

深圳简单医疗科技有限公司

产品说明书

胸部固定器

产品型号：51301 产品规格：S/M/L/XL/XXL



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：胸部固定器

1.2 产品型号：51301

1.3 产品规格：S/M/L/XL/XXL

1.4 产品结构：

产品主要由透气网布，衬垫，EVA垫，背板，塑胶滑轮系统，肩带，快速扣，拉环，尼龙线，铝合金调节杆，魔术贴等组成。

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、灵活的控制度以及稳定的支撑。可调节的伸缩金属杆适合多种身体类型选择，柔软的衬垫为患者提供舒适穿戴度。所述产品为整个胸腰段脊柱的患者提供支撑，提供一个多功能系统，在整个康复过程中提供适当的运动限制和疼痛的缓解。

1.6 适用范围

适用于稳定的、非位移性的脊柱骨折，脊髓狭窄；椎间盘突出，退行性脊柱病变，峡部裂。

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】

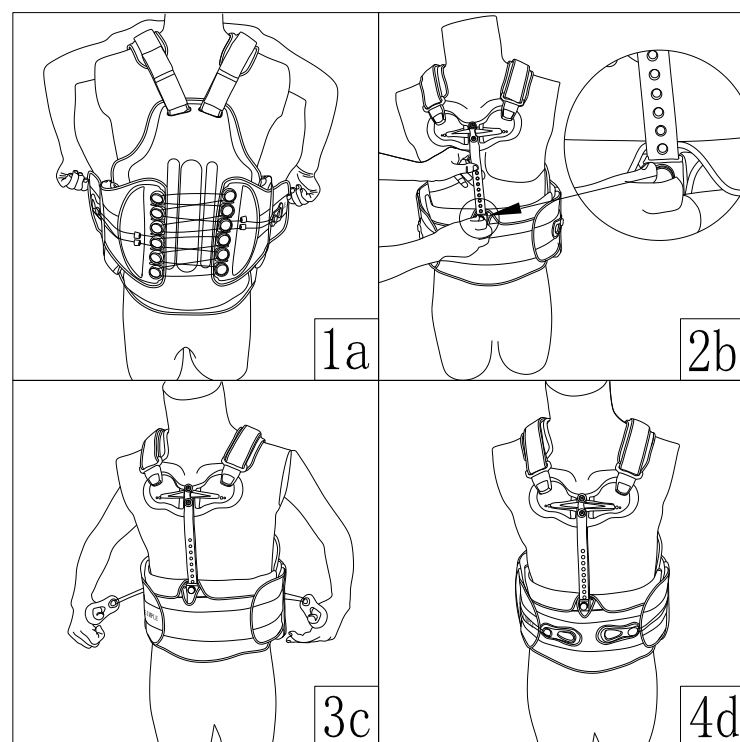
产品具有双独立滑轮系统，软垫肩带，无工具线性胸廓调整，可扩展后面板，可移动前面板以及最大舒适度和支撑。

【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: 头穿过肩带，背板中心与脊柱对齐，背板底部大约位于骶尾联合处，先将两边拉环放至在毛面板尾端，再将两边的勾面面板分别穿过松紧带后并固定在毛面板上，前板应位于腹部中央（图 1a）。

步骤 2: 将前面面板上的圆形金属纽扣往外拉后将金属调节杆上下伸缩，直到胸部衬垫上部边缘应位于胸骨颈静脉切迹下 1.27cm 左右处，再松开纽扣固定位置（图 2b）。

*重要事项 1:

正确的穿戴的位置：后背板中心与脊柱对齐，底部大约位于骶尾联合处。前板应位于腹部中央。胸部衬垫上部边缘应位于胸骨颈静脉切迹下 1.27cm 左右处且与胸骨贴合。

步骤 3: 检查穿戴位置正确和穿戴舒适后将两边的拉环往外拉使固定器收紧贴合身体后再粘附在毛面上（图 3c~）。

步骤 4: 再次查看穿戴位置正确后调节肩带的长度，使得肩带以及胸部衬垫与身体贴合。肩带可修剪需要的长度，穿脱也可使用肩带上的快速扣（图 4d）。

*重要事项 2:

1. 此产品仅作为支撑性支具使用，并非用于或确保预防脊椎损伤。

2. 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。

3. 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。

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) 衬垫：海绵/EVA

2) 硬板：聚丙烯

3) 肩带：尼龙

4) 调节杆：铝合金

5) 前面面板：尼龙

2.5 禁忌症

⚠ 出现过敏者请勿用；

⚠ 皮肤出现不明肿块者以及肿破溃疡者禁用；

⚠ 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

⚠ 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】胸部固定器

【医疗器械备案凭证编号】

粤深械备 20190424 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 20190424 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

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【说明书修订日期】2020 年 07 月 18 号

【网址】www.simplemedical.cn



Simple Medical (Shenzhen) Limited
Instruction for Use

Simple TLSO 301

Model: 51301 Size: S/M/L/XL/XXL



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 TLSO 301
- 2) product model: 51301
- 3) Product specification: S/M/L/XL/XXL
- 4) Product Structure:

The products are mainly composed of breathable mesh cloth, pad, EVA pad, backboard, plastic pulley system, shoulder strap, quick buckle, pull ring, nylon wire, aluminum alloy regulating rod and magic sticker.

