

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：52008 产品规格：S, M, L, XL, XXL, XXXL



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：52008

1.3 产品规格：S, M, L, XL, XXL, XXXL

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。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

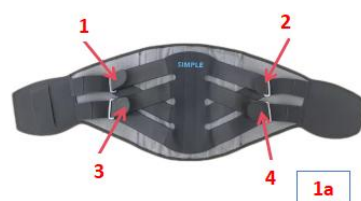
【产品特点】产品具有双独立滑轮系统，单前部紧固件，可调拉线，舒适透气。

【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】

步骤 1：打开产品（如图 1a）。



步骤 2：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。再根据适配程度往外拉 4 个魔术贴直到收紧固定带后再牢固的粘附在前面面板上（2b~3c）。



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

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。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。

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/不锈钢

2) 前支撑片：热塑性弹性体/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：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 5 年

📖 参考使用说明

六. 配件清单

说明书----- 1份

七. 配件清单

型号	52008	
尺码	S, M, L, XL, XXL, XXXL	
尺码	腰围尺寸	测量方式
S	52-62cm	
M	63-74cm	
L	75-89cm	
XL	90-105cm	
XXL	106-120cm	
XXXL	121-140cm	

八. 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

【备案人】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

【受托生产企业】东莞简单智造有限公司

【地址】广东省东莞市凤岗镇米亚路 1 号

【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】2024 年 06 月 14 号

【网址】www.simplemedical.cn

Simple Medical (Shenzhen) Limited

Instruction for Use

SIMPLE LO 106

Model: 52008 Size: S, M, L, XL, XXL, XXXL



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 106
- 2)Product model: 52008
- 3)Product specification: S, M, L, XL, XXL,XXXL
- 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 the patient with superior compression level, maximum comfort, flexible control, stable support and effective relieving pain. The flexible back-pulley system, in line with the patient's body type, can easily adjust the desired comfort in standing or sitting. The low profile front panel and the breathable mesh are comfortable and smooth for the patient.

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 double mechanical pulley system, single front fastener, adjustable pull cord, 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】**



STEP1: open the product (Fig 1a).
STEP2: Place the lumbar retainer in the waist, with the center aligned with the spine and the lower part at the tailbone. Attach the hook face panel to the wool face panel after the fixed belt is attached to the waist. Then pull four Velcro strips outward according to the degree of adaptation until the fixing belt is tightened and then firmly adhered to the front panel (2b~3c).
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:

Product can use neutral detergent and 30 °C water washed by hand, and natural dry. Do not use clothes dryer or other heat source for drying. Salt water, sand, dirt and other elements can cause damage. After exposure to these conditions, rinse thoroughly with water, dry with a towel or air dry (do not machine dry). If you need detergent, please use mild detergent, do not use softener and bleach.

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/Stainless steel
- 2) Front panel: thermoplastic elastomer/ 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: 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 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 five 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

Selection

Item	REF. 52008	
Size	S, M, L, XL, XXL, XXXL	
Colour	Grey	
Size	Waist size	Measurement method
S	52-62cm	
M	63-74cm	
L	75-89cm	
XL	90-105cm	
XXL	106-120cm	
XXXL	121-140cm	

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

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.

52008 V0.2