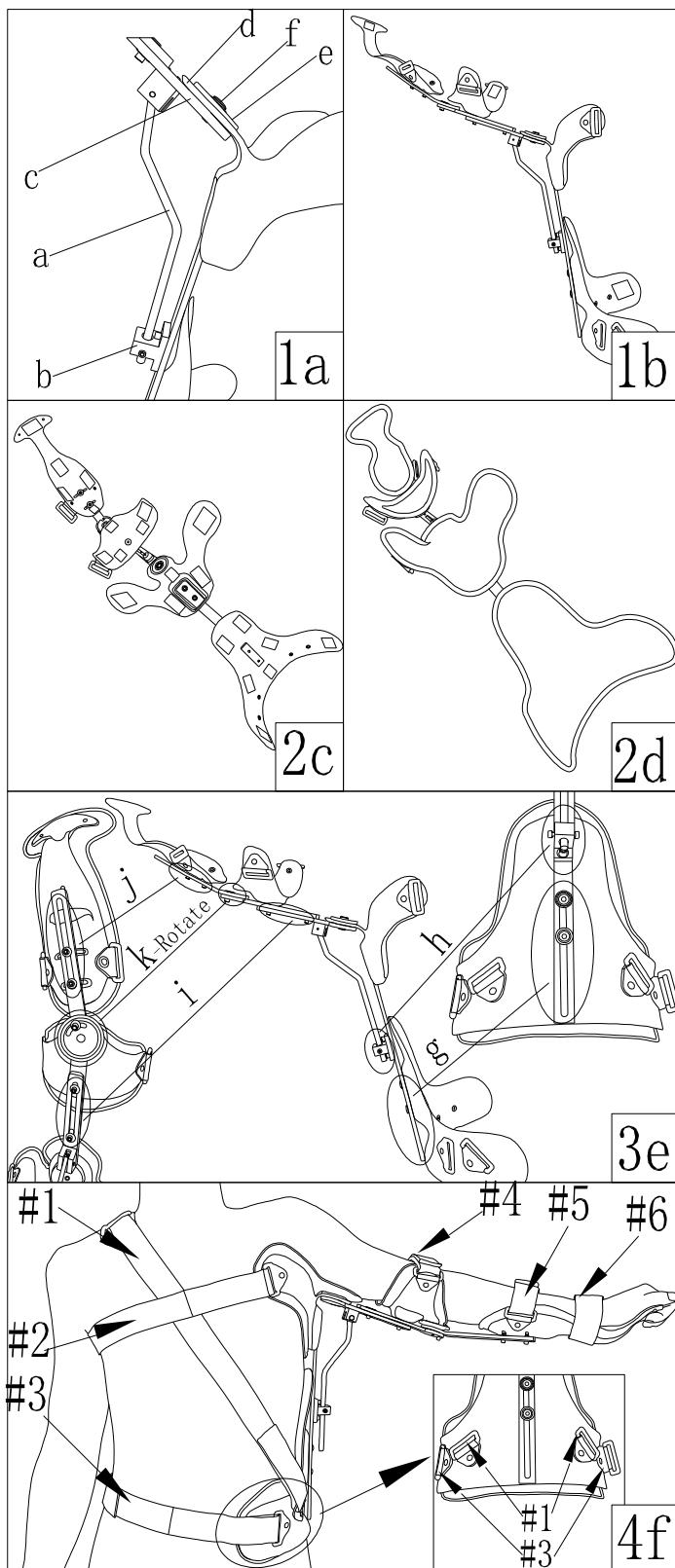


深圳简单医疗科技有限公司

产品说明书

肩部固定器

产品型号：31003/31004 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：31003/31004

1.3 产品规格：F

1.4 产品结构：

肩部固定器主要由金属支架，金属调节杆，塑胶支架，绑带，衬垫及配件等组成

1.5 工作原理

产品采用轻量化的设计，使用方便，佩戴舒适。所述产品固定效果好，可调节手臂的高低，长度及肘部的屈伸，舒适透气的衬垫能够让患者达到更好的康复效果。

1.6 适用范围

外用于肩关节术后固定，肱骨骨折合并桡神经损伤、三角肌麻痹、冈上肌腱断裂，肩关节骨折、脱位后臂丛麻痹，急性肩周炎、肩关节化脓性关节炎、肩关节结核。

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】产品简单，重量轻，多个调节，使用方便。

【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：安装支架。拧开手臂链的支架圆形固定件(c & e)，将高度调节杆(a)放进调节座里面(b)，再将手臂的圆形固定件一上一下固定肩部塑胶支架(d)再用螺丝(f)锁紧(图 1a~1b)

