

深圳简单医疗科技有限公司

产品说明书

肩臂固定带

产品型号：31802/31803 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：肩臂固定带

1.2 产品型号：31802/31803

1.3 产品规格：F

1.4 产品结构：

产品主要由 45° 肩外展枕，肩带，腰带，绑带和魔术贴等组成。

1.5 工作原理

产品采用开放式设计，通过将患者的手臂固定在中性位置上以防止内部旋转。肩带、腰带和腰部形成三角结构，有效减轻颈部压力。45° 外展枕弧形设计，更贴合腰部，施力均匀让患者更舒适。

1.6 适用范围

适用于肩部软组织损伤或术后使用，肩袖撕裂、肩关节脱位、肩部矫形术后使用，骨折的保守质量、稳定性骨折或复位后的骨折、骨折固定术后使用。

二. 产品特点及性能描述

2.1 产品特点及贮存条件

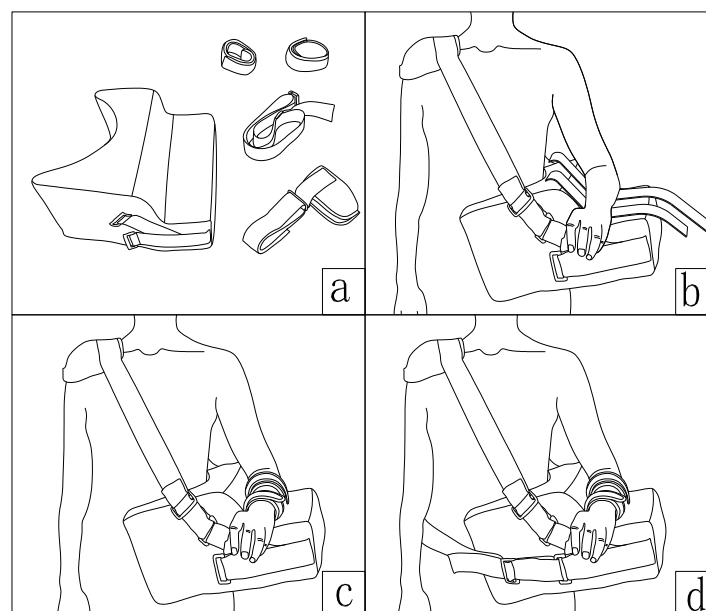
【产品特点】 肩关节外展固定，容易配合，调节方便，弧形设计，佩戴舒适。

【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 a）

步骤 2：先将绑带放在肩外展枕上，固定好肩带的一侧。再将肩外展枕放至腰部，肩带环绕肩部固定在肩外展枕的另一侧并调整到舒适的长度，手臂放至于肩外展枕处。（图 b）。

步骤 3：固定手臂下的绑带，防止手臂移动（图 c）。

步骤 4：固定腰带并调整好腰带的长度（图 d）。

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。肩外展枕内的枕芯不可清洗。

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/腰带：尼龙/海棉

2) 肩外展枕：尼龙/海绵

3) 绑带：尼龙/海绵

4) 扣：聚乙烯

5) 魔术贴：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，保证室内通气。

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

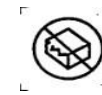
⚠ 注意，警告

🚫 禁止机洗

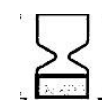
☀ 避免日晒



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

45° 肩外展枕----- 1 个

肩带----- 1 条

腰带----- 1 条

绑带----- 2 条

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】 肩臂固定带

【医疗器械备案凭证编号】

粤深械备 20200617 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 20200617 号

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1010 号智慧谷创新园 519

【电话】 0755-86038563

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【邮政编码】 518000

【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】 2020 年 07 月 08 号

【网址】 www.simplemedical.cn



Simple Medical (Shenzhen) Limited Instruction For Use

Arm Sling Shoulder Brace E9

Model: 31802/31803 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: Arm Sling Shoulder Brace E9

2)Product model: 31802/31803

3)Product specification: F

4) Product Structure:

The product mainly consists of 45° shoulder abductor, shoulder strap, belt, bandage and Velcro

5) Operating principle

The product was designed in an open format to prevent internal rotation by fixing the patient's arm in a neutral position. The shoulder strap, belt and waist form triangle structure, which can effectively reduce the neck pressure. 45° Outward pillow arc design, more close to the waist, uniform force to make patients more comfortable.

6) Scope of application:

Suitable for shoulder soft tissue injury or postoperative use, rotator cuff tear, dislocation of shoulder joint, after shoulder or thoplasty, conservative quality of fracture, stable fracture or fracture after reduction, fracture fixation after operation.

Product features and performance description

1)Product features and storage conditions

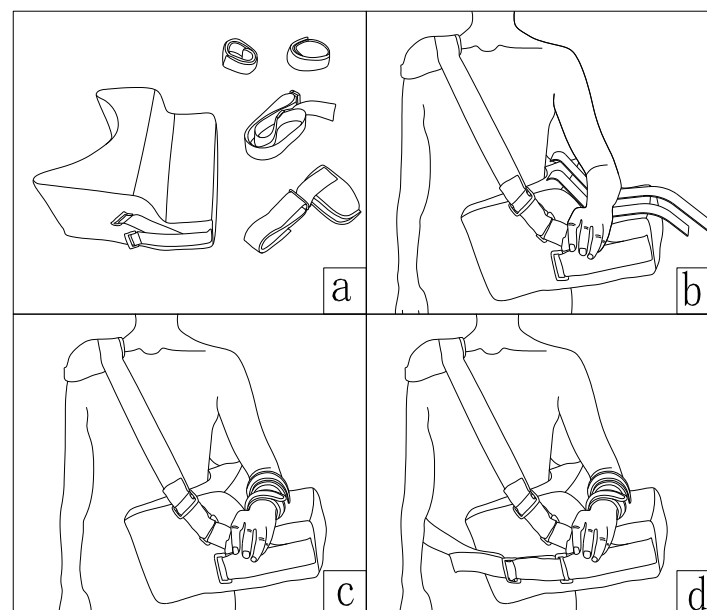
【Product features】 shoulder joint abduction fixation, easy to fit, easy to adjust, arc design, comfortable to wear

【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 a)

STEP 2: First place the strap on the shoulder outer pillow and fix the side of the shoulder strap. Then put the shoulder-extension pillow to the waist, the shoulder strap around the shoulder is fixed on the other side of the shoulder-extension pillow and adjusted to the comfortable length, and the arm is placed at the shoulder-extension pillow. (Fig b).

STEP 3: Fix the strap under the arm to prevent arm movement (Fig c).

STEP 4: Fix the belt and adjust the length of the belt (Fig d)

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. The occipital core in the external pillow of the shoulder cannot be cleaned

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) Shoulder strap: nylon/ sponge

2) Straps: nylon

3) shoulder abduction pillow: nylon/ sponge

4) Buckle: Polyethylene

5) magic patch: 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

Outer shoulder pillow 45°----- 1 PCS

Belt ---- 1PCS

Straps ----- 2 PCS

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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 SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

*Please refer to the Instructions before usage