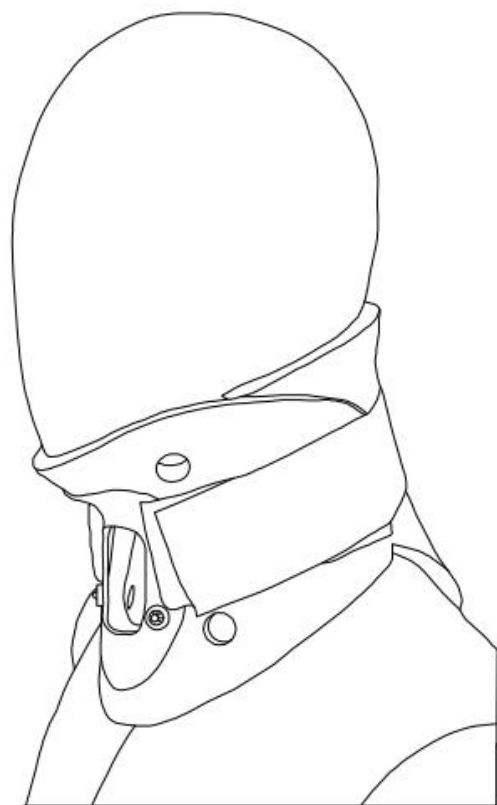


深圳简单医疗科技有限公司

产品说明书

颈部固定器

产品型号：51002 产品规格：S, M, L



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：颈部固定器

1.2 产品型号：51002

1.3 产品规格：S, M, L

1.4 产品结构：

由聚乙烯、海绵、塑胶、魔术贴组成，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。无源产品。

1.5 工作原理：

产品采用流线型轻量化的设计，符合生物力学和人体工程学设计。特殊的曲面剪裁，使得颈部有全方位的稳固和穿戴的舒适性。多点支撑受力均匀，如量身定做般舒适。

1.6 预期用途：

用于对人体颈部部位的外固定或支撑。

1.7 适应范围：

适用于颈椎病，颈肌劳损等颈椎综合症的预防和辅助治疗以及颈椎术后康复期的颈部固定辅助治疗。

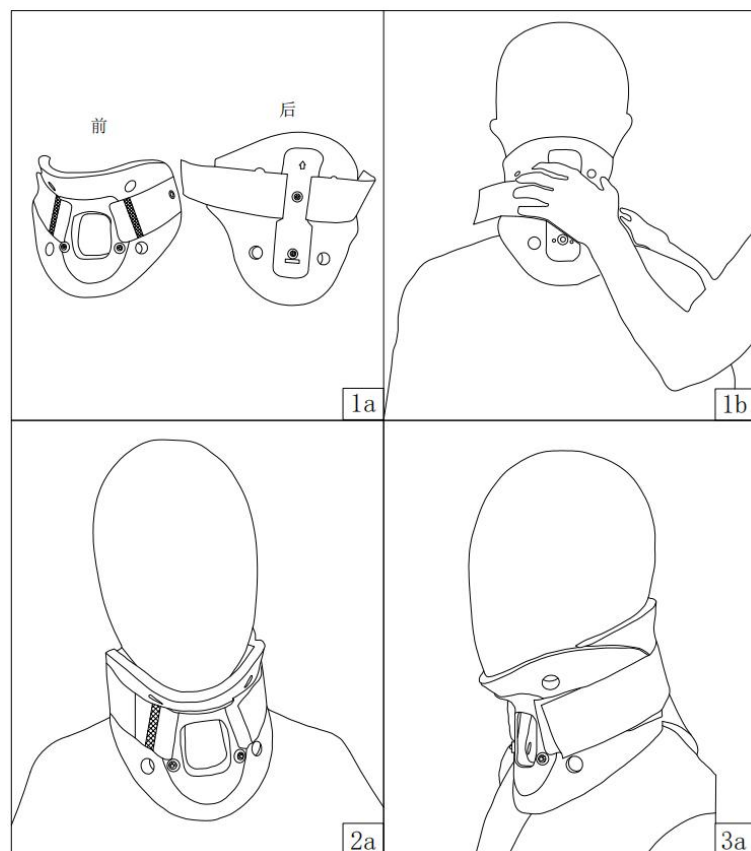
二. 产品特点及性能描述

2.1 产品特点及贮存条件

【产品特点】 安全、环保，重量轻，有透气孔，佩戴舒适方便。

【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：

头部仰至嘴角和耳垂的连线与地面平行，鼻尖与肚脐成同一直线，将后片颈托小心的穿入后颈。（图 1a、1b）

步骤 2：

将前片颈托下颌垫与下颌吻合，前片压后片，并将魔术贴固定。（图 2a）。

步骤 3：

检查产品穿戴是否正确和舒适。（图 3a）

注意：请在医生或专业人员的指导下使用。

注意事项

- 要经常检查各个部位是否牢固、粘扣等是否安全可靠，如发现问题应及时修理或更换。
- 训练时间应根据医生或康复训练师嘱咐训练。
- 使用过程中如出现疼痛或感觉异常，请立即停止使用并联系您的医生。

保养与维护

产品用清水手洗，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。

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：聚乙烯/尼龙/海绵

2.5 禁忌症

- ⚠ 有出血倾向者慎用。
- ⚠ 恶性肿瘤及高热患者慎用。
- ⚠ 严重高血压及心血管疾病患者慎用。
- ⚠ 有严重皮肤过敏者慎用。

三. 产品的保管，运输及有效期

3.1 产品有效期：3年。

