

Simple Medical(Shenzhen)Limited Instruction for Use

Post-Op Elbow Brace E1

Model: 41003 & 41004 Size: F



1a



2a



3a



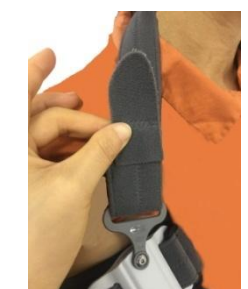
3b



3c



4a



5a



5b

Product Structure and Performance

The supports are mainly made of aluminum alloy supports, polymer material accessories, straps, linings and accessories. The product is used to limit flexion and extension and control the range of activities after elbow trauma and repair after surgery. The product adopts streamlined lightweight design. Equipped with a support and comfortable non-slip lining, through the support so that the elbow joint with the upper and lower arms have proper protection, special contour design to provide smooth flow to the elbow and improve patient protection.

INDICATIONS

- Post-operative immobilization or ROM control for elbow.
- Conservative treatment of elbow dislocation or luxation
- The distal humerus, radius and proximal ulna are stable or fixed for fracture

APPLICATION INSTRUCTION

NOTICE: This product must be installed and adjusted by a doctor or professional.

STEP 1. Open the product, remove the strap from the strap buckle, and then position the pivot center of the product link on the external epicondyle of the humerus (external elbow)(Fig 1a).

STEP2: Adjust the length of the connecting rod. Push the telescopic adjustment key on the connecting rod support in the direction of "UNLOCK " to unlock the connecting rod, slide the support to the required length, and then push in the direction of" LOCK " to lock the connecting rod. When wearing, make sure that the telescopic adjustment key of the connecting rod is in the "LOCK " position (Fig 2a).

NOTICE: The lower extension (ulnar side of arm) should extend to styloid process (mass inside wrist). The upper extension (humerus side of the arm) should extend to the armpit or the most comfortable position of the armpit.

STEP3: Fasten the strap. Hold the brace by hand to prevent movement. Start close to the elbow, then wrap the strap down around the arm through the strap, then clip the strap with the crocodile's mouth. The order of ties is as follows:

Strap #1: Fasten the lower elbow.

Strap #2: Fasten upper elbow.

Strap #3: Tie wrist.

Strap #4: Tie the upper part of the arm, don't be too tight. too tight may lead to slow blood circulation or uncomfortable wearing (Fig3a-3c).

STEP 4: Adjust the range of activities. Press the flexion or extension angle adjustment button, move to the marked angle scale as needed, and then press the lock button on the chuck to prevent the connecting rod from moving (figure 4a).

STEP 5: First, the longest strap goes from inside to outside through the "T" strap buckle at the top of the arm. (Fig.5a) The straps were then placed around the neck from the inside to the outside around the wrist through the "T" strap buckle with the alligator's mouth clamped to the straps as needed (5b).

Note:

The locking button on the connecting rod support of the reducer is not in the "UNLOCK" direction for a long time.

Post-operative wearing:

It is up to the doctor to set the angle of hinge brace and the angle of flexion and extension as well as the amount of time to wear each day until your attending physician agrees that you can remove the bracing.

***Please purchase and use the product under the guidance of your doctor or professional.**

* IMPORTANT :

- 1) Products are for individual patients and are not recommended for multiple patients.
- 2) Before adjusting the brace, the patient should consult his own doctor.

3) This product shall be purchased and installed on prescription by a medical practitioner and worn.

4) Proper rehabilitation and activity improvement are also indispensable processes in safe treatment planning.

Strap length adjustment

Determine the required length, open the Velcro at the strap end, separate the Velcro at the strap end stick and strap, cut strap to the desired length, and then stick the Velcro at the strap end back to the end of the strap.

LOCKING INSTRUCTION

- 1) Determine the desired locking angle
- 2) Slide the adjustment button toward the center of the hinge to lock the hinge angle.

CARE AND MAINTENANCE

Liners 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.

Metal parts should not be washed with water.

WARNINGS:

If you feel pain, swelling, change of sensation, or discomfort when using this product, please stop using it and contact your doctor.

