

深圳简单医疗科技有限公司

产品说明书

手指固定器

产品型号：31903&31904

产品规格：XS, 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：手指固定器

1.2 产品型号：31903&31904

1.3 产品规格：XS, S, M, L, XL

1.4 产品结构：

由铝合金、塑胶、氨纶、尼龙、魔术勾材料制成，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，产品两处设有可拆卸的支撑器，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。贴合手腕和拇指轮廓的支撑片，使得手腕拇指与手指固定器有妥帖的支撑和保护。帮助缓解肌肉和关节疼痛，为受过伤的手腕和拇指提供支撑和防护，避免再次伤害，帮助患者得到很好的恢复。

1.6 预期用途：

用于对人体手指部位的外固定或支撑。

1.7 适用范围：

用于辅助治疗拇指扭伤、手腕和/或拇指扭伤、非手术性肩胛骨骨折、非手术性腕部骨折、手腕/拇指外伤后或术后固定、腕部和/或拇指肌腱病、类风湿性关节炎、腕管综合征保守治疗、拇指/手腕骨关节炎、神经肌肉缺陷（挛缩、手下垂、痉挛...）。

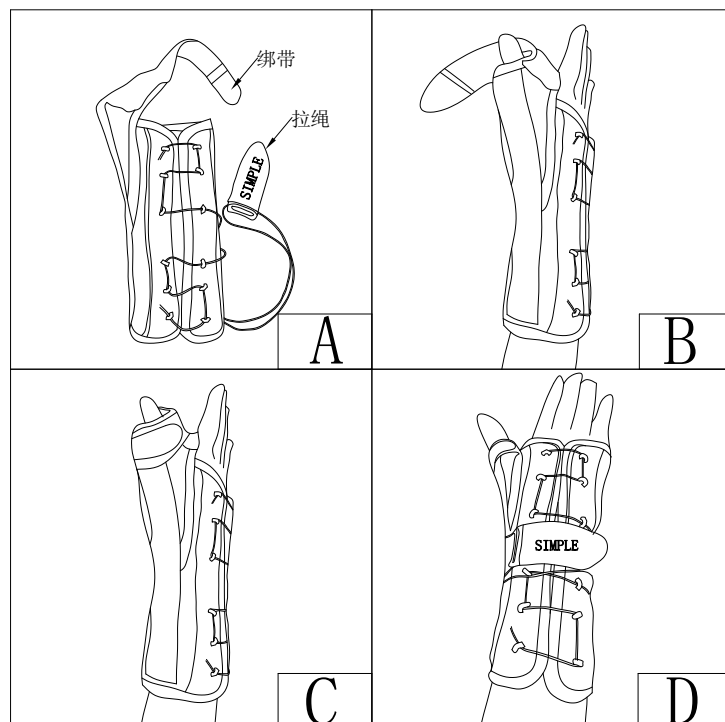
二、产品特点及性能描述

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，加强拇指/手腕部固定。

【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：解开手指固定器的拇指绑带和拉绳，将手掌穿入产品中（图A&B）。

步骤2：将小绑带缠绕在拇指上并对其进行调整，使其达到所需要的支护力度（图B&C）。

步骤3：利用拉绳收紧产品，使其达到所需要的支护力度，收紧时，根据需要调整保护性面料内衬（图C）。

注意：如果穿戴过紧可能会产生压迫现象或压迫血管或压迫神经导致知觉障碍血流不畅和皮肤刺激，请在使用前咨询医生并在医生的指导下穿戴。

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：涤纶+锦纶+尼龙

2) 支撑器：铝合金+塑胶

3) 拉片：尼龙

4) 绑带：尼龙/涤纶

2.5 禁忌症

⚠ 手部不稳定的骨折；

⚠ 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：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：本产品在储存及运输的过程，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



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	31903 (左)	31904 (右)
尺码	XS, S, M, L, XL	
	尺码	测量方法
XS	110-130mm	
S	130-153mm	
M	153-178mm	
L	178-203mm	
XL	203-230mm	

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】手指固定器

【医疗器械备案凭证编号】

粤深械备 20190644 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 20190644 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4月22号

【网址】www.simplemedical.cn

Simple Medical (Shenzhen) Limited
Instruction for Use

SIMPLE Thumb brace W4

Model:31903&31904 Size: XS, 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: SIMPLE Thumb brace W4
- 2)product model: 31903&31904
- 3)Product specification: XS, S, M, L, XL
- 4)Product Structure:

Products are mainly composed of breathable and comfortable soft body, aluminum alloy support, strap, plastic buckle and so on.

