

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：62005 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此使用说明书！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：62005

1.3 产品规格：S/M/L

1.4 产品结构：

产品主要由透气舒适的大身，绑带，伸缩带等组成。

1.5 工作原理

产品采用轻量化的设计，使用方便，佩戴舒适且固定性好。所述产品采用“8”字形固定带和鞋带式绑带，能有效固定受伤的踝关节和预防运动中的拉伤。大身采用透气柔软的面料来提高患者的佩戴舒适度。

1.6 适用范围

适用于轻微至中度踝关节扭伤、慢性踝关节不稳定、踝关节运动损伤的防护和治疗。

二. 产品特点及性能描述

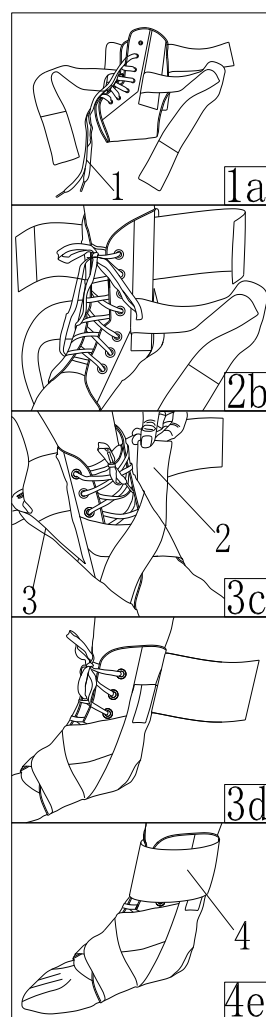
2.1 产品特点及贮存条件

【产品特点】产品简单，透气、轻便、系带设计，8字型绑带固定、右脚和左脚通用。

【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

步骤 1：打开产品并将绑带 #1 穿好（图 1a）。

步骤 2：把脚放进产品，调整好绑带#1 的松紧度再绑紧（图 2b）。

步骤 3：绑带#2-#3 交叉缠绕住脚踝并牢牢的固定住（图 3c~3d）。

步骤 4：调整好所有绑带的松紧度，确保穿戴时的舒适感再将两边的绑带#4 往前面靠拢并固定住。（图 4e）

注意：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：

如果您在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) 绑带：尼龙/伸缩带

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：3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 在储存及运输的过程，应防尘、防潮、防污染。

四. 废弃物处理

包装纸（包装袋）的处理：本产品的包装请跟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 3 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，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】

粤深食药监械生产备 20170002 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

【生产企业】深圳简单医疗科技有限公司

【地址】深圳市龙华区民治街道新牛社区布龙路 1010 号智慧谷创新园 519

【电话】0755-86038563

【传真】0755-86038509

【邮政编码】518109

【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】2020 年 07 月 02 号

【网址】www.simplemedical.cn



Simple Medical (Shenzhen) Limited

Instruction For Use

Lace-up Ankle Brace A2

Model: 62005 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: Lace-up Ankle Brace A2
- 2)Product model: 62005
- 3)Product specification: S/M/L
- 4)Product Structure:

The product is mainly composed of breathable and comfortable body, straps, telescopic belt and so on.

5)Operating principle:

The product adopts lightweight design, easy to use, comfortable to wear and good fixation. The product uses ``8" shaped fixing belt and shoe strap, which can effectively fix the injured ankle joint and prevent sports injury. Large body is made of soft, breathable fabric to improve patient's comfort. .

6)Scope of application:

Suitable for Mild to moderate ankle distortion, Chronic ankle instability, Prophylactic and therapeutic use in sport activities.

Product features and performance description

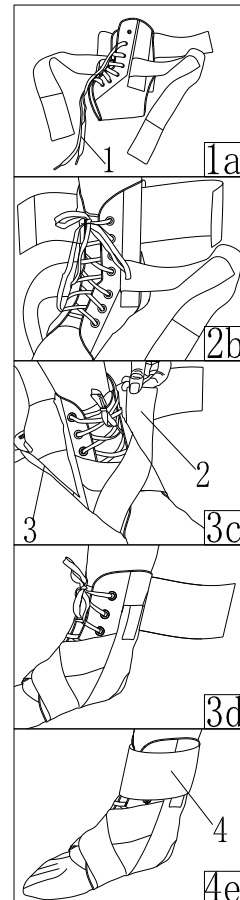
1) Product features and storage conditions

【Product features】 The product is Mesh fabric, great ventilation, Better fitting, supportive, light weight, Lace-up design, custom fastening, Fits right and left foot.

【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】



APPLICATION INSTRUCTIONS.

STEP 1: open the product and wear the shoelace # 1 (Fig 1a).

STEP 2: put your feet into the product, adjust the tightness of the straps and tie the straps # 1 (Fig 2b).

STEP 3: straps # 2 / 3 cross around the ankle and fasten firmly (Fig 3c~3d).

STEP 4: adjust the tightness of all straps to ensure that the comfort of wearing brings the straps on both sides closer to the front and fastens them. (Fig 4e)

NOTICE: the straps should not be too tight. Please adjust the length of the strap 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: plastic
- 3) Straps: 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: Three years.
- 2) Product storage: Please place it in a dry and clean room before use to ensure ventilation.
- 3) Transportation: the product shall be dustproof, 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

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
Address: 519 Wisdom Valley, No.1010 Bulong Road,

Minzhi Street,Longhua District, Shenzhen, China.518109

Tel : +86-755-86038563

Web: www.simplemedical.cn

E-mail: info@simplemedicla.cn`

SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

*Please refer to the Instructions before usage