步骤 2：装衬垫。将衬垫安装在相应的位置(图 2c~2d)。

步骤 3：调节支具(图 3c)。将肩部支撑架放置在腋下一点处，并用手固定住。

a) 调节腰部支架(g)的高度至腰部。

b) 然后根据患者的需求来调节高度调节杆(a)，并用工具拧紧调节座两边的螺丝，使调节杆固定住(h)。

c) 调节手臂链的长度(j & i)调节后再拧紧各调节的螺丝，确保支具的安全使用。

d) 调节手肘部位的屈伸角度(k-Rotate)。

步骤 4：固定绑带。在固定绑带时，固定器应保持支撑状态，以防支具移动。先将绑带套套在绑带#1(最长)上。将绑带穿过绑带扣，魔术贴贴紧在绑带上绕过各部位再穿过另一个绑带扣并固定住(图 4f)。系绑带顺序如下：

绑带#1：系肩部，固定支具。

绑带#2：系上半身部。

绑带#3：系腰部。

绑带#4：系手肘部。

绑带#5：系手腕与手肘中间部。

绑带#6：系手腕处。

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。

*此产品仅为支撑装置，不用于预防伤害或者防止再次发生伤害。

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) 塑胶支架：聚丙烯

2) 金属支架：铝合金

3) 衬垫：尼龙/PU

4) 绑带：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

大六角扳手----- 1个

中六角扳手----- 1个

小六角扳手----- 1个

绑带套----- 1个

衬垫----- 5个

绑带----- 6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】

粤深食药监械生产备 20170002 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

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【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 16 号

