

深圳简单医疗科技有限公司

产品说明书

肩部固定器

产品型号：31002 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：肩部固定器

1.2 产品型号：31002

1.3 产品规格：F

1.4 产品结构：

产品采用聚乙烯、尼龙、海绵材料制成。不与体内使用的医疗器械连接。非无菌提供。

1.5 工作原理

产品采用开放式设计和柔软透气型材料，使得产品使用方便，佩戴舒适。加固型的胸围带使手臂不易晃动具有双重保护作用。

1.6 预期用途

用于骨折或软组织损伤的外固定。

1.7 适用范围

外用于肩关节脱位和/或慢性半脱位后的非手术辅助治疗、肩胛骨骨折（非手术，术后）、肱骨头近端骨折（术后，非手术）、撞击综合症（非手术，术后）、肩锁关节脱位（术后，非手术）、肩锁关节关节炎（术后，非手术）、骨关节炎疼痛的非手术辅助治疗。

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】舒适透气，穿戴方便，调整方便，左右臂通用。

【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：佩戴前将吊带打开，将受伤的手臂放进打开的吊带中。（图 1a）

步骤 2：将吊带利用魔术贴合上。（图 1a~2b）

步骤 3：将未受伤的手臂穿过由绑带 1、绑带 2 和绑带 3 组成的套环，将绑带 1 拉至胸前，合上绑带 1 的插扣，调整肩带至合适位置。（图 3c）

注意：如有可能，脱下和穿戴都应在桌子上进行。如果辅助用具穿戴过紧，可能产生局部压力或者压迫血管或神经。因此，请在主治医师的建议下进行佩戴。



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) 肩带：尼龙

2) 肩衬垫：海绵

3) 大身网兜：海绵

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；

⚠ 需要外展和外旋的适应症禁用。

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 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

📖 参考使用说明

📅 制造日期

六. 配件清单

说明书----- 1 份

七. 保修

深圳简单医疗科技有限公司保证该产品在购买时不存在材料和工艺方面的缺陷，如果保修期内有产品问题，深圳简单医疗科技有限公司的唯一义务是维修或更换有缺陷的产品或零部件。

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 20180613 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 20180613 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 07 月 22 号

【网址】www.simplemedical.cn

Instruction for Use

SIMPLE Shoulder Brace E3

Model: 31002 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 Shoulder Brace E3

2)Product model: 31002

3)Product specification: F

4) Product Structure

The products are made of polyester fiber and nonwoven fabric. Not connected to medical devices used in the body. Non-sterile delivery.

5)Operating principle

The product adopts open design and soft and breathable material, making the product easy to use and comfortable to wear. The reinforced chest strap makes the arm not easy to move with double protection.

6)Scope of application:

Nonsurgical treatment after anterior shoulder dislocation and /or chronic subluxation, After rotator cuff repair, Acromioclavicular joint dislocation (nonsurgical, postoperative), Scapula fractures (nonsurgical, postoperative), Fractures of the humerus head (nonsurgical, postoperative).


Product features and performance description

1) Product features and storage conditions

【Product features】 The product is comfortable and breathable, easy to wear, easy to adjust, left and right arms universal.


【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】**

 Step 1: Open the sling before wearing and place the injured arm into the open sling. (Fig 1a)

Step 2: Apply a magic fit to the sling. (Fig 1a~2b)

 Step 3: Put your uninjured arm through the collar consisting of Strap 1, strap 2, and strap 3, pull strap 1 to your chest, close the buckle of strap 1, and adjust the shoulder strap to the appropriate position. (Fig 3c)

 **Note: If possible, take off and put on at the table. If the AIDS are worn too tightly, they may create local pressure or compress blood vessels or nerves. Therefore, please wear it on the advice of your attending physician.**

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)chest strap / shoulder strap: Polyester


2) shoulder pad: non woven fabric


3) big net pocket: Polyester

Contraindication

 Do not use in case of allergy;

 Those with unknown skin masses are forbidden;

 Those with swollen or ulcerated skin are forbidden;

 Do not use indications that require abduction and external rotation.

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

 Hand wash only

 Protect from sunlight

 Do not use when the packing is damaged

 Warnings and Precautions

 Expiry Date

 Reference instructions

Accessories list

Instructions ----- 1 copy

Warranty

Simple Medical (Shenzhen) Limited warrants to the user who originally purchases this product that it is free from defects in material and workmanship. The sole obligation of Simple Medical (Shenzhen) Limited in the event of breach of warranty shall be to repair or replace the defective product or part(s).

 **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**

 **31002 V0.3**