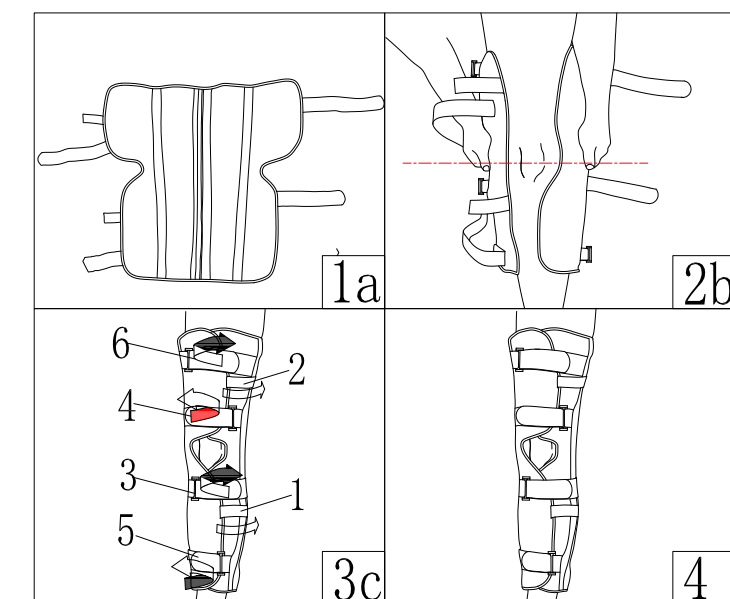


Simple Medical(Shenzhen)Limited Instruction for Use

SIMPLE Knee Immobilizer K3

Model: 11016 Size: S, M, L, XL



Product Structure and Performance

Knee retainer is mainly composed of breathable soft body, support, straps and so on. Emergency fixation of the main knee and knee fixation and traumatic knee injury before and after operation. The product adopts streamline lightweight design. The outer side of the product is provided with a support, through which the knee joint and large / calf are properly protected and stable.

INDICATIONS

- Fixation of knee ligament strain
- Meniscus injury fixation
- Fixation of patella fracture
- Postoperative rehabilitation

APPLICATION INSTRUCTION

STEP 1.

Loosen the fastening (Fig 1a).

STEP 2.

The center of the gap on both sides is aligned with and wrapped around the center of the knee (Fig. 2b)

STEP 3.

Fasten the straps. Hold both sides with your hands to prevent movement. And fasten the straps 1/2 in turn. Then tie the strap 3 / 4 / 5 / 6 (around the leg through the strap buckle and fasten it in the opposite direction (Fig3c-4)

NOTICE: Fasten the strap on upper thigh, not too tight. Too tight may lead to slow blood circulation or downward movement of the bracket.. Adjust the position of the straps and bracing if necessary.

"Wearing time" :

Adjust the wearing time of the brace when the body allows it.

Preoperative wearing time:

The wearing standard and wearing time of the knee retainer should be set by the doctor until your attending doctor agrees to remove the brace.

***Please purchase and use the product under the guidance of your doctor or professional.**

* IMPORTANT :

- 1) The product is for use by a single patient and is not recommended for multiple patients.
- 2) The knee joint and this product should be checked before and after each use. This product should be used in good skin.
- 3) This device cannot prevent or reduce all injuries, and proper rehabilitation and activity improvement are also an indispensable process in the safety treatment plan.

CARE AND MAINTENANCE

Liners 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

Metal parts should not be washed with water.

WARNINGS:

If you feel pain, swelling, change of sensation, or discomfort when using this product, please stop using it and contact your doctor.

Basic application environment

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

Product materials

- 1) Support: aluminum alloy
- 2) Buckle: nylon
- 3) Accessories: Nylon
- 4)Straps/ main body: nylon/ polyurethane/ polyester/ EVA/ magic tape

Contraindication

- ⚠ Use with caution for unstable fractures;
- ⚠ Use with caution in osteoporosis;
- ⚠ Use with caution for cognitive impairment;
- ⚠ Use with caution for bony ankylosis;

Storage, transportation and expiry date of products

- 1) Term of validity: Three years.

- 2) Storage of the product: please put it in a dry and clean room before use to ensure indoor ventilation.
- 3) Transportation: the product shall be dustproof, moisture-proof and pollution-proof during storage and transportation.

Waste disposal

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
	It is valid for five years
	Protect from sunlight
	Hand wash only
	Do not use when the packing is damaged
	Warnings and Precautions
	Reference instructions

Accessories list

Instructions ----- 1 copy

After-sales warranty

Warranty: all products from the date of purchase as the original date, normal wear and tear of the product in the use of the process is not considered defective.

The following parts from the date of purchase to the warranty period, if there is any material or process defects, please contact your seller directly, Simple medical will completely or partially repair or replace the braces and accessories.

