

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：62034 产品规格：XS, 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：62034

1.3 产品规格：XS, S, M, L

1.4 产品结构：

由尼龙、海绵、塑胶等材料制成。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，佩戴舒适且固定性好。所述产品采用快速调节系统和“8”字形固定带，两侧具有支撑器，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 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

适用于轻微至中度踝关节扭伤、慢性踝关节不稳定、踝关节运动损伤的辅助防护和辅助治疗。

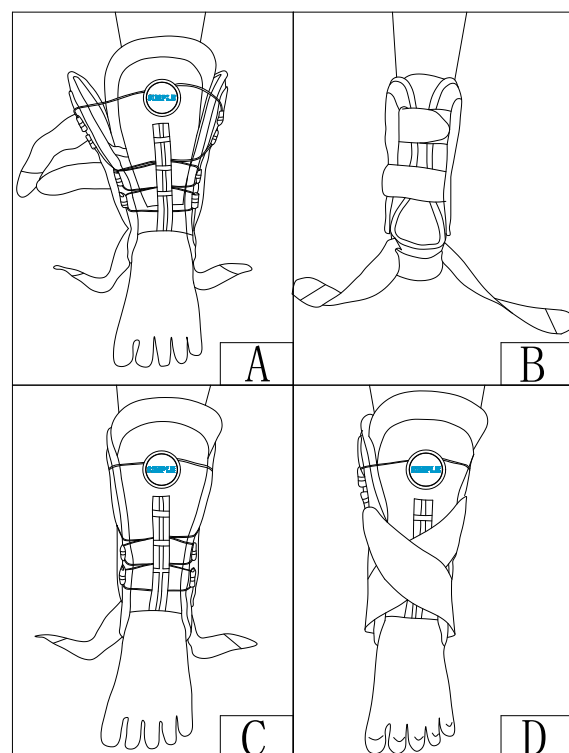
二. 产品特点及性能描述

2.1 产品特点及贮存条件

【产品特点】产品具有快速调节系统，透气轻便，穿脱简捷舒适，稳固支撑，加强踝部固定，左右脚通用。

【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】

步骤1：打开产品并将松紧带和绑带打开，把脚放进踝部固定器（图A）。

步骤2：调节背面绑带松紧，直至舒适（图B）。

步骤3：根据舒适度和支撑效果来调节旋转旋钮，并调节内里衬垫直至舒适（图C）。

步骤4：交叉系紧松紧带，并将魔术贴接头粘在踝托的两侧（图D）。

注意：若要松脱可拨开旋钮并将两侧细绳拉松，若要紧固按下旋钮顺时针旋转即为紧固。

警告：穿戴松紧度切勿过紧，可能导致穿戴不舒适或血液不通畅，请根据需要调整松紧度。

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：涤纶+锦纶+尼龙

2) 伸缩带：氨纶+尼龙

3) 快速调节系统：塑胶+尼龙

4) 支撑器：合成橡胶

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；

⚠ 驾驶车辆时禁用；

⚠ 医学成像系统中禁用；

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：本产品存储及运输的过程，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

📅 制造日期

六. 配件清单

说明书----- 1份

七. 尺码表

型号	62034	
尺码	XS, S, M, L	
	尺码	测量方法
XS	160-190mm	
S	190-220mm	
M	220-260mm	
L	260-300mm	

八. 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。

九. 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

【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】518131

【受托生产企业】东莞简单智造有限公司

【地址】广东省东莞市凤岗镇米亚路1号

【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

Simple Medical (Shenzhen) Limited

Instruction For Use

SIMPLE Lace-up Ankle Brace A13

Model: 62034 Size: XS, 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 Lace-up Ankle Brace A13
- 2)Product model: 62034
- 3)Product specification: XS, S, M, L
- 4)Product Structure:

The product mainly consists of breathable and comfortable soft body, support device, telescopic belt, and fast adjustment system and so on

5)Operating principle:

The product adopts lightweight design, easy to use, comfortable to wear and good fixation. The product uses a fast adjustment system and an "8" fixation band with supports on both sides to effectively fix the injured ankle joint and prevent strain during exercise. The Soft body uses breathable and soft fabric to improve patient wearing comfort.

6) Scope of application:

Ankle immobilisation. Moderate to severe ankle sprain. Joint laxity/chronic instability prevention during sport activities resumption. Sport activities resumption. Tendinopathy treatment. Conservative treatment of Achilles tendon injuries.

