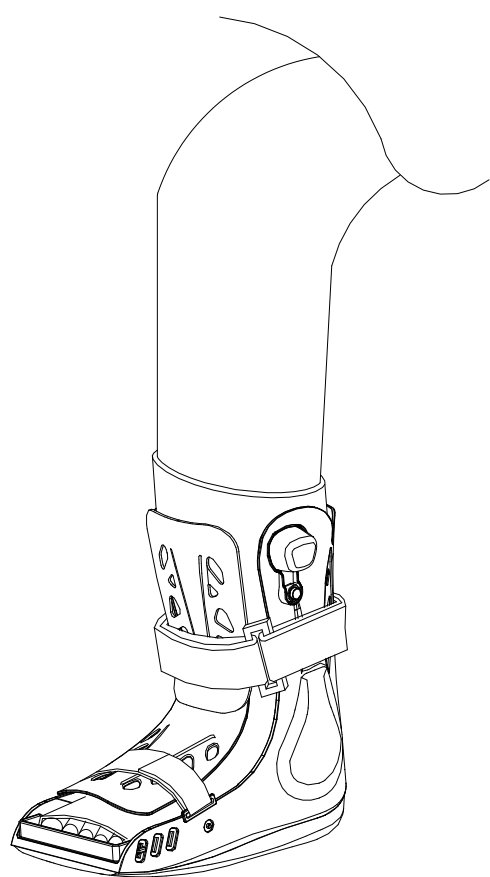


深圳简单医疗科技有限公司

产品说明书

足部固定器

产品型号：61004 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将来查阅。

一. 产品概述

1.1 产品名称：足部固定器

1.2 产品型号：61004

1.3 产品规格：XS, S, M, L, XL

1.4 产品结构：

足部固定器由高分子材料、织物、皮革、金属等材料制成。

1.5 工作原理

产品主体大身设有支撑器、防滑软鞋底和减震垫。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。鞋体大身和小腿前面盖的组合，使患者腿部得到完善的保护。设置的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。鞋内柔软减震垫和防滑软鞋底的相互结合作用，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 预期用途

用于人体足部部位的外固定或支撑。

1.7 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、术后康复时等的夹持骨骼固定或支撑。

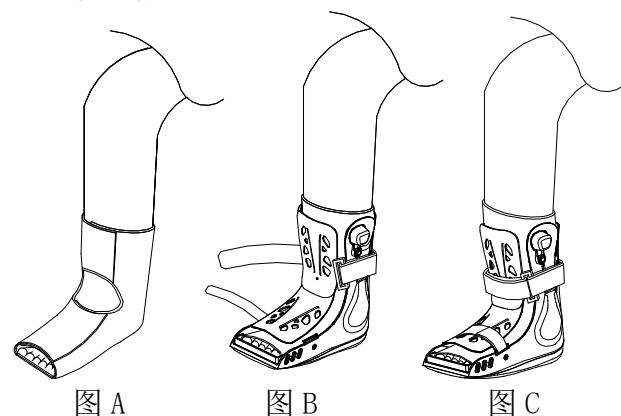
二. 产品特点及性能描述

2.1 产品特点及贮存条件

【产品特点】产品简单, 固定性好, 舒适透气。

【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：棉质或石膏衬垫将增加舒适度。

步骤 1：解开带子，取下前面板，然后打开衬里。

步骤 2：坐下并将脚放入足部固定器，脚跟紧靠足部固定器的后部。将衬里环足部跟腿部缠绕（图 A）。

步骤 3：放前面板，使（面板 LOGO）标志位于脚趾上方，并将面板上部固定到衬里上，底部到顶部系紧带子拉紧，直到感觉牢靠而舒适（图 B~C）。

步骤 4：调整气囊压力：简单步行足部固定器的初始气囊是排空的。从受伤侧开始使气囊膨胀，将手指放在气囊的大充气泵顶部，向下施压，直到气囊紧固为止。同样对另一侧的气囊充气，直到气囊牢固为止。如果充气过度，请对气囊进行适当放气。如要排空气囊，按住需要排空气囊一方的小按钮即可放气，直到感觉压力适当。

警告及注意事项：注意：不要将衬里直接与皮肤接触

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：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。

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) 外壳：聚丙烯

2) 前面板：高密度聚乙烯

3) 调节带：尼龙

4) 衬垫：尼龙/聚氨酯/聚酯（外网/泡沫/内网面）

5) 气囊：聚氨酯

6) 鞋外底/减震垫/鞋内底：热塑性弹性体/聚丙烯

7) 鞋垫：EVA

8) 铆钉：不锈钢

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

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。

高分子材料外壳 ----- 1 年

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】

粤莞食药监械生产备 20200057 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

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【邮政编码】518131

【受托生产企业】东莞简单智造有限公司

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【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】2023 年 07 月 27 号

