

深圳简单医疗科技有限公司

肩部固定带

说明书

产品型号：31501/31502 产品规格：F



感谢您购买本公司产品！请在操作前仔细阅读本使用说明书！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：肩部固定带

1.2 产品型号：31501/31502

1.3 产品规格：F

1.4 产品结构：

肩部固定带主要由肩带，臂带和绑带等组成。

1.5 工作原理

产品使用方便，佩戴舒适，固定效果好。固定带采用柔软透气的材料，让患者配戴更舒适。可调节的肩带和臂带，让患者达到更好的康复效果。

1.6 适用范围

外用于肩关节脱臼或松脱，急慢性疼痛和炎症，肩关节退行性病变，肩关节扭伤。

二. 产品特点及性能描述

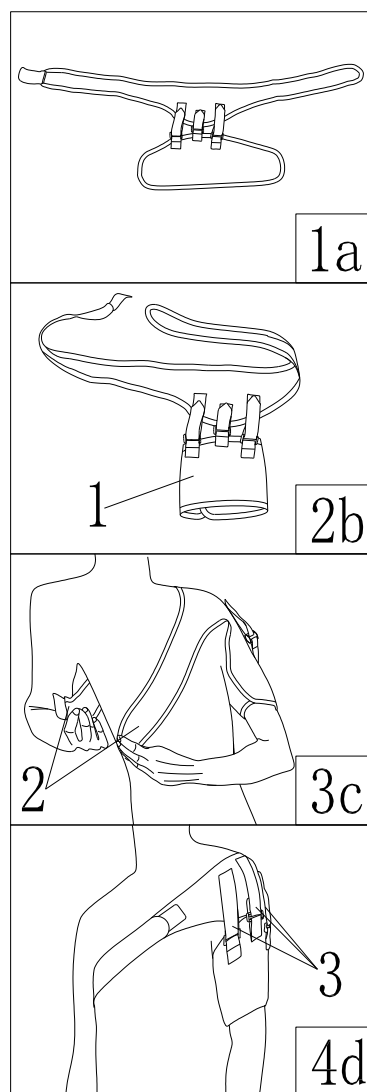
2.1 产品特点及贮存条件

【产品特点】产品简单，重量轻，多个调节，使用方便。

【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（图 1a）

步骤 2：将臂带 1 弯成手臂大小的圈再固定住（图 2b）

步骤 3：手穿过臂带 1 将肩带 2 放在肩部，再将肩带 2 前后固定住。（图 3c）

步骤 4：调整臂带 2 和绑带 3 的松紧度（图 4d）

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。

*此产品仅为固定装置，不用于预防伤害或者防止再次发生伤害更不能替代药品和医生的正确诊断。

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) 臂带/肩带：弹力布

2) 绑带：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，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】肩部固定器

【医疗器械备案凭证编号】

粤深械备 20200770 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 20200770 号

【备案人】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 08 月 12 号

【网址】www.simplemedical.cn



**Instruction For Use
Shoulder Brace E8**

Model: 31501/31502 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: Shoulder Brace E8
- 2)Product model: 31501/31502
- 3)Product specification: F
- 4)Product Structure:

Shoulder straps are mainly composed of shoulder straps, arm straps and straps.

5)Operating principle

The product is convenient to use, comfortable to wear and good in fixing effect. The fixing band adopts a soft and air-permeable material, so that the patient is more comfortable to wear. The adjustable shoulder strap and the arm strap allow the patient to achieve a better rehabilitation effect.

6)Scope of application

External use for dislocated or loose shoulder joint, acute and chronic pain and inflammation, degenerative lesions of shoulder joint, sprain of shoulder joint.

Product features and performance description

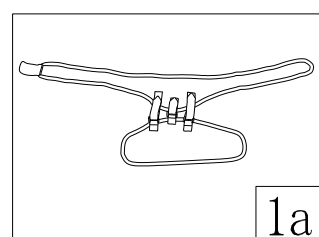
1) Product features and storage conditions

【Product features】 The product is simple and can be applied topically to patients with plantar fasciitis and pain

【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

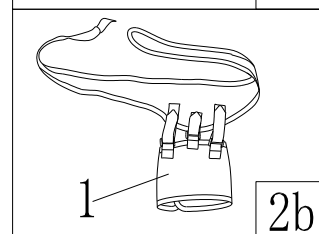
2) Using the operating

【Application Instructions】

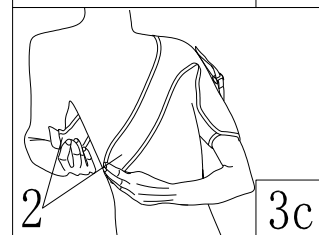


APPLICATION INSTRUCTIONS

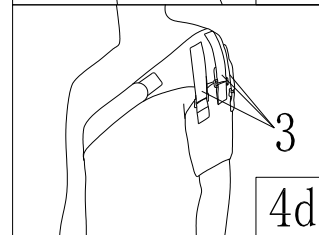
STEP 1: open the product (Fig 1a)



STEP 2: bend the wall band 1 into an arm-sized ring (Fig 2b)



STEP 3: put the shoulder strap on the shoulder through the arm band 1, And Then fasten the shoulder strap 2 back and forth. (Fig3c)



STEP 4:adjust the tightness of arm band 2 and tie band 3 (Fig 4d)

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.

Warning:

If you experience pain, swelling, irritation, or discomfort while using this product, discontinue use and consult your doctor.

*This product is only a fixture and is not used to prevent injury or prevent recurrence of injury, much less to replace the correct diagnosis of drugs and doctors

Basic product environment

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

Product material

- 1) Arm strap / shoulder strap: elastic cloth
- 2) 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
- CE Symbol

- Hand wash only
- Protect from sunlight
- 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
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Tel : +86-755-86038563
Web: www.simplemedical.cn
E-mail: info@simplemedicla.cn`

SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

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