

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：52004 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：52004

1.3 产品规格：S, M, L, XL

1.4 产品结构：

由聚乙烯、热塑性弹性体、聚酰胺、海绵组成。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。柔软的衬垫为患者提供舒适的穿戴度。

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

适用于椎间盘切除术/融合术下腰痛/劳损腰椎间盘突出、压缩性骨折、骨质疏松、椎间盘突出及退变性腰椎滑脱辅助治疗。

二. 产品特点及性能描述

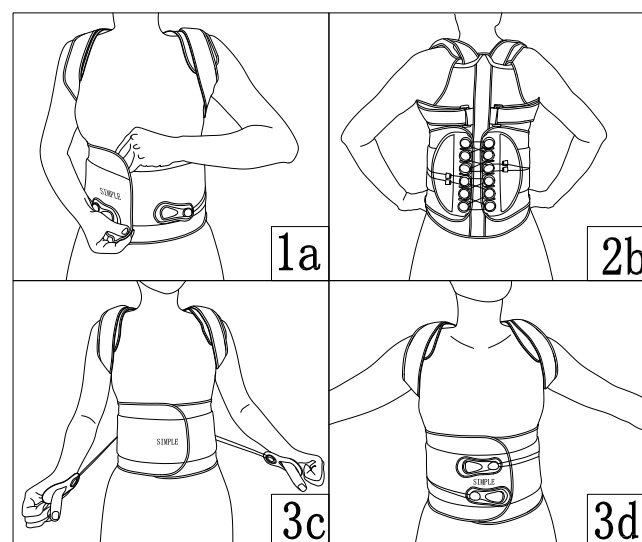
2.1 产品特点及贮存条件

【产品特点】双独立滑轮系统，等高线垫板，可调拉线手柄，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

【使用方法】



使用说明

步骤 1：打开前面的两个腰带，像背包一样双手穿过肩带。背板的中心与脊柱对齐，底部大约位于骶尾联合处。用力将勾面腰带固定在毛面腰带上，使得腰部固定器与身体紧密贴合（图 1a）。

步骤 2：调整肩带。取下肩带尾端的魔术贴，将肩带和

肩衬垫调整到舒适的位置，使得肩带和衬垫与身体贴合。如果肩带过长，可将肩带剪裁到需要的长度，再将取下的魔术贴头装上并固定在肩带上即可（图 2b）。

步骤 3：在检查好穿戴位置正确和穿戴舒适后，将腰带两边的拉环往外拉使得固定器收紧贴合身体后再粘附在腰带的毛面上（图 3a~3d）

***重要事项：**

1. 以上步骤应由合格的专业人员使用。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。
2. 不要过度拉紧加压系统，以免引起不适或呼吸困难。坐下时，患者可能需要稍微松开加压系统。

保养与维护

软体部份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。

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) 腰带/肩带：尼龙
- 2) 硬板：聚乙烯
- 3) 拉环：热塑性弹性体
- 4) 衬垫：尼龙/海绵
- 5) 肩带扣：聚乙烯

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；
- ⚠ 孕妇以及患有血液循环、肺部、心血管或骨骼疾病的人士禁用，因为腹部挤压和/或受压可能会造成这些病症恶化；

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，保证室内通气。

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 3 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】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】

粤莞食药监械生产备 20200057 号

【产品技术要求编号】

粤深械备 20180614 号

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【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

Simple Medical (Shenzhen) Limited Instruction for Use

SIMPLE LSO 203

Model: 52004 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 LSO 203
- 2)Product model: 52004
- 3)Product specification: S, M, L, XL
- 4)Product Structure:

The product is mainly composed of air-permeable mesh cloth, nylon wire, pull ring, liner, plastic pulley support system and magic tape.

5)Operating principle:

The product adopts double independent mechanical pulley system, which provides patients with superior compression level, maximum comfort, flexible control system, stable support and effective pain relief. Flexible rear pulley system, in line with the patient's body type, standing or sitting can easily adjust the required comfort. Soft cushions provide comfortable wear for patients.

6)Scope of application:

It is suitable for lumbar discectomy / fusion surgery with low back pain / strain lumbar disc injury, compression fracture, osteoporosis, disc herniation and degenerative lumbar spondylolisthesis.