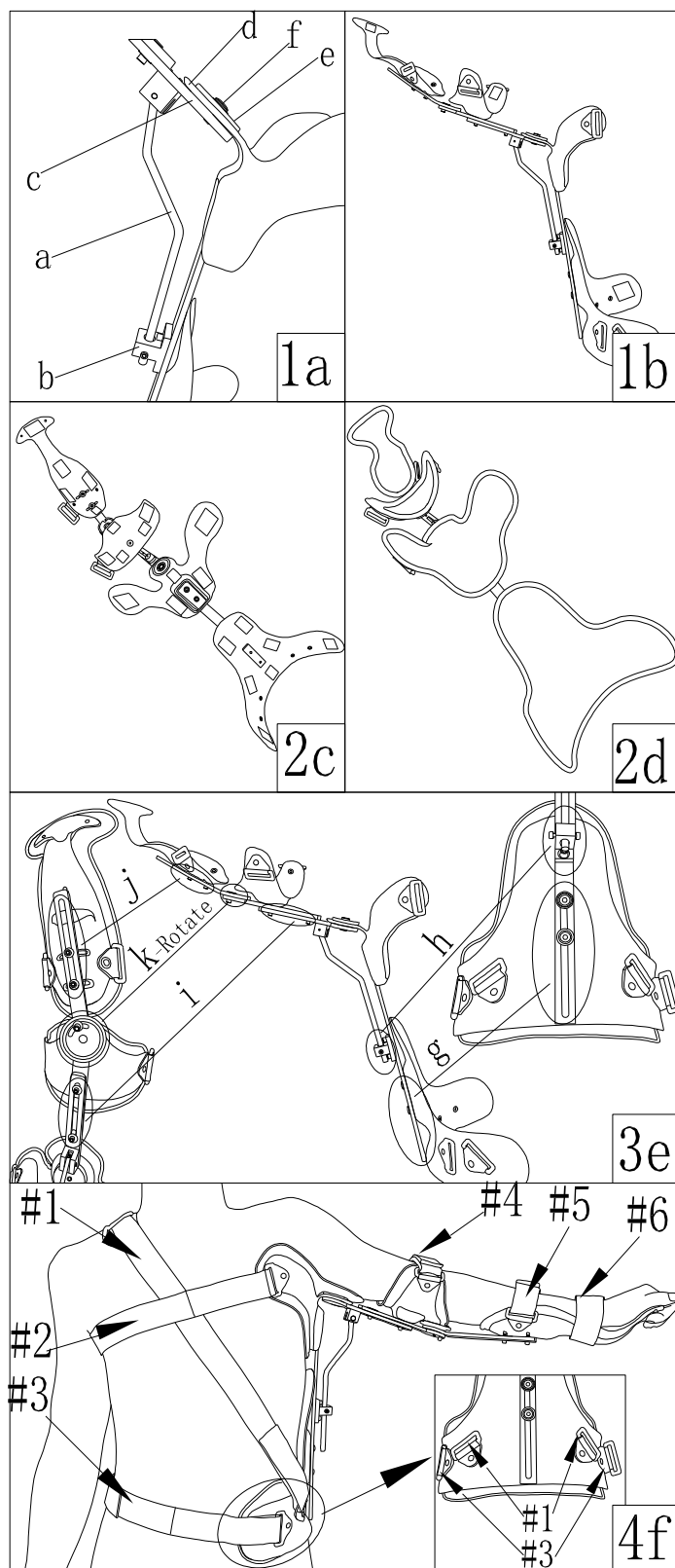
【网址】www.simplemedical.cn



Simple Medical(Shenzhen)Limited Instruction For Use

Shoulder Abduction Immobilizer E6

Model: 31003/31004 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: Shoulder Abduction Immobilizer E6
- 2)Product model: 31003/31004
- 3)Product specification: F
- 4)Product Structure:

The shoulder Brace is mainly composed of metal support, metal adjusting rod, plastic bracket, strap, liner and accessories.

5)Operating principle: The product adopts lightweight design, easy to use and comfortable to wear. The product has good fixing effect, adjustable arm height, length and elbow flexion and extension, comfortable and breathable gasket, so that the patient can achieve better recovery effect.

6)Scope of application

external use for shoulder joint postoperative fixation, humeral fracture with radial nerve injury, deltoid muscle paralysis, supraspinatus tendon rupture, shoulder fracture, posterior brachial plexus paralysis, acute shoulder peri arthritis, shoulder suppurative arthritis, and shoulder tuberculosis.

Product features and performance description

1) Product features and storage conditions

【Product features】 The product is simple and can be applied topically to patients with plantar fasciitis and pain

【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: Install the bracket. Unscrew the bracing circular retainer (c & e) of the bracelet chain and put the height adjusting rod (a) into the inside of the adjusting seat (b), Then fix the circular fixture of the arm on the shoulder plastic bracket (d) Use the screw (f) to lock (Fig1a~1b).

STEP 2: Install the liners. Install the liner in the appropriate position (Fig2c~2d).

STEP 3: Adjust the brace (Fig 3c). Place the shoulder support at a point under the armpit and fix it with your hands.

A) Adjust the height of the waist bracket (g) to the waist.

B) Then adjust the height adjusting rod (a), according to the patient's needs and tighten the screws on both sides of the adjusting seat with tools so that the adjusting rod is fixed to the (h).

C) Adjust the length of the bracelet chain (j & i) and then tighten the adjusting screws to ensure the safe use of the braces.

D) Adjust the flexion and extension angle of elbow (k-Rotate).

STEP 4: Fasten the straps. When fixing the straps, the retainer should maintain a supporting state to prevent the brace from moving. First put the binding sleeve on the strap # 1 (longest).

Fasten the straps through the strap buckle, magic fasten around each part of the strap and fasten it through another strap buckle (Fig. 4F).

The order of straps is as follows:

Strap# 1: Tie the shoulder and fix the brace..

Strap # 2: Fasten the upper body.

Strap # 3: Fasten the waist.

Strap # 4: Fasten your elbows.

Strap # 5: Fasten the middle of the wrist and elbow.

Strap # 6: Fasten your wrists.

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 for support only and is not intended to prevent injury or to prevent the recurrence of injuries.

Basic product environment

- 1) Ambient temperature: -15 ~ 60 °C
- 2) Relative humidity: 80%

Product material

- 1) Plastic bracket: polypropylene
- 2) Metal support: aluminum alloy
- 3) Liners: nylon / PU
- 4) Strap: 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
- Large hexagonal wrench ----- 1 PCS
- Middle hexagonal wrench ----- 1 PCS
- Small hexagonal wrench ----- 1 PCS
- Strap sleeve ----- 1PCS
- Liners ----- 5 PCS (sets)
- Straps----- 6 PCS (sets)

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.

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SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

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