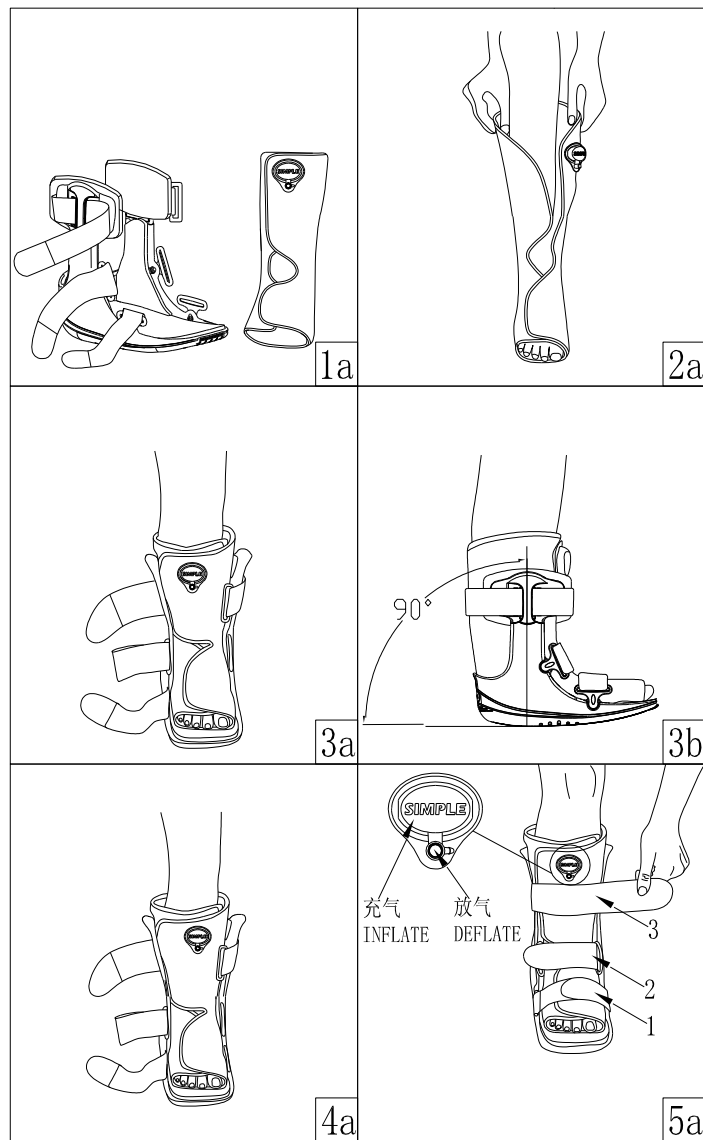


深圳简单医疗科技有限公司

产品说明书

足部固定器

产品型号：61002 产品规格：XS/S/M/L/XL



一. 产品概述

1.1 产品名称：足部固定器

1.2 产品型号：61002

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，气泵，气囊等组成。

1.5 工作原理

产品主体大身设有支撑器、防滑软鞋底和气囊。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，为足部骨折、足部韧带损伤固定、脚掌和脚趾损伤固定、轻微及中等程度脚拇指外翻、足底疼痛、术后康复提供压缩空气支撑。

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】新一代空气泵系统、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

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:

松开尼龙绑带，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:

轻轻地展开侧支柱，并将小腿放入支架中。踝关节应在支柱中心处，使足部和踝关节呈 90°（图 a）。

步骤 4:

正确对齐后，调整绑带和衬垫，直到舒适位置（图 4a）。

步骤 5:

从脚趾开始从下往上依次绑带 1-2-3 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。固定好后再给要为衬垫充气，按压并释放中央气泡球，直到衬垫可提供舒适的缓冲和支撑。不要过度充气。要放气或调节压力，按下较小的圆形侧按钮即可（图 5a）。

步骤 6:

若要拆卸，先按放气按钮直至放完再松开带子，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。

警告及注意事项：1. 切勿使气囊过度充气。不适当的气囊充气可能对患有糖尿病神经病变的病人造成明显刺激。如果出现任何可见的皮肤变化或病人报告不适，请降低气囊的压力。切勿将本产品用于无法表达身体不适的病人。

2. 应当时常监控无感觉患者（如：术后麻醉、神经疾病等）的“热点”、皮肤刺激或伤口护理情况。

3. 在湿滑表面行走时，应当小心，以避免受伤。在高海拔地区，气囊的扩张将超出最佳水平，拉紧或放松调节带以调整气囊压力。

4. 使用前，请务必进行检查。检查缝线或部件是否破损，材料是否撕裂、切断或磨损，带扣或粘扣带是否牢固。请勿使用已损坏的产品。若本器械出现任何撕裂、磨损、磨破，请停止使用。

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) 调节带：尼龙

3) 衬垫：尼龙/聚氨酯/聚酯（外网/泡沫/内网面）

4) 气囊/气泵：聚氨酯

5) 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设备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

