

## 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：31001 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：31001

1.3 产品规格：F

1.4 产品结构：

采用聚乙烯、尼龙、海绵等材料制成。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。吊带和腰带采用插扣式连接让患者穿戴更方便。

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

适用于三角肌麻痹，上肌腱断裂，肩臂关节骨折脱位，肩臂关节手术支撑，臂丛损伤辅助治疗。

#### 二. 产品特点及性能描述

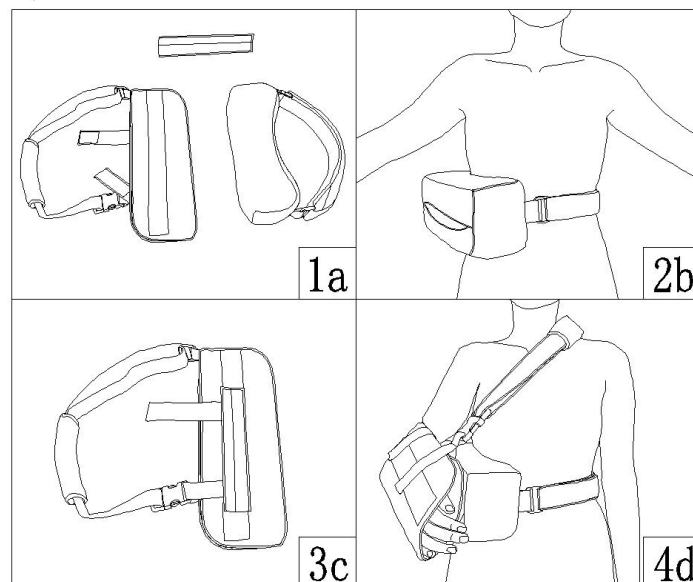
2.1 产品特点及贮存条件

【产品特点】肩关节外展固定，容易配合，调节方便。

【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：松开腰带的插扣，将肩枕放置腰部，连接插扣。再调整腰带的长度，使腰带与腰部贴合（图 2b）。

步骤 3：将双面魔术贴条贴在靠近身体一侧的主体吊兜毛面上（图 3c）。

步骤 4：松开吊兜外侧的两条固定带和肩带插扣，将手放入吊兜内，把固定带固定在吊兜的毛面上后，将吊兜放在肩外展枕上，肩带穿过肩膀连接肩带插扣，再调整肩带到合适的长度使肩垫位于肩膀处（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。

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：尼龙/海棉

2) 主体吊兜：尼龙/海绵

3) 肩枕：尼龙/海绵

4) 扣：聚乙烯

5) 双面魔术贴片：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

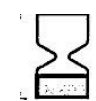
🚫 禁止机洗



避免日晒



包装破损时切勿使用



有效期



制造日期



参考使用说明

#### 六. 配件清单

说明书----- 1 份

30° 肩外枕----- 1 个

双面魔术贴条----- 1 个

#### 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

## Simple Medical (Shenzhen) Limited Instruction For Use

SIMPLE Shoulder Brace E5

Model: 31001 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 E5

2)Product model: 31001

3)Product specification: F

### 4) Product Structure:

It is made of polyethylene, nylon, sponge and other materials. Non-sterile delivery, not connected to medical devices used in the body.

### 5) Operating principle

The product is open-ended designed to prevent internal rotation by fixing the patient's arm in a neutral position. The shoulder belt, the waistband and the waist form a triangular structure, and the neck pressure is effectively reduced. The detachable holding force rehabilitation ball is convenient to use and can exercise the gripping force of the hand finger at any time. The strap and the belt are in a snap-fit connection to make the patient wear more convenient.

### 6) Scope of application:

It is suitable for trigonometry, upper tendon rupture, shoulder and arm joint fracture and dislocation, shoulder and arm joint operation support, brachial plexus injury.

