

深圳简单医疗科技有限公司

产品说明书

腰部固定器

产品型号：52002 产品规格：F



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：腰部固定器

1.2 产品型号：52002

1.3 产品规格：F

1.4 产品结构：

产品主要由高分子材料、织物、皮革、金属等材料制成。

1.5 工作原理

产品采用双独立的机械滑轮系统，为患者提供优越的压缩水平、最大限度的舒适度、灵活的控制度、稳定的支撑和有效的缓解疼痛。灵活的后滑轮系统，符合患者身体类型，在站立或坐着都能够轻松调整所需的舒适度。低轮廓的前面板以及透气的网布为患者舒适穿戴度和顺畅性。

1.6 预期用途

用于对人体腰部部位的外固定或支撑。

1.7 适用范围

适用于腰椎机械性背痛，椎管狭窄，退行性椎间盘滑脱，腰椎滑脱，腰外伤，椎间盘突出症患者。

二. 产品特点及性能描述

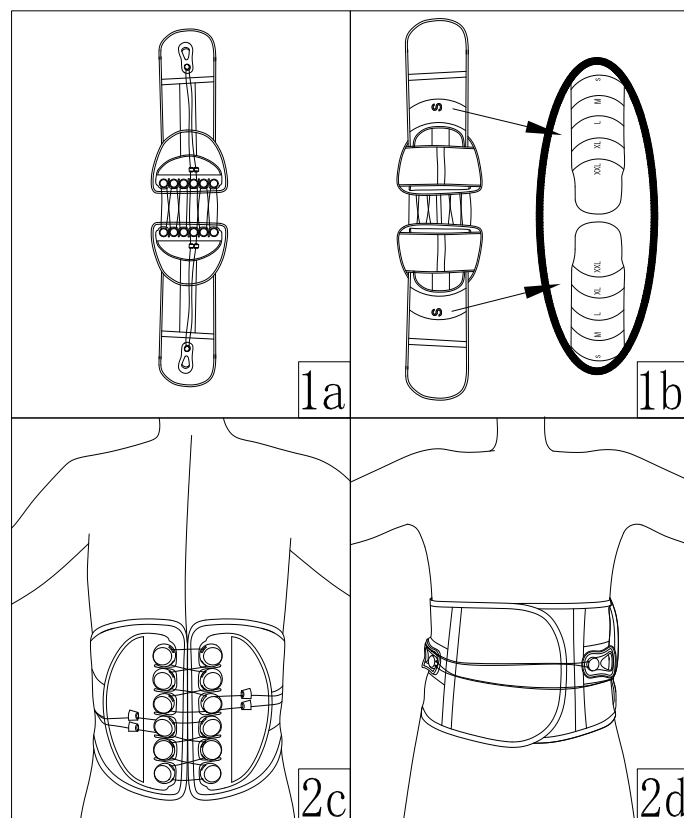
2.1 产品特点及贮存条件

【产品特点】产品多种尺寸调整选项，双独立滑轮系统，低轮廓的前面板，宽调整以及更大的舒适性和顺畅性。

【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

步骤 1：打开产品，分别将横向延伸宽固定带剥离连接板，再将宽固定带穿过固定口，然后根据个人身体类型调整到合适的尺寸（内标记 S/M/L/XL/XXL）以中间连接板边缘为界反折进固定口内再固定好（图 1a~1b）。

步骤 2：将腰部固定器放至腰部，中心与脊椎对齐，下方位于尾骨处。固定带与腰部贴紧后将勾面面板贴在毛面面板上。再将拉环往外拉直到收紧固定带后再牢固的粘附在前面板上（图 2c~2d）。

警告：

1. 固定带不要过于太紧，请注意固定带的穿戴舒适度。
2. 上面列出的应用说明仅供合格的专业人员使用。除非骨科专业人员另有指示，否则不建议患者尝试使用或调整该设备。任何关于进一步调整或佩戴频率以及配戴时间都由您的骨科专业人员决定。

保养与维护

软体部分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。

刚性部件可用湿布擦拭干净。

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。
- *仅适用于单个患者，不建议用于多个患者。
 - *此产品仅为保护装置，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：尼龙
- 2) 滑轮支撑器：聚乙烯
- 3) 拉环：热塑性弹性体

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：3 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



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，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】腰部固定器

【医疗器械备案凭证编号】

粤深械备 20180614 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 20180614 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】518131

【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 06 月 30 号

【网址】www.simplemedical.cn



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 LO 108
- 2)Product model: 52002
- 3)Product specification: F
- 4)Product Structure:

The products are mainly composed of breathable mesh cloth, nylon wire, pull ring, plastic pulley support system and magic sticker.