5) Operating principle: The product adopts double independent mechanical pulley system, which provides patients with superior compression level, maximum comfort, flexible control system and stable support. Adjustable metal rods are suitable for a variety of body types, and soft cushions provide comfortable wear for patients. The product provides support for patients with the entire thoracolumbar spine and provides a multifunctional system to provide appropriate exercise restrictions and pain relief throughout the rehabilitation process.

6) Scope of application

Suitable for stable, non-displacement spinal fractures, spinal stenosis; disc herniation, degenerative spinal lesions, and isthmus fissure.

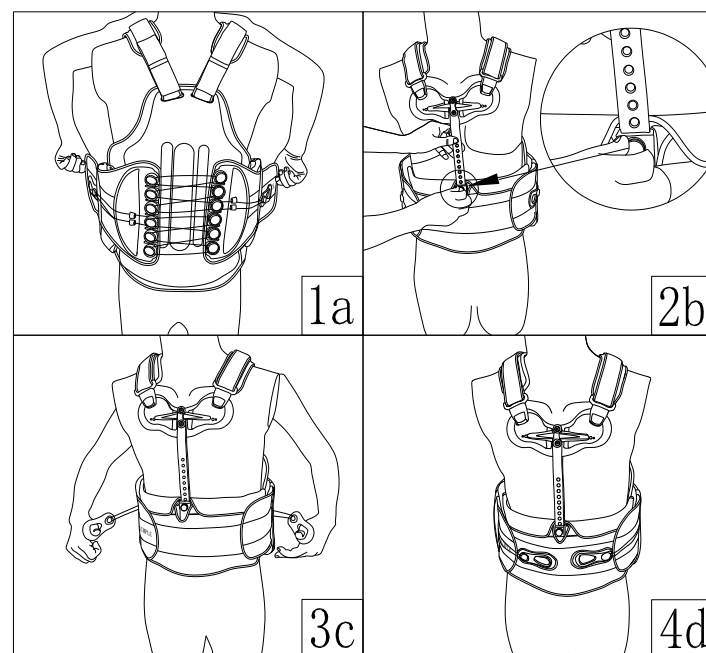
Product features and performance description

1) Product features and storage conditions

【Product features】 double independent pulley system, soft padded shoulder straps, tool-free linear thoracic adjustment, extendable posterior panel, removable anterior panel, maximum comfort and support

【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: The head passes through the shoulder straps, the center of the back plate is aligned with the spine, and the bottom of the back plate is about the sacra and tailjoint. First, the two sides of the pull ring are placed at the end of the hair surface and then the hook panel of both sides passes through the loose belt and is fixed to the hair surface panel. The front plate should be located in the center of the abdomen (Fig. 1a).

STEP2: Pull the circular metal button on the front panel and stretch the metal adjusting rod up and down until the upper edge of the chest pad should be located around the 1.27cm under the sternal jugular vein notch, and then loosen the button fixed position (Fig 2b).

***CAUTION 1:**

The correct position to wear: the center of the posterior dorsal plate is aligned with the spine, and the bottom is about the sacra and coccyx joint. The front plate should be in the center of the abdomen. The upper edge of the chest liner should be located in the left and right of 1.27cm under the sternal jugular vein notch and fitted to the sternum.

STEP 3: check that the wearing position is correct and comfortable, pull the pull rings on both sides outward so that the retainer tightens and pastes the body, and then adheres to the wool surface (Fig. 3c~).

STEP 4: Check again for the correct wearing position to adjust the length of the straps so that the straps and chest pads fit into line with the body. The length required for straps can be trimmed, and the quick buckle on the straps can also be used (figure 4 d).

***CAUTION 2:**

1. **This product is used only as a supporting brace and is not used or ensured to prevent spinal injuries.**
2. **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.**
3. **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: Lining 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. 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.

Basic product environment

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

Product material

- 1) Pad :sponge / EVA
- 2) hard board: polypropylene
- 3) shoulder straps: nylon
- 4)regulating rod: aluminum alloy

5) front panel: nylon

Contraindication

- ⚠ Do not use in case of allergy;
- ⚠ Those with unknown skin masses are forbidden;
- ⚠ The occurrence of unknown masses of the skin and those with broken ulcers are prohibited;
- ⚠ 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

	Manufacture Date		Batch Code
	medical device		CE Symbol
	Protect from sunlight		Hand wash only
	Do not use when the packing is damaged		
	Warnings and Precautions		
	Reference instructions		

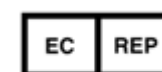
Accessories list

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**