

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：62011&62012 产品规格：S, M, L, XL



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：62011&62012

1.3 产品规格：S, M, L, XL

1.4 产品结构：

由尼龙、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。所述产品是一种功能性的踝关节固定器，可以稳定上踝关节，并有助于防止足内翻和足外翻。符合人体解剖学形状的坚固外壳为患者提供牢固而舒适的贴合体验。预充气的可调节气囊在运动过程中发挥轻柔的按摩作用，有利于消肿和减轻患者的疼痛。特殊设计的柔性边为患者提供舒适的穿戴感。可调节的绑带便于患者的轻松使用。此产品结构纤细可在鞋子中穿戴。

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

上踝关节韧带和关节囊受伤（例如韧带断裂、劳损、扭曲），软组织轻微受伤，慢性踝关节不稳，踝关节损伤康复与预防，急性、慢性和炎性水肿的辅助治疗。

二. 产品特点及性能描述

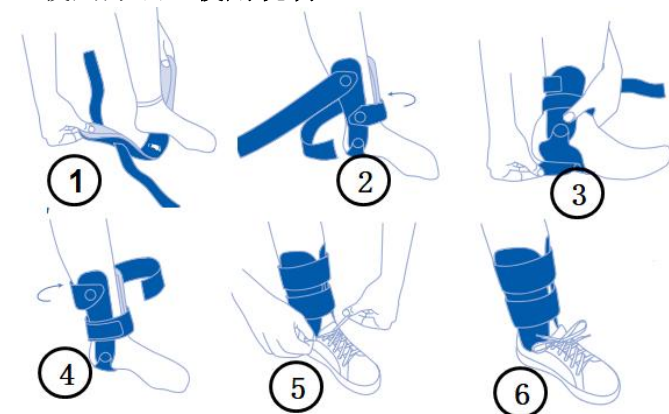
2.1 产品特点及贮存条件

【产品特点】产品使用方便且舒适，透气性好、强度高、固定性好、可清洗。

【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：为了最佳的穿着舒适度，建议穿着袜子穿戴。

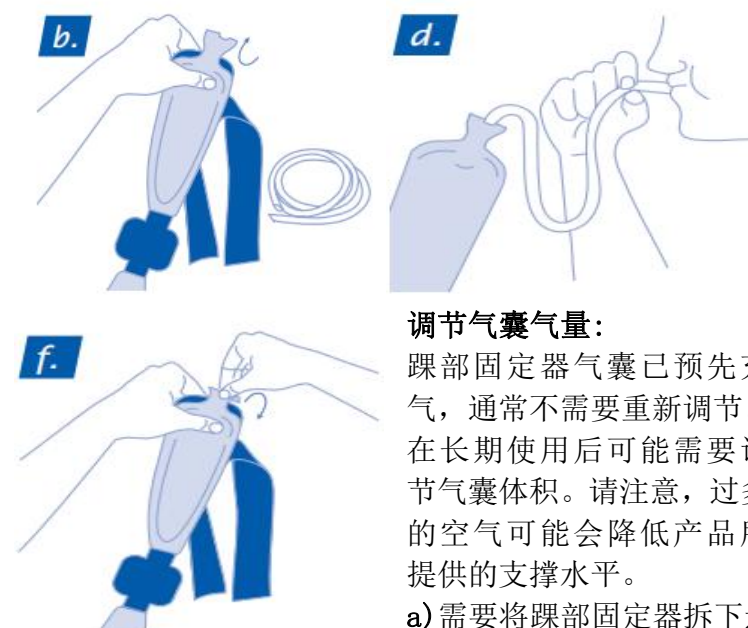
步骤 1：将脚放在两个外壳之间的足跟护带上（图 1）。

步骤 2：固定好下部的绑带（图 2）。

步骤 3：打开足跟护带并调整到舒适的宽度（图 3）。

步骤 4：将上部绑带固定住（图 4）。

步骤 5：穿上鞋在正常步态下得到最佳支撑（图 5 & 6）。



调节气囊气量：

踝部固定器气囊已预先充气，通常不需要重新调节。在长期使用后可能需要调节气囊体积。请注意，过多的空气可能会降低产品所提供的支撑水平。

a) 需要将踝部固定器拆下进行气囊调节 b) 打开踝部固定器上端的气阀 c) 将提供的管子插入气阀 d) 向管内加入少量空气，或轻轻挤压气囊排出少量空气 e) 将气阀捏扁，取下管子 f) 将气阀折回气囊和外壳之间的空间处即可。

注意，气囊的压力取决于周围的空气压力。在空气压力异常的情况下（如飞行期间），可能需要重新调节气囊。

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。

所有部件在再次使用前必须风干并完全干燥。

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。

*仅适用于单例患者。

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) 外壳：丙烯腈-苯乙烯-丁二烯共聚物+聚碳酸酯/热塑性弹性体

2) 气囊：PU

3) 铆钉：不锈钢

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。勿与酸、碱等腐蚀性物质混放，远离火源。

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

【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

Instruction For Use

SIMPLE Ankle Brace A3

Model: 62011&62012 Size: S/M, L/XL



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 Ankle Brace A3
- 2)Product model: 62011&62012
- 3)Product specification: S/M, L/XL
- 4)Product Structure:

The product is mainly composed of polymer material shell, air bag, hose, binding band, rivet, magic tape, etc.

