

## 深圳简单医疗科技有限公司

### 产品说明书

#### 髌部固定器

产品型号：21003 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：髌部固定器

1.2 产品型号：21003

1.3 产品规格：F

1.4 产品结构：

由不锈钢尼龙、聚乙烯组成。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。

1.5 工作原理

产品采用开放式设计，腰带和髌部支架结合有效减轻髌部压力。更贴合腰部，施力均匀让患者更舒适。

1.6 预期用途

用于骨折或软组织损伤的外固定。

1.7 适用范围

适用于髌部损伤，髌关节软组织损伤，髌关节置换术后的保护固定，防止髌关节骨折移位或脱臼辅助治疗。

#### 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】产品使用方便舒适，受力均匀，松紧可调。

【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：佩戴前将腰带和腿部固定带展开，将腰带穿过支具槽，并将腰带调整至合适的腰围。（图 1a&2a&3a）

步骤 2：使用拉环微调腰带尺寸贴合腰围。（图 1b）

步骤 3：定位骨盆外壳和铰接装置，使其在侧面居中。

步骤 4：调整连杆的长度。把支架上的调整键往下按住随即推动支架到所需的长度，松开即为锁住塑胶支架。

步骤 5：调整髌部弯曲活动范围。往下按住屈伸或伸展的角度调整按钮扣，根据需要移动到标示的角度刻度上后将再角度调整按钮扣的旋钮往腿内侧按下成 90° 即可锁住。（图 2c）

步骤 6：紧固腿部绑带。用手固定住固定器防止移动。并依次扣住搭扣，搭扣要扣到位。搭扣位置紧固后，调整好绑带长度和软垫的舒适度再紧固绑带。（图 3d）

绑带长度调整

确定所需长度，打开尾端的绑带头魔术贴，分开魔术贴和绑带剪切至所需长度，再将绑带头贴回至绑带尾部。

外展/内收说明

如果需要，临床医生可以使用提供的扳手工具改变外展/内收角度。

术后穿戴时间：固定器穿戴的标准应由医生来制定铰链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固定器。

**\*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) 在调整固定器之前，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。

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。

肩外展枕内的枕芯不可清洗。

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。

\*此产品仅为固定装置，不用于预防伤害或者防止再次发生伤害更不能替代药品和医生的正确诊断。

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) 腰带：尼龙
- 2) 支架扣：聚乙烯
- 3) 魔术贴：尼龙
- 4) 连杆：不锈钢

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：5 年。

3.2 产品的保管：未使用前请放置在干燥、清洁的室内，保证室内通气。

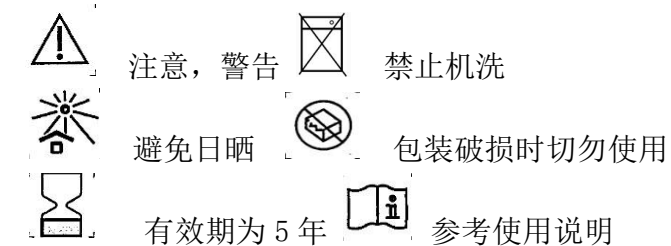
3.2 产品的保管：未使用前请放置在干燥、清洁的室内，保证室内通气。

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



#### 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，深圳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】肩臂固定带  
【医疗器械备案凭证编号】  
粤深械备 20180612 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 20180612 号  
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【说明书修订日期】2024 年 07 月 08 号  
【网址】www.simplemedical.cn

## Simple Medical (Shenzhen) Limited Instruction For Use

SIMPLE Hip Brace N3

Model: 21003 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: SIMPLE Hip Brace N3
- 2) Product model: 21003
- 3) Product specification: F
- 4) **Product Structure**

It is composed of aluminum alloy, stainless steel, sponge and plastic. It is worn on the body surface of the body to achieve the purpose of maintaining the stability of the body by restricting the movement of the body. It has no orthopedic function.

### 5) Operating principle

The product has an open design, and the belt and hip support combine to effectively reduce pressure on the hip. It fits the waist better and applies even force to make the patient more comfortable.

### 6) Scope of application:

Post-Op use following minimally invasive hip procedures; Labral repair, with or without gluteus medius repair; ROM control following primary or hip revision surgery; Post-op use following proximal hamstring repair.

### Product features and performance description

#### 1) Product features and storage conditions

**【Product features】** The product is easy to use and comfortable, the force is uniform, and the tightness is adjustable.

**【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:** Before wearing, unroll the belt and leg fastener, pass the belt through the brace slot, and adjust the belt to fit the waist. (Figure 1a&2a&3a)

**Step 2:** Use pull loops to fine-tune the belt size to fit the waist. (Figure 1b)

**Step 3:** Step 3: Position the pelvic shell and articulation device so that it is centered on the side.

**Step 4:** Adjust the length of the rod. Press and hold the adjusting button on the support and push the support to the required length. Release it to lock the plastic support.

**Step 5:** Adjust hip range of motion.. Press and hold down the Angle adjustment button of flexion or extension, move it to the marked Angle scale as needed, and press the knob of the re-angle adjustment button to the inside of the leg to 90° to lock it. (Figure 2c)

**Step 6:** Tighten leg straps. Hold the retainer in place by hand to prevent movement. And fasten the buckle in turn, buckle the buckle in place. After securing the strap position, adjust the strap length and cushion comfort before tightening the strap. (Figure 3d)

### The strap length is adjusted

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

### Outreach/adduction instructions

If needed, the clinician can change the abduction/adduction Angle using the wrench tool provided.

Time to wear the retractor after surgery: The standard for wearing the retractor should be determined by the doctor to determine the Angle of hinge support and flexion and the time to wear it each day until your primary care doctor gives you permission to remove the retractor.

### Maintenance:

Lining can use neutral detergent and 30℃ 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. The occipital core in the external pillow of the shoulder cannot be cleaned

### Warning:

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

\*This product is only a fixture and is not used to prevent injury or prevent recurrence of injury, much less to replace the correct diagnosis of drugs and doctors.

### Basic product environment

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

### Product material

- 1) Belt: Nylon
- 2) Bracket buckle: polyethylene
- 3) Velcro: Nylon
- 4) Connecting rod: stainless steel

### Contraindication

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

⚠ Do not use for indications greater than 45° pronation or abduction.

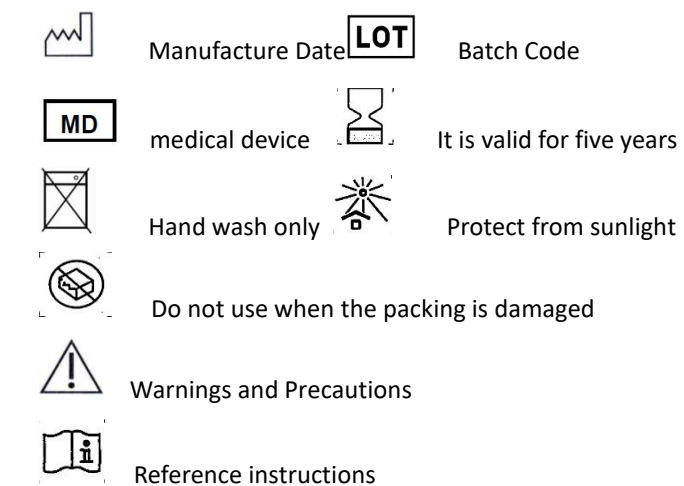
### Storage, transportation and expiry date of products

- 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



### 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.

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\*Please refer to the Instructions before usage.



21003 V0.2