

## 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：42001

产品规格：XS, S, L



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：42001

1.3 产品规格：XS, S, L

1.4 产品结构：

由铝合金、聚丙烯、聚酰胺、氨纶、聚氨酯制成。穿戴于肢体体表，通过限制肢体活动，达到保持肢体稳定的目的。不具备矫形功能。无源产品。

1.5 工作原理：

产品采用轻量化的设计，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，使得手腕与腕关节固定器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 预期用途：

用于人体腕关节部位的外固定或支撑。

1.7 适用范围：

用于腕部扭伤、非手术性腕部骨折、腕部创伤后或术后固定、腕部肌腱病、腕管综合征保守治疗、侧上髁炎、类风湿性关节炎、腕部骨关节炎辅助治疗。

#### 二、产品特点及性能描述

2.1 产品特点及贮存条件

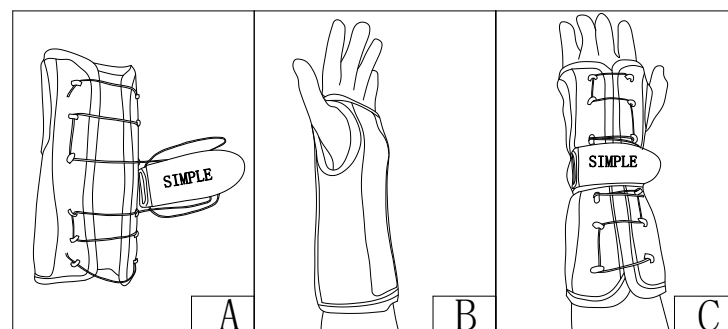
**【产品特点】**符合人体工学设计，透气轻便，穿脱简捷舒适，稳固支撑，加强手腕部固定，左右手通用。

**【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：解开绑带，手伸入产品里面（图A&B）。

步骤2：系紧绑带，根据舒适度和支撑效果来调节绑带，如有必要，在收紧时调整防护内衬。（图C）。

保养与维护

洗涤前拆下支撑条并扣紧魔术贴，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。

**注意：如果穿戴过紧，可能会导致皮肤刺激或产生压迫现象。请在穿戴前咨询并在医生指导下进行穿戴。**

保养与维护

洗涤前拆下支撑条并扣紧魔术贴，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出现不适，手指麻木损伤等任何不适的反应，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：涤纶+锦纶+尼龙

2) 支撑器：铝合金+塑胶

3) 绑带： 尼龙/涤纶

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；

⚠ 手部不稳定的骨折禁用；

#### 三、产品的保养及保管

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，保证室内通风。

3.3 产品的运输：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在地区法规进行弃置处理，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5年

📖 参考使用说明

🏭 制造日期

#### 六. 配件清单

说明书----- 1份

#### 七. 尺码表

型号	42001	
尺码	XS, S, L	
尺码		测量方法
XS	110-130mm	
S	130-153mm	
L	178-203mm	

#### 八. 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，深圳简单医疗科技有限公司将对产品进行维修或更换。

#### 九. 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】**

粤莞食药监械生产备20200057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

**【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04月22号

**【网址】**www.simplemedical.cn

**Simple Medical (Shenzhen) Limited**  
**Instruction for Use**

**SIMPLE Wrist brace W3**

Model:42001

Size: XS,S,L



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 Wrist brace W3
- 2)product model: 42001
- 3)Product specification: XS,S,L
- 4)Product Structure:

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

5)Operating principle:

The lightweight design of the product enhances patient comfort through supports and breathable and soft fabrics. The support piece fits the wrist contour, so that the wrist and guard have proper support and protection. Help relieve wrist muscle and joint pain, provide support and protection for injured wrists, avoid re-injury, and effectively ensure that patients get a good recovery.

6) Adapt to symptoms:

Wrist sprain. Non surgical wrist fracture. Post-operative or post-traumatic wrist immobilisation. Wrist tendinopathies. Conservative treatment of carpal tunnel syndrome. Rheumatoid arthritis. Wrist osteoarthritis.

**Product features and performance description**

1) Product features and storage conditions

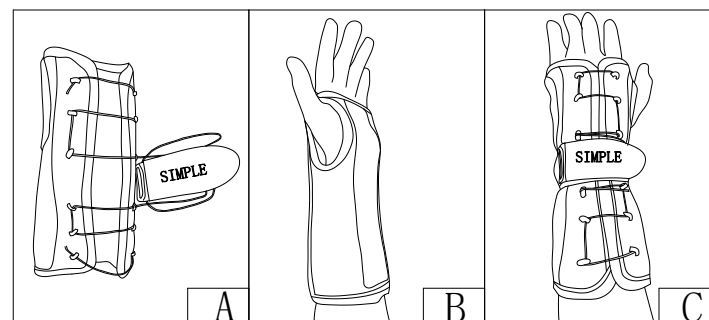
**【 Product features 】** Ergonomic design, breathable and lightweight, easy to wear and easy to take off, stable support, strengthen the wrist fixed, left and right hand universal.

**【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.**

Remove all the straps of the wrist joint retainer and reach into the wrist joint retainer (Figure A&B).

**STEP 2.**

Tighten the straps, adjust the straps according to comfort and support, and, if necessary, adjust the protective lining when tightened.(Figure C).

**STEP3.**

If necessary, adjust the protective lining during tightening.

**Note: If worn too tightly, it may cause skin irritation or pressure. Please consult before wearing and wear under the guidance of a doctor.**

**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 any uncomfortable reaction such as pain, swelling, allergies, sensory disturbances, poor blood flow, etc. while using this product, discontinue use and consult a doctor.

**Product basic parameter**

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

**Product materials**

- 1) Body material: Polyester, nylon
- 2) Support sheet: Aluminum + Plastic
- 3) Strap: Nylon/Polyester

**Contraindication**

- ⚠ Do not use in case of allergy;
- ⚠ Those with unknown skin masses are forbidden;
- ⚠ Those with swollen or ulcerated skin are forbidden;
- ⚠ Unstable fractures of the hand;

**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**

- ⚠ Attention, warning
- ☒ Hand wash only
- ☀ Protect from sunlight

- ☒ Do not use when the packing is damaged
- ⌚ It is valid for five years
- 📖 Reference instructions

**Accessories list**

Instructions ----- 1 copy

**Selection**

<b>Item</b>	42001	
<b>Size</b>	XS, S, L	
	<b>Size</b>	<b>Measurement method</b>
<b>XS</b>	110-130mm	
<b>S</b>	130-153mm	
<b>L</b>	178-203mm	

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

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\*Please refer to the Instructions before usage

**CE** 42001 V0.2