

## 深圳简单医疗科技有限公司

### 产品说明书

#### 腕关节固定器

产品型号：42003/42004 产品规格：S/M/L/XL



感谢您购买本公司产品！请在操作前仔细阅读此使用说明书！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：腕关节固定器

1.2 产品型号：42003/42004

1.3 产品规格：S/M/L/XL

1.4 产品结构：

腕关节固定器主要由透气柔软的大身，支撑器，绑带等组成

1.5 工作原理

产品采用轻量化的设计，表面两处设有支撑器，所述产品通过支撑器和透气柔软的面料来提高患者的佩戴舒适度。贴合手腕轮廓的支撑片，使得手腕与护具有妥帖的支撑和保护。帮助缓解手腕肌肉和关节疼痛，为受过伤的手腕提供支撑和防护，避免再次伤害，有效保障患者得到很好的恢复。

1.6 适用范围

用于手腕韧带损伤，手腕脱臼固定，腕关节损伤和骨折固定，术后的手腕固定，术后手腕康复。

#### 二、产品特点及性能描述

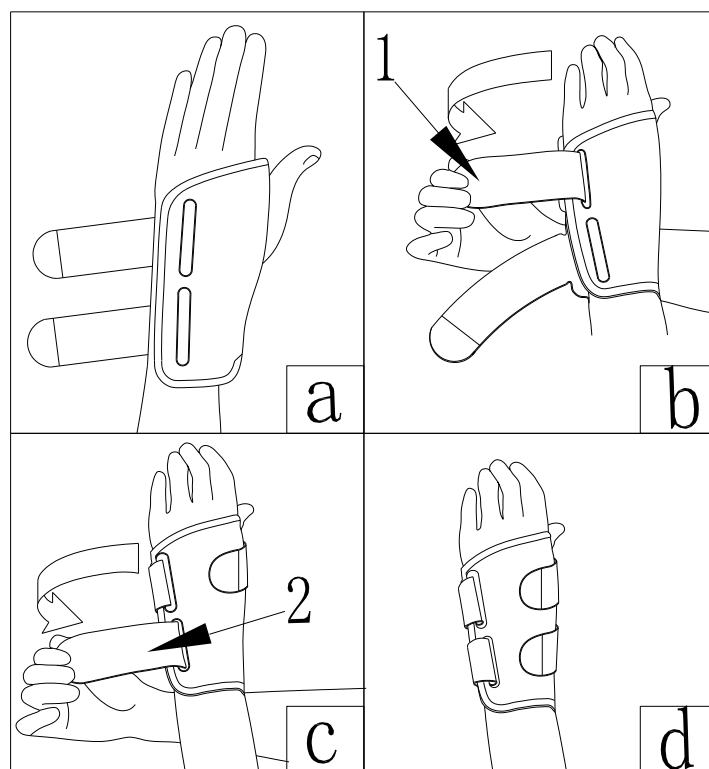
2.1 产品特点及贮存条件

【产品特点】产品简单，增强支撑，穿戴可调，开放式设计，重量轻，使用方便，透气、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：解开腕护具的两条绑带，手放入护具里面且拇指穿过拇指洞（图 a）。

步骤 2：系紧绑带 #1（图 b）。

步骤 3：系紧绑带 #2（图 c）。

步骤 4：根据舒适度和支撑效果来调节绑带（图 d）。

#### 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。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。

#### 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) 大身材料：氨纶，尼龙，聚酯 PU

2) 支撑器：铝合金/聚丙烯

3) 搭扣：聚丙烯

4) 绑带：尼龙/聚氨酯/聚酯

#### 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、产品的保养及保管

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。

#### 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

#### 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】腕关节固定器

【医疗器械备案凭证编号】

粤深械备 20180615 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 20180615 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

【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】518109

【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 18 号

【网址】www.simplemedical.cn



# Simple Medical (Shenzhen) Limited Instruction for Use

## Wrist brace W2

Model:42003/42004 Size: S/M/L/XL



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: Wrist brace W2
- 2)product model: 42003/42004
- 3)Product specification: S/M/L/XL
- 4)Product Structure:

The wrist fixed support mainly by breathable soft material, aluminum alloy, plastic parts, fixed belt

#### 5)Operating principle

The product is designed to be lightweight and has two support devices on the surface. The support device and breathable soft fabric are used to improve the wearing comfort of patients. The support plate fitting the wrist contour makes the wrist and the protector have proper support and protection to help relieve the wrist muscle and joint pain, provide support and protection for the injured wrist, avoid re-injury, and effectively ensure the patient to get a good recovery.

#### 6)Scope of application

It is used in patients with Carpal Tunnel Syndrome, wrist joint and wrist muscle pain

### Product features and performance description

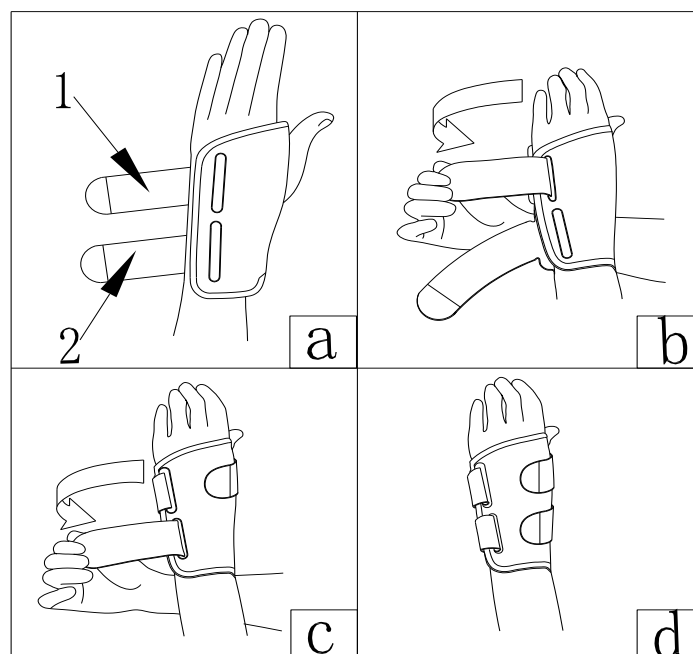
#### 1) Product features and storage conditions

【Product features】 Reinforced support. Elastic adjustable fit. Open design, light weight, easy use. Breathable, comfortable

【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.

Loosen the two straps of the wrist guard, put your hand into the guard and pass your thumb through the thumb hole (fig a)

#### STEP 2.

Fasten strap# 1(fig b)

#### STEP 3.

Fasten strap# 2(fig c)

#### STEP4.

Strap can be adjusted according to comfort level and supporting effect (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.

### Warning:

If you experience pain, swelling, irritation, or discomfort while using this product, discontinue use and consult your doctor.

### Product basic parameter

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

### Product materials

- 1) Body material: spandex, nylon, polyester PU
- 2) Support sheet: aluminum alloy/PP
- 3) Buckle: polypropylene
- 4) Strap: nylon/polyurethane/polyester

### 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

### 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**  
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`

**EC REP**  
SUNGO Europe B.V.

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

\*Please refer to the Instructions before usage