

深圳简单医疗科技有限公司

锁骨固定带

说明书

产品型号：52301 产品规格：S/M/L



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：锁骨固定带

1.2 产品型号：52301

1.3 产品规格：S/M/L

1.4 产品结构：

产品主要由复合布，三角扣和魔术贴等组成。

1.5 工作原理

产品采用轻量化的设计，使用方便，佩戴舒适。产品适用于多种用途，穿脱方便。

1.6 适用范围

用于骨折或软组织等损伤的外固定。

二. 产品特点及性能描述

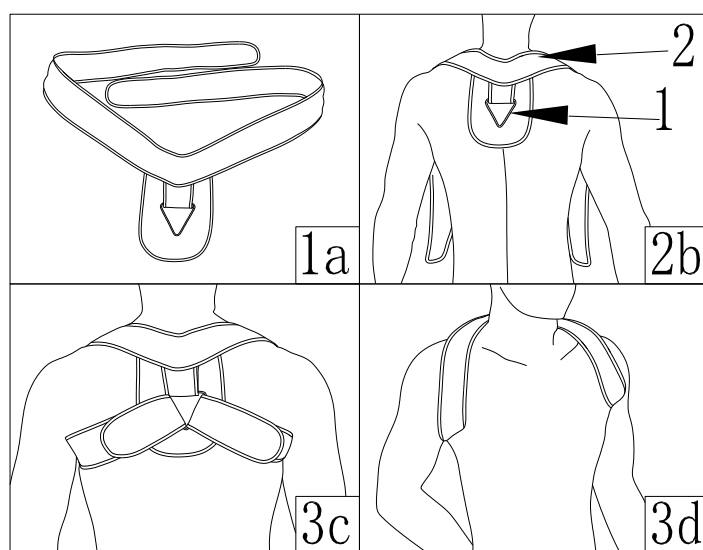
2.1 产品特点及贮存条件

【产品特点】产品使用方便舒适，受力均匀，松紧可调。

【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（如图 1a）。

步骤 2：将固定带 2 放在肩背部，金属三角扣 1 对准脊柱（如图 2）

步骤 3：分别将两侧的固定带 2 穿过三角扣 1 根据自身的穿戴舒适感再固定住（如图 3c~3d）。

警告：

固定带不要过紧，否则会有影响血液循环的风险，请慎重调整固定带的松紧度。

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。

*此产品仅为固定装置，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) 复合布：EVA 泡棉/尼龙

2) 三角扣：不锈钢

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：本产品在储存及运输的过程，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】锁骨固定带

【医疗器械备案凭证编号】

粤深械备 20200766 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 20200766 号

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【说明书修订日期】2020 年 07 月 21 号

【网址】www.simplemedical.cn



Instructions for Use Clavicle Support E7

(Model: 52301 Size: S/M/L)



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: Clavicle Support E7

2)Product model: 52301

3)Product specification: S/M/L

4)Product Structure:

Products are mainly composed of composite cloth, triangle buckle and magic paste.

5)Operating principle:

The product is designed with light weight and is convenient to use and comfortable to wear. The product is suitable for various purposes, and is convenient to wear and remove.

6)Scope of application:

For external fixation of injuries such as fractures or soft tissues.

Product features and performance description

1) Product features and storage conditions

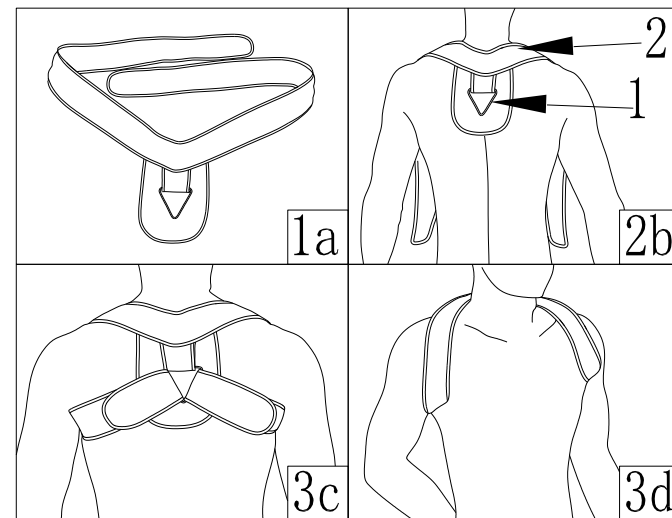
【Product features】

The product is easy to use, comfortable, light and adjustable.

【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).

STEP2: place the retainer 2 on the back of the shoulder, and the metal triangle buckle 1 pair the quasi-spine (Fig 2b).

STEP 3: refasten the fixed strap 2 through the triangular buckle 1 according to your wearing comfort (Fig 3c~3d).

NOTICE: Do not tighten the fixing tape too tightly; otherwise there will be a risk of affecting the blood circulation. Please carefully adjust the tightness of the fixing belt.

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) composite cloth: EVA foam / nylon

2) triangle buckle: stainless steel

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
Address: 519 Wisdom Valley, No.1010 Bulong Road,
Minzhi Street, Longhua District,
Shenzhen, China.518109
Tel : +86-755-86038563
Web: www.simplemedical.cn
E-mail: info@simplemedicla.cn`

EC REP
SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

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