Product features and performance description

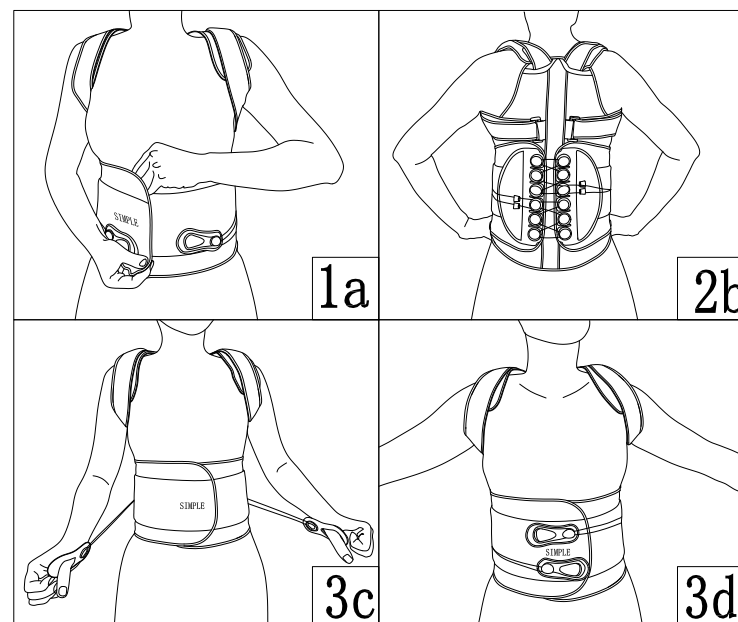
1) Product features and storage conditions

【Product features】double independent pulley system, contoured padded panels, adjustable pull cord handles, comfortable, breathable

【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 two belts in front and put your hands through the straps like a backpack. The center of the dorsal plate is aligned with the spine, and the bottom is about the sacra joint. The hook belt is fastened to the hairy belt so that the waist retainer fits closely with the body (Fig. 1a).

STEP 2: Adjust the shoulder strap. Remove the magic sticker at the end of the shoulder strap and adjust the shoulder strap and shoulder pad to a comfortable position to fit the shoulder strap and pad to the body. If the straps are too long, cut the straps to the desired length, and then install the removed magic stickers and fasten them to the straps (Fig.2b).

STEP 3: After the proper and comfortable wearing position is checked, pull the pull rings on both sides of the wide belt to pull out, so that the fixer is tightened and attached to the body and then adhered to the surface of the wide belt (Fig. 3c~3d).

*CAUTION:

1. The above steps should be used by qualified professionals. Any further adjustment or wear frequency and wear time will be determined by your orthopedic professional.
2. Don't tighten the pressure system too much to avoid discomfort or dyspnea. When sitting down, the patient may need to loosen the pressure system a little.

Maintenance:

Soft items can be washed with neutral detergents and 30 °C and dried naturally. Do not put in the clothes dryer or use other heat sources for drying. Salt water, sand, dirt and other elements can cause damage. After exposure to these conditions, rinse thoroughly with clean water and dry or dry towels (not machine dry). If you need detergent, please use mild detergent; do not use softener and bleach. Rigid parts can be wiped clean with wet cloth.

Warning:

If you experience pain, swelling, irritation, or discomfort while using this product, please discontinue use and consult your doctor.
* 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
- 4) backing 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;

⚠ Pregnancy and circulation, pulmonary, cardiovascular or skeletal conditions which pose risk to be made worse as a result of compression of the abdomen and/or pressure.

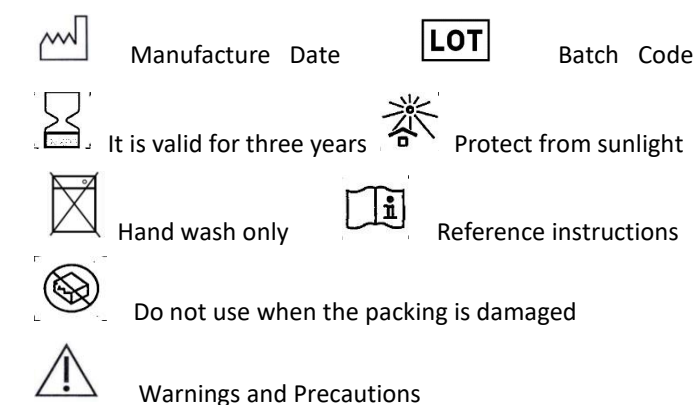
Storage, transportation and expiry date of products

- 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



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.

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*Please refer to the Instructions before usage.