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【说明书修订日期】2020 年 07 月 02 号

【网址】www.simplemedical.cn



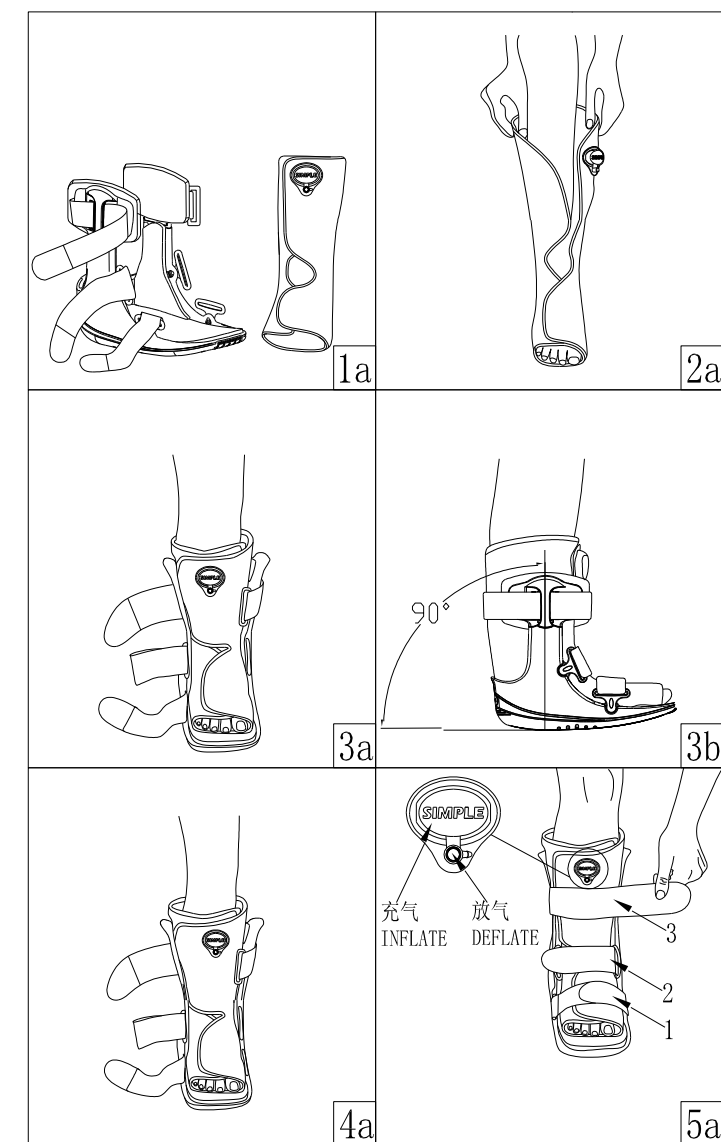
感谢您购买本公司产品！请在操作前仔细阅读本使用说明书！以充分了解本产品，以保证本产品的安全性及有效性，并请妥当保存说明书以备查阅。

Simple Medical (Shenzhen) Limited

Instruction For Use

Walker B2

Model: 61002 Size: XS/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: Walker B2

2)Product model: 61002

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

4)Product Structure: The product is mainly composed of base, Strut, strap, lining, adhesive and bladder.

5)Operating principle:

The main body of the product is equipped with support, non-skid soft sole and bladder. The ankle joint and calf are properly protected by supporting device. Through software and shock absorption systems, patients have more comfort in their legs during exercise. The combination of the upper body of the shoe and the front cover of the calf makes the leg of the patient well protected. The breathable soft insole makes the product provide comprehensive protection to the foot before and after the use of the foot, prevent secondary injury, and provide soft contact between the calf and the fixed support to make it more comfortable to walk. The combination of soft shock absorber and anti-skid soft sole can give the patient's foot a good cushioning effect and help the patient get a good recovery.

Scope of application:

External use, provides compressed air support for foot fracture, foot ligament injury fixation, foot sole and toe injury fixation, mild and moderate foot thumb valgus, plantar pain, postoperative rehabilitation.

Product features and performance description

1) Product features and storage conditions

【Product features】 New Generation Air pump system, 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】**

Note1: 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 °(Fig3b).

STEP 4: After correct alignment, adjust the straps and gaskets to know the comfortable position (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 in one day, it may be

desirable to adjust the degree of tightness of the strap for comfort After fixation, inflate the liner, press and release the central bubble ball until the liner provides a Comfortable cushioning and support. Do not overfill. To deflate or adjust the pressure, press the smaller circular side button (Fig5a)

STEP 6: To remove press the release button until the air is finished and then loosen the straps. Pull the heel and ankle forward. If you want to wear again, put the foot and ankle in the pad and fix the straps again.

Note 2: 1. Do not inflate the airbag too much. Inappropriate balloon inflation may cause significant stimulation in patients with diabetic neuropathy. If any visible skin changes occur or the patient reports discomfort, reduce the pressure on the airbag. Do not use this instrument for patients who are unable to express their discomfort.

2. When walking on a slippery surface, care should be taken to avoid injury. At high altitude, the expansion of airbags will exceed the optimal level.

3. Be sure to check before using it. Do not use damaged products. If there is any tear, wear and tear in this instrument, please stop using it.

Maintenance: The software part can be washed with a neutral detergent and a 30°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) Bladder/pump: thermoplasticpolyurethane

5)Shoecoutsole/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

Protect from sunlight

Hand wash only

Do not use when the packing is damaged

Warnings and Precautions

Reference instructions

Accessories list

Instructions ----- 1 copy

Pad ----- 3 pcs

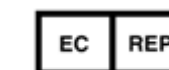
After-sales warranty

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.

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*Please refer to the Instructions before usage