5)Operating principle

The product adopts lightweight design, easy to use and comfortable to wear. The product is a functional ankle protector, which can stabilize the upper ankle joint and help prevent foot varus and foot valgus. A solid shell in accordance with the anatomical shape of the human body provides a solid and comfortable fitting experience for patients. The preinflated adjustable airbag plays a gentle massage role in the course of exercise, which is beneficial to detumescence and relieve the pain of the patient. Specially designed flexible edges provide patients with a comfortable sense of wearing. Adjustable straps are easy for patients to use. The structure of this product can be worn in all kinds of shoes.

6)Scope of application

- Ligament and capsule injuries at the upper ankle joint (e.g. ligament ruptures, strains, distortions)
- Slight soft tissue injuries
- Chronic ankle instability
- Rehabilitation and prevention of ankle injuries
- Acute, chronic, and inflammatory edema

Product features and performance description

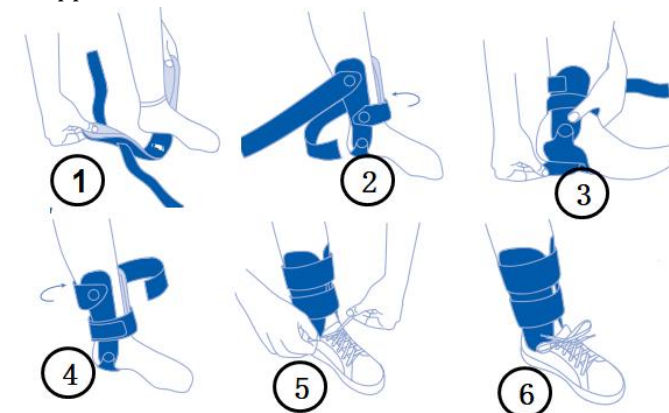
1) Product features and storage conditions

【 Product features 】 The product is convenient to use and comfortable, has good air permeability, high strength, good fixation and can be cleaned.

【 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 】



Note: for the best wearing comfort, it is recommended to wear socks and then wear protective gear.

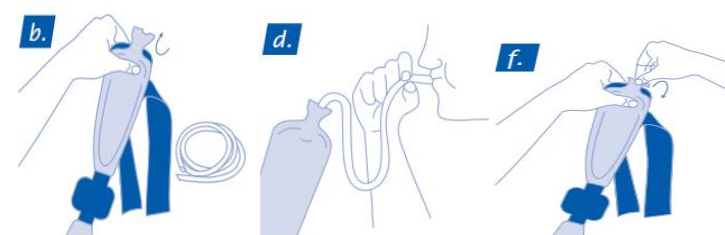
STEP 1: place the foot on the heel strap between the two shells (Fig 1)

STEP 2: fix the lower strap (Fig2).

STEP 3: open the heel strap and adjust to a comfortable width(Fig 3)

STEP 4: fix the upper strap(Fig4).

STEP 5: put on your shoes and get the best support at normal gait (Fig 5 & 6).



Adjust the air volume of the air bag:

The protective airbag has been pre-inflated and does not normally need to be reconditioned. The volume of the balloon may need to be adjusted after long-term use. Note that excessive air may reduce the level of support provided by the product.

- a) need to remove the guard for airbag adjustment
- b) open the air valve at the upper end of the guard
- c) insert the supplied pipe into the valve
- d) add a small amount of air into the tube, or gently squeeze the airbag to drain a small amount of air
- e) squash the valve, remove the pipe
- f) Fold the valve back to the space between the airbag and the housing.

Note that the pressure of the airbag depends on the air pressure around it. In the case of abnormal air pressure, such as during flight, the airbag may need to be readjusted.

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.

All parts must be air-dried and completely dry before use

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.

*For Single Patient Use Only

Basic product environment

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

Product material

- 1) Housing: ABS+PC/TPE2) Airbag: PU
- 3) Rivet: stainless steel 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 put in a dry and clean room for indoor ventilation before use. Do not mix with corrosive substances such as acid and alkali and keep away from the fire source.
- 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

- ⚠ Attention, warning
- ☒ Hand wash only
- ☀ Protect from sunlight
- ⊘ Do not use when the packing is damaged
- ⌚ It is valid for five years
- 📖 Reference instructions

Accessories list

Instructions ----- 1 copy

After-sales warranty

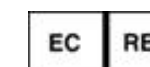
If there is any defect in the material or process of the product, please contact your vendor directly, and the Simple medical will repair or replace the product.

Simple Medical (Shenzhen) Limited

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



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.

