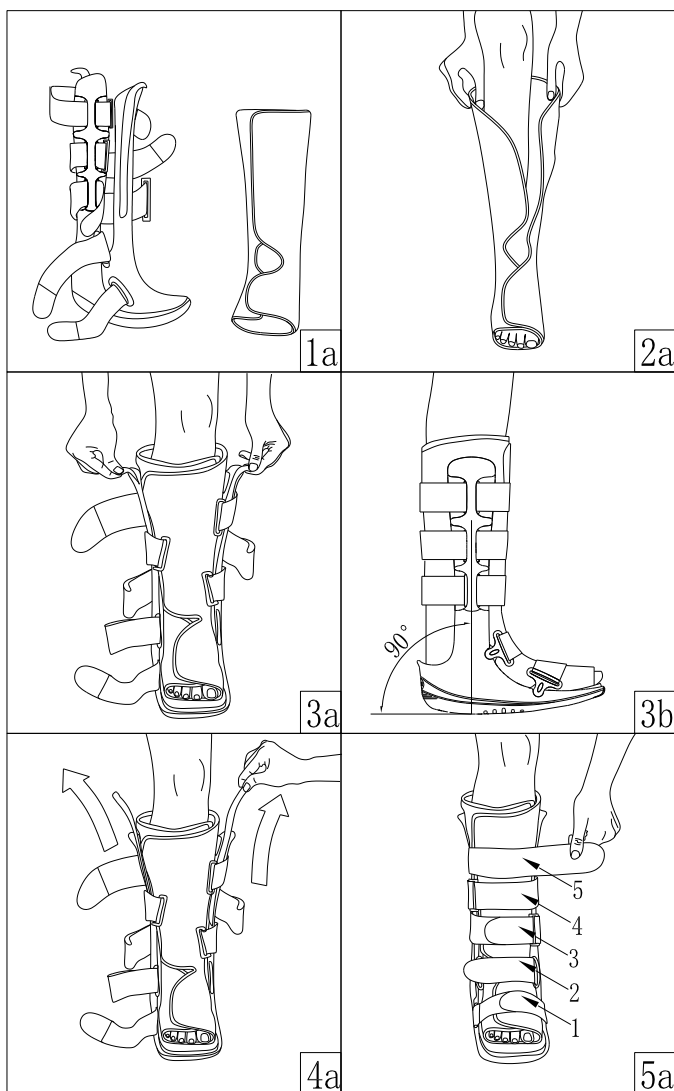


深圳简单医疗科技有限公司

产品说明书

足部固定器

产品型号：61005 产品规格：XS/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查阅。

一. 产品概述

1.1 产品名称：足部固定器

1.2 产品型号：61005

1.3 产品规格：XS/S/M/L/XL

1.4 产品结构：

足部固定器主要由基座，支撑架，调节带，衬垫等组成。

1.5 工作原理

产品主体大身设有支撑器、防滑软鞋底和减震系统。通过支撑器使得踝关节与小腿有妥帖的保护。通过软体和减震系统使得患者在锻炼时腿部有更多的舒适感。鞋体大身和小腿组合，使患者腿部得到完善的保护。透气软鞋垫使产品在使用过程中为脚提供前后左右的全面保护，防止二次伤害，且对小腿与固定的支撑提供柔软的接触让行走更加舒适，能够给病患的脚有一个很好的缓冲作用，帮助患者得到很好的恢复。

1.6 适用范围

外用，为足部和/或脚踝稳定性骨折、严重脚踝扭伤以及术后康复提供支撑，对骨折愈合和水肿（肿胀）治疗有效。

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】

助力式减震鞋底、高强度、重量轻、可拆式绑带。

【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】

注意：不要将衬垫直接与皮肤接触。

***请在医生或专业人士指导下购买和使用。**

步骤 1:

松开尼龙搭扣带，将内部的衬垫取出（图 1a）。

步骤 2:

把脚放进衬垫内，脚后跟紧贴衬垫后部，将足部跟腿部包裹住。要确保腿部和足部与衬垫紧贴（图 2a）。

步骤 3:

在白色拉条完好无损的情况下，轻轻地展开侧支柱，并将小腿放入支架中。踝关节应集中在支柱上，足部和踝关节在 90° 处（图 3a~3b）。

步骤 4:

正确对齐后，拆卸白色拉条，轻轻地将支柱推到衬垫上，与衬垫结合（图 4a）。

步骤 5:

脚趾开始从下往上依次将绑带 1-2-3-4-5 紧固，注意绑带孔位与支撑架上的柱位不能够脱离，紧固绑带不要过紧。随着肿胀模式在一天中的变化，为了舒适起见，可能需要调整带子的松紧度（图 5a）。