5)Operating principle:

The product adopts a lightweight design, and the product has a removable support at two places. The product improves the wearing comfort of the patient through the support and the breathable and soft fabric. The support piece fits the outline of the wrist and thumb, so that the wrist thumb and guard have proper support and protection. Help relieve muscle and joint pain, provide support and protection for injured wrists and thumbs, avoid re-injury, and help patients recover well

6)Scope of application:

Thumb sprain. Wrist and/or thumb sprain

Non surgical scaphoid fracture. Non surgical wrist fracture

Post-operative or post-traumatic wrist/thumb immobilisation

Wrist and/or thumb tendinopathies.Rheumatoid arthritis

Conservative treatment of carpal tunnel syndrome.Thumb/wrist

osteoarthritis.Neuro-muscular impairments (contracture, hand drop or spasticity····)

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 thumb/wrist fixation.

【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

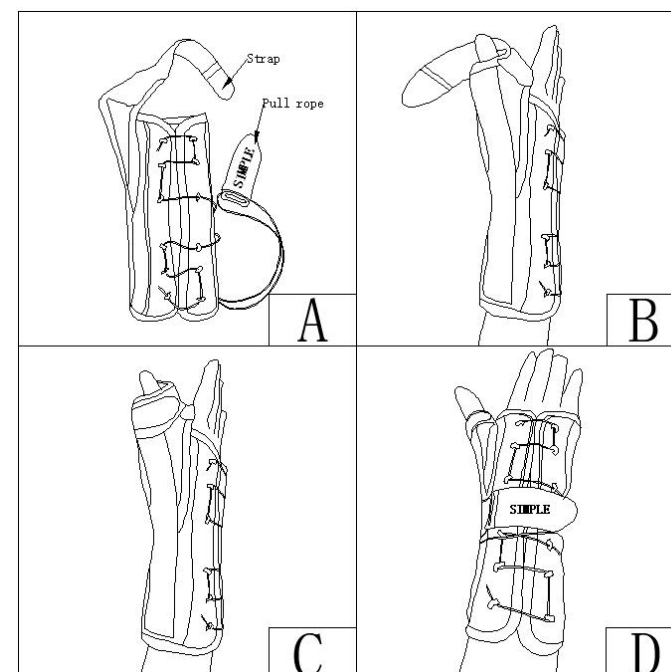
【Application Instructions】

APPLICATION INSTRUCTIONS

STEP 1: Remove the binding and drawstring of the finger retainer and insert the palm into the brace (Figure A&B).

STEP 2: Wrap the small band around the thumb and adjust it to achieve the required support force (Figure B&C).

STEP 3: Tighten the brace with a drawstring to the required support strength, and adjust the protective fabric lining as needed when tightening (Figure C).



Note: If wearing too tight may cause compression or pressure on blood vessels or nerves leading to perceptual disturbance, poor blood flow and skin irritation, please consult a doctor before use 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 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: Polyester, nylon
- 2) Support sheet: Aluminum + Plastic
- 3) Zipper: Polypropylene + Nylon
- 4) Strap: Nylon/Polyester

Contraindication

- ⚠ Unstable fractures of the hand;
- ⚠ 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: 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

	Manufacture Date		Batch Code
	Medical device		CE Symbol
	Hand wash only		Protect from sunlight
	Warnings and Precautions		
	It is valid for five years		
	Reference instructions		
	Do not use when the packing is damaged		

Selection

Item	REF. 31903 (Left)	REF. 31904(Right)
Size	XS, S, M, L, XL	
	Size	Measurement method
	XS	110-130mm
	S	130-153mm
	M	153-178mm
	L	178-203mm
	XL	203-230mm

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: service@simplegroup.net

SUNGO Europe B.V.

Fascinatio Boulevard 522 ,Unit1.7,2909VA Capelle aan den IJssel ,The Netherlands

Tel : +31(0)10-3034500; +31(0)2021-11106

*Please refer to the Instructions before usage