Basic application environment

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

Product materials

- 1)Metal bracket: aluminum alloy/stainless steel
- 2)plastic bracket: polyamide
- 3)Button / buckle: polyformaldehyde
- 4) Rivet: stainless steel
- 5)Strap/pad: nylon / polyurethane / polyester / EVA/ magic paste

Contraindication

- ⚠ Use with caution for unstable fractures;
- ⚠ Use with caution in osteoporosis;
- ⚠ Use with caution for cognitive impairment;
- ⚠ Use with caution for bony ankylosis;

Storage, transportation and expiry date of products

- 1) Term of validity: 5 years.
- 2) Storage of the product: please put it in a dry and clean room before use to ensure indoor ventilation.
- 3) Transportation: the product shall be dustproof, moisture-proof and pollution-proof during storage and transportation.

Waste disposal

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
- Protect from sunlight
- Hand wash only
- Do not use when the packing is damaged
- Warnings and Precautions
- Reference instructions

Accessories list

Instructions ----- 1 copy

After-sales warranty

Warranty: all products from the date of purchase as the original date, normal wear and tear of the product in the use of the process is not considered defective.

The following parts from the date of purchase to the warranty period, if there is any material or process defects, please contact your seller directly, Simple medical will completely or partially repair or replace the braces and accessories.

Metal bracket ---- 1 year

Simple Medical (Shenzhen) Limited
Address: 519 Wisdom Valley, No.1010 Bulong Road,
Minzhi Street, Longhua District,
Shenzhen, China.518109
Tel : +86-755-86038563
Web: www.simplemedical.cn
E-mail: info@simplemedicla.cn`

SUNGO Europe B.V.

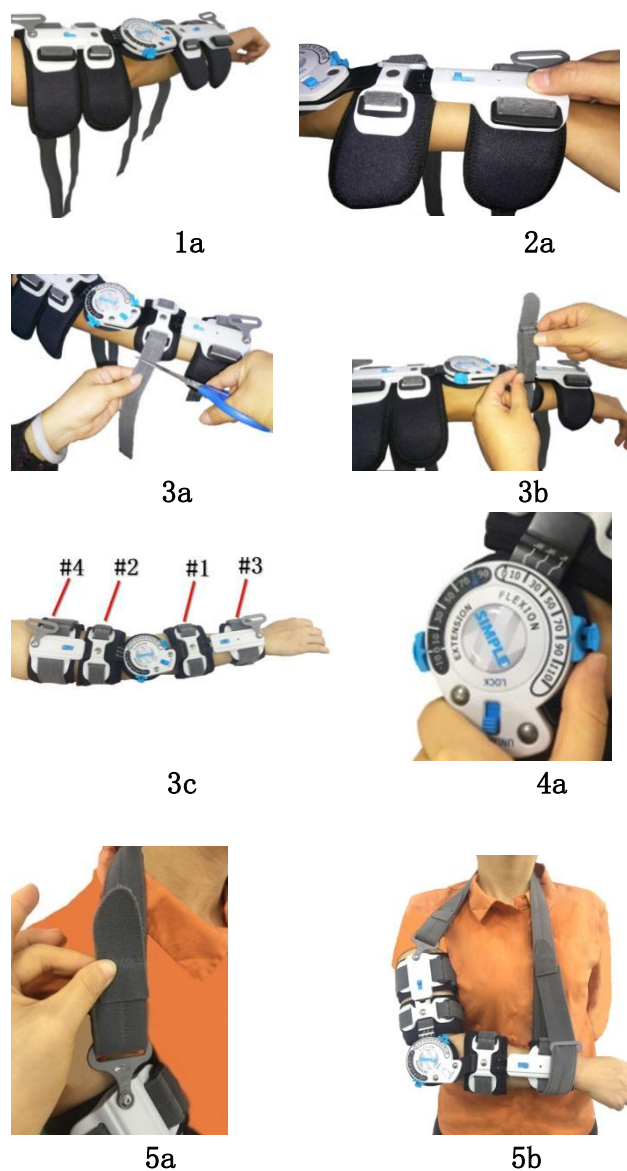
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

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

深圳简单医疗科技有限公司 产品说明书

肘部固定器

产品型号：41003/41004 产品规格：F



一. 产品结构及性能

支具主要由铝合金支架，高分子材料配件，绑带，衬里及配件等组成。产品用于限制屈伸和伸展，控制肘关节创伤后以及手术后修复的活动范围。产品采用流线型轻量化的设计。设置有支撑器和舒适的防滑衬里，通过支撑器使得肘关节与上下手臂有妥帖的保护，特别的轮廓设计，为肘部提供顺畅的流动性和提高患者的保护性。