### Product features and performance description

1)Product features and storage conditions

#### 【Product features】

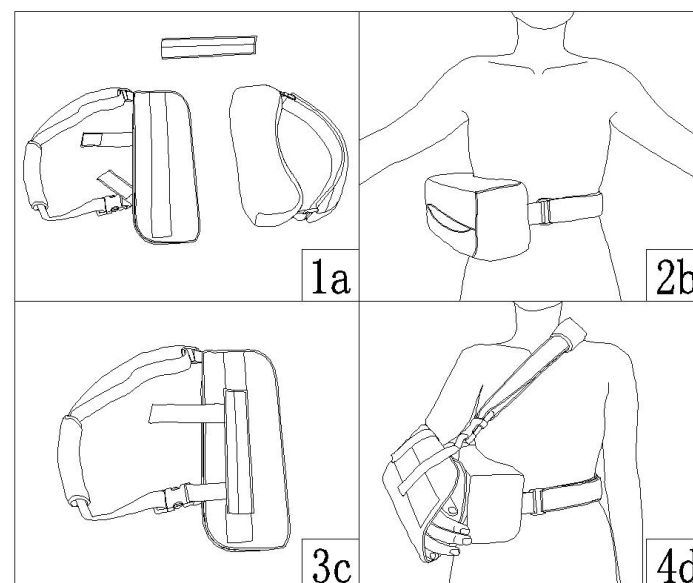
Fixation with shoulder abduction, Easy fit and convenient adjust

#### 【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:** Loosen the buckle of the belt, place the shoulder pillow at the waist, and connect the buckle. Adjust the length of the belt so that the belt fits with the waist (Fig. 2b).

**STEP 3:** Stick the double-sided magic sticker on the hair surface of the main pocket near one side of the body (Fig. 3 c).

**STEP 4:** Loosen the two straps and shoulder straps on the outside of the sling pocket, place the hand in the sling pocket, fix the fastening belt on the hairy surface of the sling pocket, place the sling on the shoulder spread pillow, connect the shoulder strap buckle through the shoulder, and adjust the shoulder belt to the appropriate length so that the shoulder pad is located at the shoulder (Fig4 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 ccipital 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) Main body suspension: nylon/ sponge

3) shoulder abduction pillow: nylon/ sponge

4) Buckle: Polyethylene

5) grip ball: EVA

6) Double-sided 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

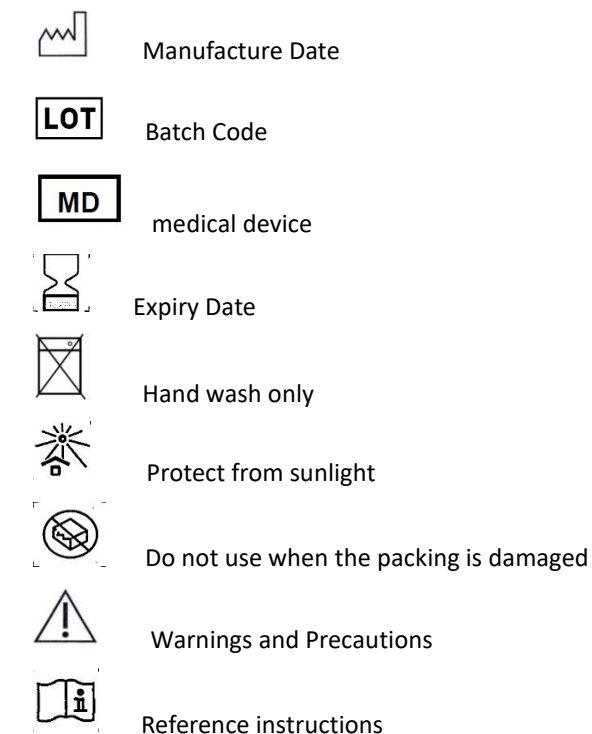
2 )Product storage: Please place it in a dry and clean room before use to ensure ventilation

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



### Accessories list

Instructions ----- 1 copy

Outer shoulder pillow 30°----- 1 PCS

Grip ball----- 1 PCS

Double sided magic sticker----- 1 PCS

### 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

**EC REP**  
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

**CE** 31001 V0.2