5)Operating principle:

The product adopts a double independent mechanical pulley system to provide patients with superior compression level, maximum comfort, flexible control, stable support and effective pain relief. The flexible rear pulley system conforms to the patient's body type and can easily adjust the required comfort level when standing or sitting. A single product has many choices of suitable sizes. The contoured filling panel and breathable mesh cloth provide comfortable wearing and smoothness for patients.

6)Scope of application:

It is suitable for Lumbar mechanical back pain, Spinal stenosis, Degenerative disc, Spondylolysis, Spondylolisthesis, Trauma, Herniated, Disc, Bulging Disc, Facet Syndrome

Product features and performance description

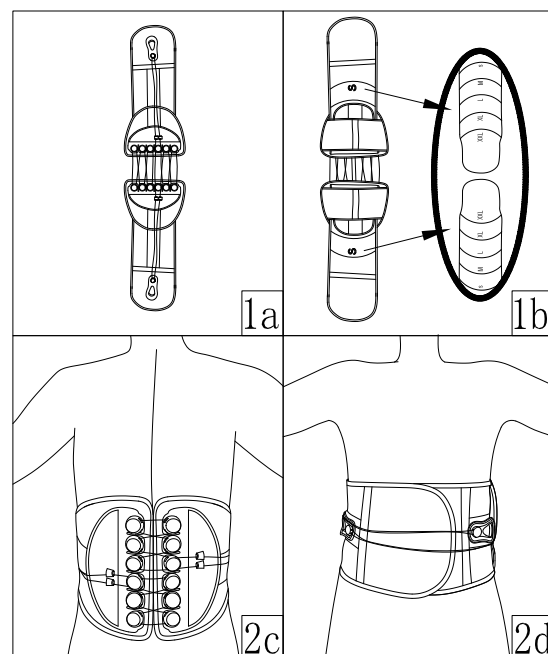
1) Product features and storage conditions

【Product features】 The product is Multi-fit sizing options, double independent pulley system, low profile anterior panel, wide adjustments, greater comfort & compliance

【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】



APPLICATION INSTRUCTIONS

STEP 1: Open the product, peel off the transverse extension wide fixed band, then pass the wide fixing band through the fixing port, and then adjust to the appropriate size according to the personal body type (inner mark S/M/L/XL/XXL) and fold back into the fixing port according to the edge of the middle connection plate (Fig1a~1b).

STEP 2: Place the Lumbar Brace at the waist, the center is aligned with the spine, and the bottom is at the coccyx. After the fixed belt is fastened to the waist, the hook panel will be affixed to the hairy surface panel. Then pull the pull ring out until the fastening band is tightened and then firmly adhered to the front panel (Fig 2c~2d).

WARNING:

- 1) **The fastening belt is not too tight, please pay attention to the wearing comfort of the fixed belt..**
- 2) **The application instructions listed above are for use only by qualified professionals. Unless otherwise directed by orthopedic professionals, patients are not advised to try to use or adjust the device. Any further adjustment or wear frequency and wear time will be determined by your orthopedic professional.**

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 parts can be wiped clean with a damp cloth.

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 a single patient only, not recommended for multiple patients.

Basic product environment

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

Product material

- 1) Main body: nylon.
- 2) pulley support: polyethylene
- 3) pull ring: thermoplastic elastomer

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: three 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

- Manufacture Date
- Batch Code
- medical device
- It is valid for three years
- Protect from sunlight
- Hand wash only
- Do not use when the packing is damaged
- Warnings and Precautions
- 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

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.