3.2 产品的保管：应存放在干燥和通风良好的室内，勿与酸、碱等腐蚀性物质混放，远离火源。

3.3 运输：本产品存储及运输的过程，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

🚫 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，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】 颈部固定器

【医疗器械备案凭证编号】

粤深械备 20190643 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 20190643 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

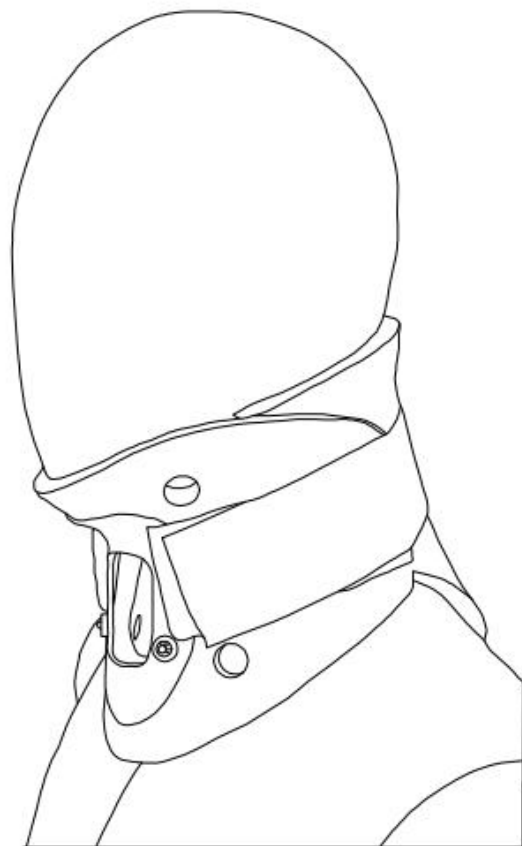
【网址】 www.simplemedical.cn

Simple Medical (Shenzhen) Limited

Instruction for Use

SIMPLE Cervical Collar C1

Model: 51002 Size: S, M, 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 Cervical Collar C1
- 2)Product model: 51002
- 3)Product specification: S, M, L
- 4)Product Structure:

The product is usually made of polymer materials, fabrics, metals and other materials.

5)Operating principle:

The product adopts a streamlined and lightweight design, conforming to biomechanical and ergonomic design. Special curved cutting, so that the neck has a full range of stability and comfort. The multi-point support force is uniform, as if tailor-made comfort.

6)Intended Use:

Used for neck repositioning fixation.