Metal bracket ---- -- 1 year

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

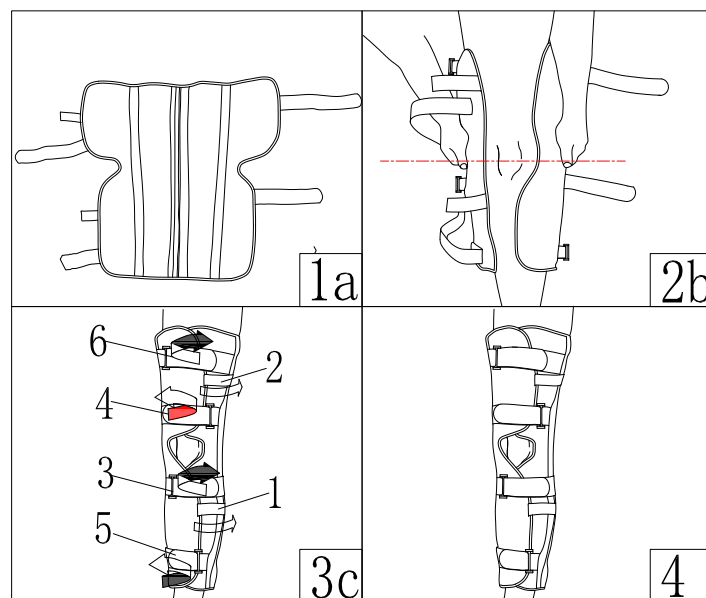


深圳简单医疗科技有限公司

产品说明

膝部固定器

产品型号：11016 产品规格：S, M, L, XL



一. 产品结构及性能

支具采用高分子材料、织物、皮革、金属等材料制成。产品主要膝部的紧急固定和术前术后膝关节固定和创伤性膝关节损伤。产品采用流线型轻量化的设计。

二. 预期用途

用于膝部部位的外固定或支撑。

三. 适应症

- 膝盖韧带拉伤固定
- 半月板受伤固定
- 髌骨骨折固定
- 术后康复

四. 应用说明

步骤 1:

松开固定带, (图 1a)。

步骤 2:

两边缺口中心与膝盖中心位置对齐并包裹住 (图 2b)。

步骤 3:

紧固绑带。用手固定住两边防止移动。并依次将绑带 1-固定住。再将绑带 3-4-5-6 (环绕腿部穿过绑带扣并紧在相反的方向上 (图 3c-4)。

注意: 系大腿部分的绑带, 不要过紧。过紧可能会导致血液循环缓慢。必要时进行绑带和位置调整。

“穿戴时间”:

在身体允许的状态下调整支具的穿戴时间。

术后穿戴时间: 膝部固定器的穿戴标准和穿戴时间应由医生来制定, 直至你的主治医生同意你取下支具。

*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) 每次使用前都要检查其膝关节和此产品。此产品要用在完好的皮肤上。对末梢循环不良或皮肤感觉减退的患者要慎用
- 3) 本装置不能预防或减少所有伤害, 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

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。金属部分不可用水清洗。

警告: 如果您在使用此产品时感到疼痛, 肿胀, 感觉变化, 或有不适的反应, 请停止使用并联系您的医生。

五. 产品基本环境

- 1) 环境温度: $-15\sim 60^{\circ}\text{C}$
- 2) 相对湿度: $\leq 80\%$

六. 产品材料

- 1) 支撑器: 铝合金
- 2) 绑带扣: 尼龙
- 3) 配件: 尼龙
- 4) 绑带/主体大身: 尼龙/聚氨酯/聚酯/EVA/魔术贴

七. 禁忌症

- ⚠ 非稳定性骨折慎用;
- ⚠ 骨质疏松症慎用;
- ⚠ 认知缺陷慎用;
- ⚠ 骨质性关节强硬等慎用;

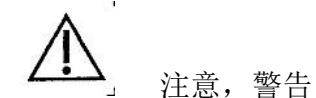
八. 产品的保管, 运输及有效期

- 1) 产品有效期: 3 年。
- 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) 运输: 本产品在储存及运输的过程, 应防尘、防潮、防污染。

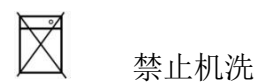
九. 废弃物处理

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。

十. 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

十一. 配件清单

说明书----- 1 份

十二. 售后承诺

保修: 所有产品从购买之日起为原始日期, 正常磨损和撕裂的产品在使用过程中不被视为缺陷。

以下部件自购买之日起至质保期内, 如果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设备及附件进行完全或部分维修或更换。

支撑器----- 1 年

十三. 厂家信息

【产品名称】膝部固定器

【医疗器械备案凭证编号】

粤深械备 20180573 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 20180573 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】518131

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【说明书修订日期】2023 年 06 月 30 号

【网址】www.simplemedical.cn