二. 适应症

- 肘关节术后固定
- 肘关节脱臼的保守治疗
- 肱骨远端，桡骨、尺骨近端的稳定或骨折固定

三. 应用说明

注意：本产品须由医生或专业人员来安装和调整。

步骤 1:

打开产品，将绑带从绑带扣上取出后，再将产品连杆枢轴中心定位在肱骨外上髁上(外肘) (图 1a)。

步骤 2:

调整连杆的长度。把连杆支架上的伸缩调整键往“UNLOCK”方向推为解锁连杆，滑动支架到所需的长度，再往“LOCK”方向推来锁住连杆。**穿戴时请确保连杆的伸缩调整键处于“LOCK”位置上** (图 2a)。

注意：

下延伸部分(手臂尺骨侧)应延伸至茎突(手腕内侧的肿块)。上延伸部分(手臂的肱骨侧)应该延伸到腋窝或腋窝最舒适的位置。

步骤 3:

紧固绑带。用手固定住支具防止移动。从靠近肘部开始，依次将绑带往下环绕手臂穿过绑带扣，再用鳄鱼嘴魔术贴夹住绑带，最后紧固绑带。系绑带的顺序如下：

绑带#1：系肘下部。

绑带#2：系肘上部。

绑带#3：系手腕处。

绑带#4：系手臂上部，不要过紧。过紧可能会导致血液循环缓慢或佩戴不舒适 (图 3a~3c)。

步骤 4:

调整活动范围。按下屈伸或伸展的角度调整按钮，根据需要移动到标示的角度刻度上，再按下卡盘上的锁住按钮以防止连杆移动 (图 4a)。

步骤 5:

先将最长绑带由内往外穿过手臂上部的“T”型绑带扣，用鳄鱼嘴夹住绑带并固定住绑带。(图 5a)再将绑带绕过颈部由内往外环绕手腕穿过“T”型绑带扣用鳄鱼嘴夹住绑带，根据需要的长度固定在绑带上 (5b)。

术后穿戴时间：支具穿戴的标准应由医生来制定支撑的角度和屈伸的角度以及每天的穿戴时间，直至你的主治医生同意你取下支具。

***请在医生或专业人士指导下购买和使用。**

***重要事项：**

- 1) 产品供单个患者使用，不推荐用于多个患者。
- 2) 在调整产品之前，患者应咨询自己的医生。
- 3) 本产品须由执业医师开处方购买并安装穿戴。
- 4) 妥善的康复和活动改良也是安全治疗计划中不可或缺的过程。

绑带长度调整

确定所需长度，打开绑带尾端的鳄鱼嘴魔术贴，分开魔术贴和绑带，将绑带剪切至所需长度，再将鳄鱼嘴魔术贴贴回至绑带尾部并固定住绑带。

锁紧说明

- 1) 确定所需的锁定角度。
- 2) 朝连杆中心滑动缩进按钮以锁定连杆角度。

保养与维护

衬里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。

金属部分不可用水清洗。

警告：如果您在使用此产品时感到疼痛，肿胀，发生变化，或有不适的反应，请停止使用并立即联系您的医生。

四. 产品基本环境

1) 环境温度：-15~60℃

2) 相对湿度：≤80%

五. 产品材料

1) 金属支架：铝合金/不锈钢

2) 塑胶支架：聚酰胺

3) 按钮/绑带扣：聚甲醛

4) 铆钉：不锈钢

5) 绑带/衬垫：尼龙/聚氨酯/聚酯/EVA/魔术贴

六. 禁忌症

⚠ 非稳定性骨折慎用；

⚠ 骨质疏松症慎用；

⚠ 认知缺陷慎用；

⚠ 骨质性关节强硬等慎用；

七. 产品的保管，运输及有效期

1) 产品有效期：5 年。

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) 运输：本产品在进行储存及运输的过程，应防尘、防潮、防污染。

八. 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。

九. 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 5 年

📖 参考使用说明

十. 配件清单

说明书----- 1 份

十一. 售后承诺

保修：所有产品从购买之日起为原始日期，正常磨损和撕裂的产品在使用过程中不被视为缺陷。

以下部件自购买之日起至质保期内，如果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设备及附件进行完全或部分维修或更换。

金属支架----- 1 年

十二. 厂家信息

【产品名称】肘部固定器

【医疗器械备案凭证编号】

粤深械备 20200850 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 20200850 号

【备案人】深圳简单医疗科技有限公司

【生产企业】深圳简单医疗科技有限公司

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