7)Adaptation disease:

It is suitable for the prevention and auxiliary treatment of cervical spondylosis, cervical muscle strain and other cervical spine syndromes and neck fixation during the rehabilitation period after cervical spondylosis.

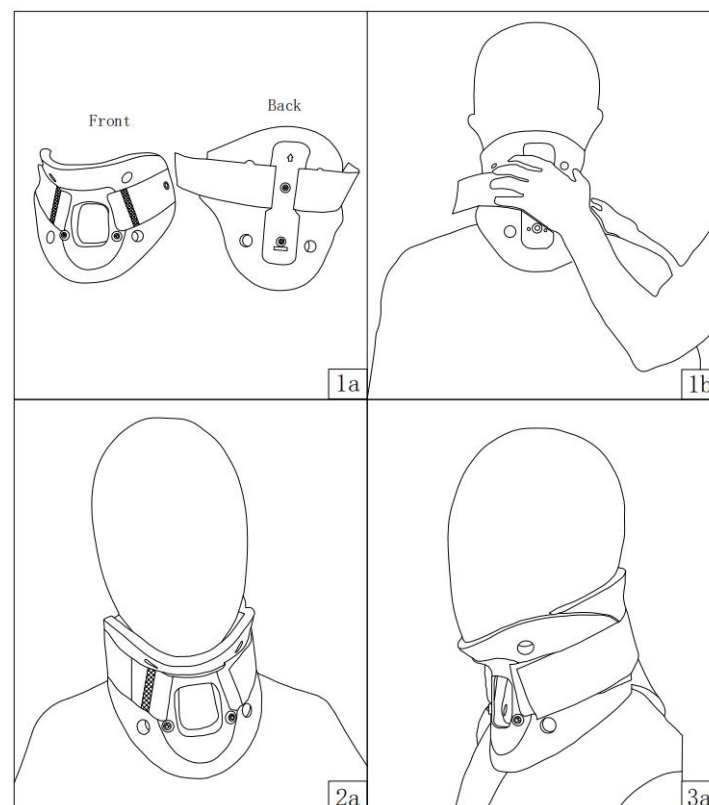
Product features and performance description

1) Product features and storage conditions

【 Product features 】 Safe, environmental protection, light weight, with air holes, comfortable and convenient to wear.

【 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:

Insert the back piece neck brace carefully into the back neck.(Fig 1a、1b)

STEP 2:

The jaw pad of the front neck support is fitted to the jaw, the front piece is pressed against the back piece, and the Velcro is fixed.(Fig. 2a)

STEP 3:

Check whether the product is worn correctly and comfortably. (Fig 3a)

Note: Use it under the guidance of a doctor or a professional.

Notes

- 1.Always check whether each part is firm, whether the hook buckle, etc. are safe and reliable,If a problem is found, it should be repaired or replaced in time.
2. The training time should be according to the instructions of the doctor or rehabilitation trainer.
3. If pain or paresthesia occurs during use, please stop using immediately and contact your doctor.

Maintenance

The product is hand-washed with clear water and is naturally air-dried. Do not put the dryer or use other heat sources for drying. Elements such as salt water, sand, dirt, etc. may cause injury. After exposure to these conditions, rinse thoroughly with clear water, dry the towel or air-dry (do not machine the machine). For detergents, use mild detergent and do not use softeners and bleaches.

Basic product environment

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

Product material

- 1) Body material: polypropylene
- 2) Liners: sponge
- 3) Strap: nylon / elastic tape / magic sticker

Contraindication

- ⚠ Those with bleeding tendency should be used with caution.
- ⚠ Patients with malignant tumors and hyperthermia should be used with caution.
- ⚠ Patients with severe hypertension and cardiovascular disease should be used with caution.
- ⚠ People with severe skin allergies should use with caution.

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

- ⚠ Attention, warning
- 🧼 Hand wash only
- ☀️ Protect from sunlight
- 🚫 Do not use when the packing is damaged
- 🕒 It is valid for three years
- 📖 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.518131
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

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

