

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：31014 产品规格：F



感谢您购买公司产品！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：31014

1.3 产品规格：F

1.4 产品结构：

采用聚乙烯、尼龙、海绵材料制成。非无菌提供，不与体内使用的医疗器械连接。

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。30° 肩枕弧形设计，更贴合腰部，施力均匀让患者更舒适。

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

适用于肩袖修复术后、肩锁关节脱位后、肩关节假体植入术后、肱骨头骨折、肩峰撞击综合症、肱二头肌肌腱撕裂术后辅助治疗。

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】尼龙卡扣连接，便于调节外展角度，按人体工学设计的弧形海绵，穿戴舒适，加宽肩带腰带设计，带透气肩垫穿戴不紧勒。

【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：佩戴前将垫枕的插扣及吊带打开，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，肩枕的腰带#4 从背后拉到前方，调整合适的松紧位置后合上插扣。（图 1a~2a）

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 3a）

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，请在主治医生的建议下进行佩戴。

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。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) 肩枕：尼龙/海绵

3) 扣：聚乙烯

4) 魔术贴：尼龙

5) 吊带：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；

⚠ 皮肤肿破溃瘍者禁用；

⚠ 大于 30° 外旋、内旋或外展的适应症禁用。

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

🏭 制造日期

📖 参考使用说明

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】

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【说明书修订日期】2024 年 07 月 22 号

【网址】www.simplemedical.cn

Simple Medical (Shenzhen) Limited Instruction For Use

SIMPLE Shoulder Brace E14

Model: 31014 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 E14
- 2) Product model: 31014
- 3) Product specification: F
- 4) **Product Structure:**

Products are mainly composed of 30° external rotation shoulder strap, shoulder strap, belt, bandage, Velcro and so on.

5) Operating principle

The product has an open design that prevents internal rotation by holding the patient's arm in a neutral position. The shoulder strap, belt and waist form a triangular structure to effectively reduce neck pressure. 30° external rotary pillow arc design, more fit waist, uniform force to make patients more comfortable.

6) Scope of application:

After rotator cuff repair, Humeral head fractures (nonsurgical, Postoperative), After insertion of shoulder prosthesis, After stabilization of acromioclavicular joint dislocations, After biceps tenodesis, After biceps tenodesis, Impingement syndrome (nonsurgical, postoperative).

Product features and performance description

1) Product features and storage conditions

【Product features】 Nylon buckle connection, easy to adjust the abduction Angle, ergonomically designed arc sponge, comfortable to wear, widened shoulder belt belt design, with breathable shoulder pad wear no tight.

【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 buckle and sling of the cushion before wearing, and place the injured arm into the open sling. (Fig 1a)



STEP 2: Use Velcro to close the suspenders, pull the belt #4 of the shoulder pillow from the back to the front, adjust the appropriate elastic position, and close the buckle. (Fig 1a~2a)



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 3a)

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℃ 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 ℃
- 2) Relative humidity: 80%

Product material

- 1) Shoulder strap: nylon/ sponge
- 2) shoulder pillow: nylon/ sponge
- 3) Buckle: Polyethylene
- 4) magic patch: nylon
- 5) Sling: sponge

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 for indications greater than 30° pronation or abduction.

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
- Expiry Date
- Hand wash only
- Protect from sunlight
- Do not use when the packing is damaged
- Warnings and Precautions
- 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).

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*Please refer to the Instructions before usage

31014 V0.1