粤莞食药监械生产备 20200057 号

【产品技术要求编号】

粤深械备 20180572 号

【备案人】深圳简单医疗科技有限公司

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【邮政编码】518131

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【邮政编码】523696

【电话】0769-82522823

【售后服务单位】深圳简单医疗科技有限公司

【说明书修订日期】2024 年 04 月 22 号

【网址】www.simplemedical.cn

**Instruction For Use**

SIMPLE Air Heel A1

Model: 62007 Size: S, M, L



Thank you for purchasing our products! Please read this instruction carefully before operation! To fully understand the product, in order to ensure the safety and effectiveness of the product, and please properly save the manual for future reference

**Product overview**

- 1)Product name: SIMPLE Air Heel A1
- 2)Product model: 62007
- 3)Product specification: S, M, L
- 4)Product Structure:

The product is mainly composed of breathable soft material, air bag, plastic parts, strap and so on

5)Operating principle

The product adopts lightweight design, easy to use and comfortable to wear. The product adopts self — pressing double airbag linkage design, massage compression, has two supporting devices, and adopts breathable and soft fabric to improve the wearing comfort of the patient. To help relieve the pain of the patient.

6)Scope of application

It is used in patients with Achilles tendonitis, Acute and chronic Plantar fasciitis pain, Heel pain caused by spurs and Heel spurs.

**Product features and performance description**

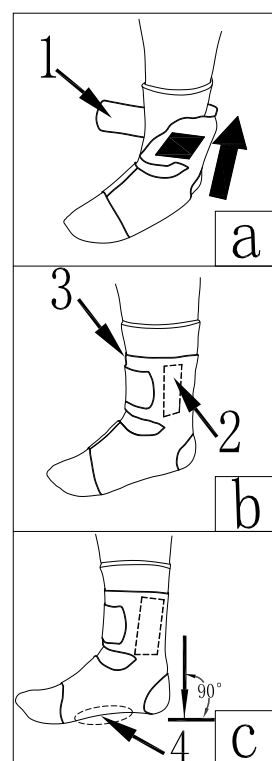
1) Product features and storage conditions

**【Product features】** The product is simple, and the self-pressure type double-air bag linkage design is adopted, and is comfortable and air-permeable.

**【Storage conditions】** This product should be stored in a room with no more than 80% relative humidity, no corrosive gas and good ventilation to avoid high temperature

2)Using the operating

**【Application Instructions】**



**Note1: please put on socks before wearing Ankle Brace.**

**STEP 1:**Loosen the strap#1, put the foot into the holder facing the bandage ( Fig a)

**STEP 2:**Adjust the airbag #2 and #3 of the retainer so that the airbag is located medial and lateral to the ankle ( Fig b)

**STEP 3:** Stand your feet on the floor, adjust the arch air bag 4 so that it is under the arch, and then tie the strap#1 (Fig c).

**Note 2: the straps should not be too tight. Please adjust the length of the strap as needed**

**Maintenance:**

Lining can use neutral detergent and 30 °C water washed by hand, and natural dry. Do not use clothes dryer or other heat source for drying. Salt water, sand, dirt and other elements can cause damage. After exposure to these conditions, rinse thoroughly with water, dry with a towel or air dry (do not machine dry).If you need detergent, please use mild detergent, do not use softener and bleach.

**Warning:**

If you experience pain, swelling, irritation, or discomfort while using this product, discontinue use and consult your doctor.

\*This product is for support only and is not intended to prevent injury or to prevent the recurrence of injuries.

**Basic product environment**

- 1) Ambient temperature: -15 ~ 60 °C
- 2) Relative humidity: 80%

**Product material**

- 1) Body material: Spandex fiber
- 2) Support sheet: Polypropylene
- 3) Balloon: TPU
- 4) Strap: nylon

**Contraindication**

- ⚠ Do not use in case of allergy;
- ⚠ Those with unknown skin masses are forbidden.
- ⚠ Those with swollen or ulcerated skin are forbidden

**Storage, transportation and expiry date of products**

- 1)Product is valid: five years
- 2 )Product storage: Please place it in a dry and clean room before use to ensure ventilation
- 3) Transportation: the product shall be dust-proof, moisture-proof and pollution-proof during storage and transportation.

**Disposal of wastes**

Disposal of wrapping paper (bags) : please dispose of the packaging of this product according to the local laws.

**Symbol and picture description**

- Manufacture Date
- Batch Code
- medical device
- CE Symbol
- Hand wash only

- Protect from sunlight
- Do not use when the packing is damaged
- Warnings and Precautions
- It is valid for five years
- Reference instructions

**Accessories list**

Instructions ----- 1 copy

**After-sales warranty**

If there is any defect in the material or process of the product, please contact your vendor directly, and the Simple medical will repair or replace the product.

**Simple Medical (Shenzhen) Limited**  
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SUNGO Europe B.V.

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**\*Please refer to the Instructions before usage**

62007 V0.2