Product features and performance description

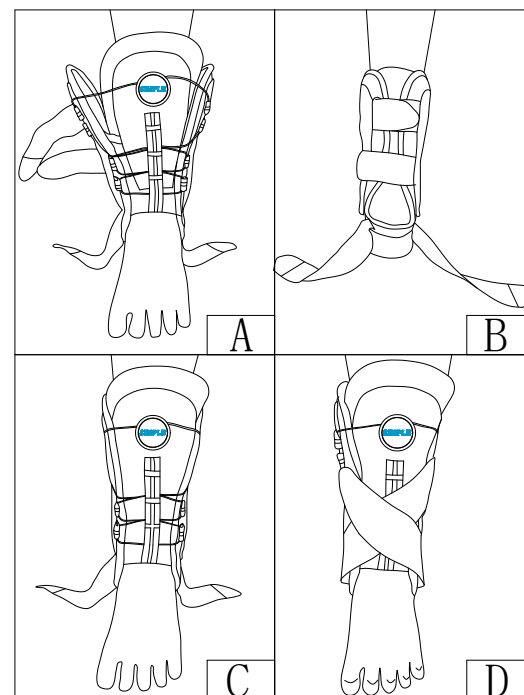
1) Product features and storage conditions

【Product features】 The product has fast adjustment system, breathable, simple and comfortable, stable support, strengthen ankle fixation,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】



STEP 1:

Open the product and open the elastic and binding, and place your foot in the ankle retainer (Figure A).

STEP2:

Adjust back strap tightness until comfortable (Figure B).

STEP3:

Adjust the rotary knob for comfort and support, and adjust the inner liner until comfortable (Figure C).

STEP4:

Cross the elastic and attach the Velcro joints to both sides of the ankle brace (Figure D).

Note: If you want to loosen, unplug the knob and pull the string on both sides. If you want to tighten, press the knob and turn clockwise to tighten.

WARNING: 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:Polyester, nylon
- 2) expansion band: spandex + nylon
- 3) fast adjustment system: plastic + nylon
- 4) support device:TPE

Contraindication

- ⚠ Do not use in case of allergy;
- ⚠ Those with unknown skin masses are forbidden;
- ⚠ Those with swollen or ulcerated skin are forbidden;
- ⚠ Disabled while driving a vehicle;
- ⚠ Disabled in medical imaging systems;

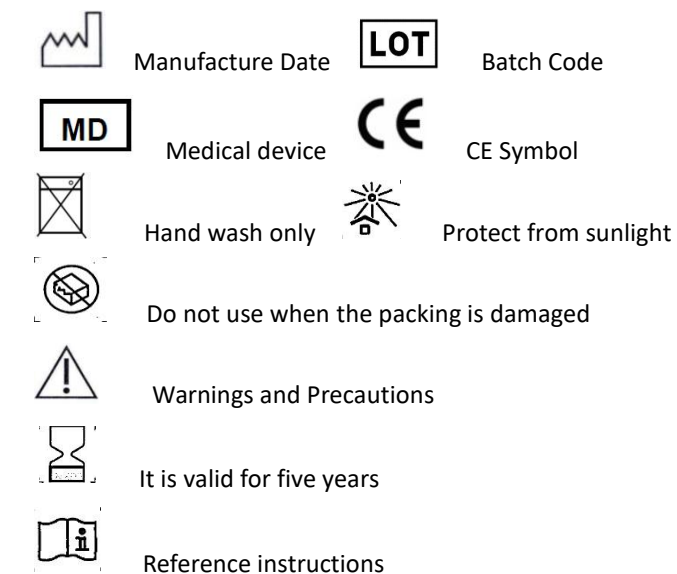
Storage, transportation and expiry date of products

- 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 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



Accessories list

Instructions ----- 1 copy

Selection

Item	REF. 62034	
Size	XS,S, M, L	
	Size	Measurement method
XS	110-130mm	
S	130-153mm	
M	153-178mm	
L	178-203mm	

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.518131
Tel : +86-755-86038563
Web: www.simplemedical.cn
E-mail: service@simplegroup.net

EC REP
SUNGO Europe B.V.

Fascinatio Boulevard 522 ,Unit1.7,2909VA Capelle aan den IJssel ,The Netherlands

Tel : +31(0)10-3034500

*Please refer to the Instructions before usage