步骤 6:

若要拆卸，只需松开带子即可，把脚和脚踝向前拉出来即可。若要重新穿戴将脚和脚踝放入衬垫内，重新固定绑带即可。

警告和注意事项：

包扎带过紧或不当可能引起严重的皮肤刺激，对于糖尿病性神经病（一种糖尿病神经状况）患者尤其如此。时常检查您的皮肤是否存在“热点”和皮肤刺激。如果您发现任何皮肤变化或感到不适，请放松包扎带的松紧。如果由于术后麻醉，神经，皮肤或其他状况而无感觉，切勿使用此产品。

保养与维护

软体部分可以用中性洗涤剂和 30℃ 左右水手洗，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。刚性部分可用湿布擦洗并自然晾干。

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) 基座/支撑架：聚丙烯+玻纤

2) 绑带：尼龙

3) 衬垫：尼龙/聚氨酯/聚酯（外网/泡沫/内网面）

4) 鞋外底/鞋内底/鞋垫：热塑性弹性体/聚丙烯/EVA

2.5 禁忌症

⚠ 非稳定性骨折慎用；

⚠ 骨质疏松症慎用；

⚠ 认知缺陷慎用；

⚠ 骨质性关节强硬等慎用

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：

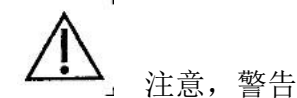
未使用前请放置在干燥、清洁的室内，保证室内通风。

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



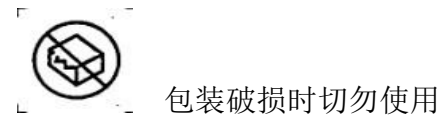
注意，警告



禁止机洗



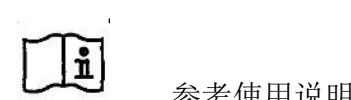
避免日晒



包装破损时切勿使用



有效期为 5 年



参考使用说明

六. 配件清单

说明书----- 1 份

衬垫----- 3 个

七. 售后承诺

保修：所有产品从购买之日起为原始日期，正常磨损和撕裂的产品在使用过程中不被视为缺陷。

以下部件自购买之日起至质保期内，如果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及附件进行完全或部分维修或更换。

八. 厂家信息

【产品名称】足部固定器

【医疗器械备案凭证编号】

粤深械备 20180574 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 20180574 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

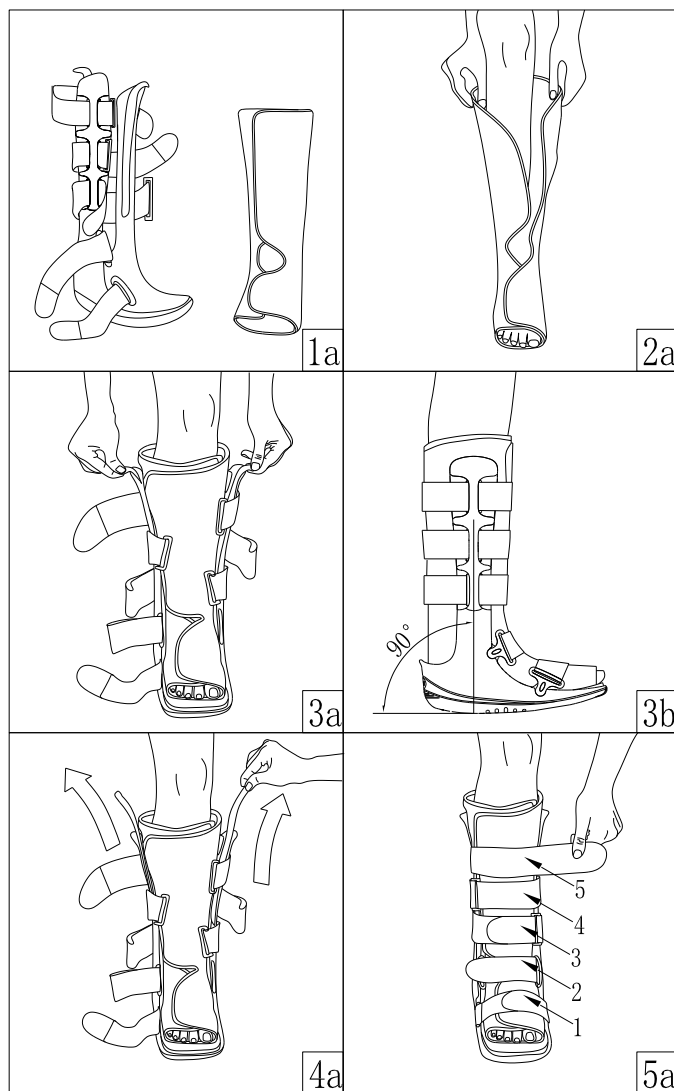
【网址】www.simplemedical.cn



Instruction For Use

Walker B2

Model: 61005 Size: XS/S/M/L/XL



Product overview

1)Product name: Walker B2

2)Product model: 61005

3)Product specification: XS/S/M/L/XL

4)**Product Structure:** The product is mainly composed of base, Strut, straps, lining etc