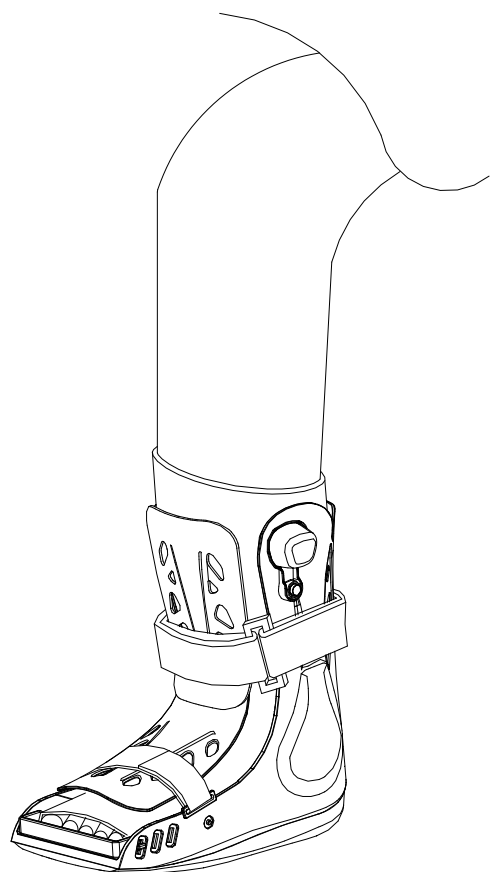
【网址】www.simplemedical.cn

Simple Medical (Shenzhen) Limited

Instruction For Use

SIMPLE Walker B1

Model: 61004 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: SIMPLE Walker B1
- 2) Product model: 61004
- 3) Product specification: XS, S, M, L, XL
- 4) **Product Structure:** The product is mainly composed of shell, front cover, strap, lining, adhesive and rivets
- 5) **Operating principle:**

The main body of the product is equipped with support, non-skid soft sole and shock absorber. 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.

6) **Scope of application:** External use is foot fracture, foot ligament injury fixation, foot soles and toes injury fixation, mild and moderate thumb valgus, plantar pain, postoperative recovery and so on clamping bone fixation or support.

Product features and performance description

- 1) Product features and storage conditions

【Product features】 The product is simple, and the self-pressure type double-air bag linkage design is adopted, and is comfortable and air-permeable.

【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】

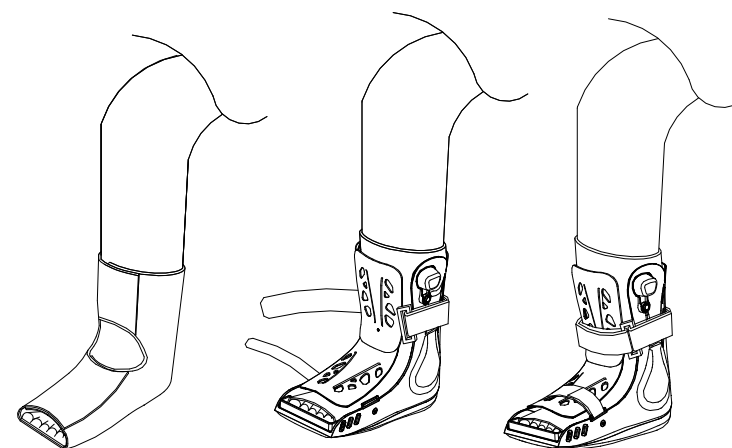


图 A

图 B 图 C

Note1: Wear the sock before wearing the ankle joint! Cotton or gypsum liners will increase comfort-not attached.

STEP 1: Untie the strap, remove the front panel, and open the liner.

STEP 2: Sit down and put your feet in the protective gear, with the heel close to the back of the guard. Wrap the lining ring foot with the leg (Fig A).

STEP 3: Place the front panel so that the (panel logo) is located above the toe, and fasten the upper panel to the lining, bottom to top to tighten the straps until they feel secure and comfortable (Fig B~C).

STEP 4: Adjust the airbag pressure: the initial airbag of the simple walking guard is emptied. Start inflating the airbag from the injured side, place your finger on the top of the inflatable pump of the airbag, and press down until the airbag is fastened. Also inflate the airbag on the other side until the airbag is firm. If inflated too much, please vent the airbag properly. If you want to empty the airbag, hold down the small button that needs to empty the airbag until you feel the right pressure.

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:

Lining can use neutral detergent and 30℃ water washed by hand, and natural dry. Do not use clothes dryer or other heat source for drying.

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 ℃
- 2) Relative humidity: 80%

Product material

- 1) shell: polypropylene
- 2) front panel: high density polyethylene
- 3) adjustment belt: nylon
- 4) pad: nylon / polyurethane / polyester (outer net / foam / inner mesh)
- 5) adhesive: polyester
- 6) shoe outsole / shock absorber / shoe inner sole: thermoplastic elastomer / polypropylene
- 7) insole: EVA
- 8) rivets: stainless steel

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
- It is valid for five years Protect from sunlight
- Hand wash only
- Warnings and Precautions
- Reference instructions

Accessories list

Instructions ----- 1 copy

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.
polymer material shell ---- 1 year

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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

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*Please refer to the Instructions before usage.

