

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：52009 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：52009

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。单个产品具有多种合适尺寸的选择。仿形填充面板以及透气的网布为患者提供舒适穿戴度。

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、椎间盘突出及退变性腰椎滑脱患者。

二. 产品特点及性能描述

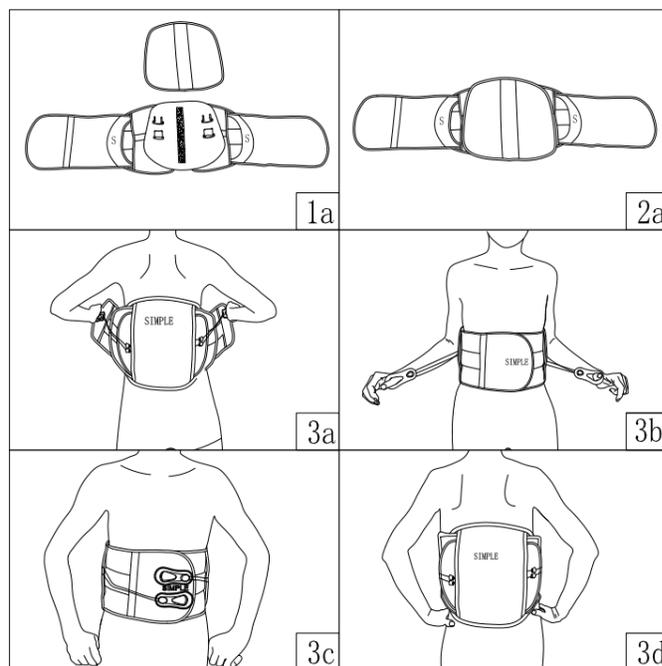
2.1 产品特点及贮存条件

【产品特点】产品多种尺寸调整选项，双独立滑轮系统，宽调整，等高线衬垫板，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：将软衬垫取下来，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和支撑器口后，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）。

步骤 2：将取下来的衬垫穿过宽绑带，衬垫的毛面对准支撑器中间的勾面魔术贴并贴合住（图 2a）

步骤 3：将腰部固定器放置腰部，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面板上（图 3a~3d）。

警告：

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

柔软的物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。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) 大身：尼龙

2) 支撑器：聚乙烯

3) 拉环：热塑性弹性体

4) 衬垫：尼龙

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 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，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

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【说明书修订日期】2023 年 06 月 30 号

【网址】www.simplemedical.cn

Simple Medical (Shenzhen) Limited

Instruction for Use

Simple LSO 200

Model: 52009 Size: F



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 200
- 2)Product model: 52009
- 3)Product specification: F
- 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 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 filler panel and breathable mesh provide comfortable wearability for patients.

6)Scope of application:

It is suitable for IDET procedures, Low back pain/strain, Lumbar disc injury, Compression fractures, Osteoporosis, Disc herniation and degeneration, Spondylolisthesis

Product features and performance description

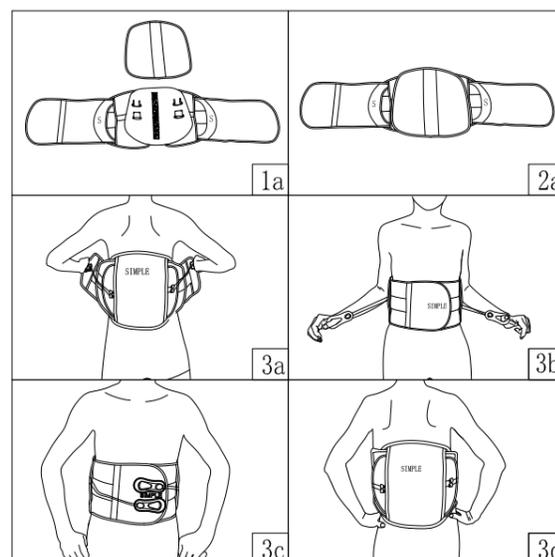
1) Product features and storage conditions

【Product features】 Multi-fit sizing options, double independent pulley system, contoured padded panels, 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: Take the soft gasket down, peel off the connecting plate with the transverse extension wide fixed band, and then adjust the wide fixing band through the fixing port and the support port according to the personal body type to the appropriate size (internal marking S/M/L/XL/XXL) fold back into the fixing port with the edge of the middle connection plate as the boundary, and then fix it back into the fixing port. (Fig1a)

STEP 2: Pass the removed gasket through the wide band, and the wool surface of the gasket is aimed at and glued to the hook in the middle of the support (Fig 2a).

STEP 3: 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 3a~3d).

WARNING:

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:

Soft items can be washed with neutral detergents and 30 °C sailors 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, 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;

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.

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***Please refer to the Instructions before usage.**