5) **Operating principle:** The main body of the product is provided with support, anti-slip soft sole and shock absorption system. The ankle and calf are properly protected through the support. Through software and shock absorption system, patients have more comfort in their legs during exercise. The shoe body big body and the calf combination, causes the patient leg to obtain the perfect protection. The breathable soft shoe pad enables the product to provide comprehensive protection for the feet before and after use, to prevent secondary injury, and to provide soft contact between the calf and the fixed support to make walking more comfortable. Can give the patient's foot a very good buffer, help the patient get a good recovery.

Scope of application:

External use, provides support for foot and/or ankle stable fractures severe ankle sprain, and postoperative rehabilitation effective for fracture healing and edema (swelling) treatment.

Product features and performance description

1) Product features and storage conditions

【Product features】 Low profile rocker sole, Shock-abosobing technology, High strength & light weight, Mechanical strap locking system.

【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: Do not contact the liner directly with the skin

***Please purchase and use the product under the guidance of your doctor or professional.**

STEP 1: Release the nylon buckle and remove the internal gasket (Fig1a).

STEP 2: Place the foot in the pad, heel close to the back of the pad, wrap the foot and leg. Make sure the legs and feet are close to the gasket (Fig 2a).

STEP 3: Gently expand the side pillar and place the calf in the bracket while the pull strip is intact. The ankle should be concentrated on the pillar, with the foot and ankle at 90° (Fig 3a~3b).

STEP 4: After correct alignment, remove the pull strip, gently push the pillar onto the gasket, and combine the buckle on the gasket (Fig 4a).

STEP 5: Fasten the strap 1-2-3-4-5 from the bottom to the top of the toe, pay attention to the hole position of the strap and the column position on the support frame can not be separated, fasten the strap not too tight.. As the swelling pattern changes over the day, it may be necessary to adjust the tightness of the strap for comfort(Fig 5)

STEP 6: to remove, simply release the tape and pad and pull the heel and ankle forward to reapply the foot and ankle into the gasket and reconnect the buckle.

IMPORTANT:

1) Do not contact the liner directly with the skin.

2) Warnings and Over tightening or improper bandaging may cause severe skin irritation, especially for diabetic neuropathy (a diabetic neurological condition). Always check for "hot spot" and skin irritation on your skin. If you find any skin changes or feel uncomfortable, loosen the tightness of the dressing. Do not use the device if it is not felt due to post-operative anesthesia, nerve, skin, or other conditions.

Maintenance:

The software part can be washed with a neutral detergent and a 30 & deg; C sailor and air-dried. Do not put the dryer or use other heat sources for drying. Elements such as salt water, sand, dirt, etc. may cause injury. After exposure to these conditions, rinse thoroughly with clear water, dry the towel or air-dry (do not machine the machine). For detergents, use mild detergent and do not use softeners and bleaches.

The rigid part can be scrubbed with wet cloth and dried naturally.

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) Base/ strut: polypropylene+GF

2) Straps: nylon

3)Pad: nylon / polyurethane / polyester (outer net / foam / inner mesh)

4) Shoeoutsole/shoe inner sole: thermoplastic elastomer / polypropylene/EVA

Contraindication

⚠ Use with caution for unstable fractures;

⚠ Use with caution in osteoporosis;

⚠ Use with caution for cognitive impairment;

⚠ Use with caution for bony ankylosis;

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

Reference instructions

Accessories list

Instructions ----- 1 copy

Pad ----- 3 pcs

After-sales warranty

Warranty: all products from the date of purchase as the original date, normal wear and tear of the product in the use of the process is not considered defective.

The following parts from the date of purchase to the warranty period, if there is any material or process defects, please contact your seller directly, Simple medical will complete or partial repair or replacement of equipment and accessories.

Simple Medical (Shenzhen) Limited

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

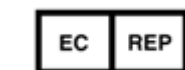
Minzhi Street,Longhua District,

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

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.