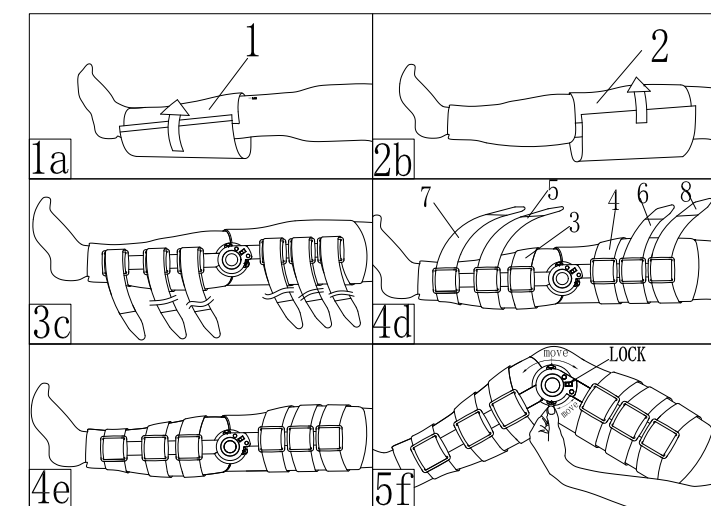


Simple Medical(Shenzhen)Limited Instruction for Use

SIMPLE Post-Op Knee Brace K2

Model: 11015 Size: L&S



APPLICATION INSTRUCTION

NOTICE: This product must be installed and adjusted by a doctor or professional. The long model is the same as the short one, and the difference between the long one and the short one is that there are more straps # 7 and # 8 more than the short ones.

STEP 1. Loosen the fastening belt and wrap foam 1 around the calf below the center of the knee and fasten it (Fig 1a).

STEP 2. Wrap foam 2 around the thigh above the center of the knee and fasten it (Fig2b).

STEP 3. Place the leg in the brace, the supports on both sides of the leg should correspond to each side of the leg and the center position of the hinge should be aligned with the center position of the knee (Fig. 3c).

STEP 4. Fasten the straps. Secure the brace with your hand to prevent movement. And in turn, the straps 3 / 4 / 5 / 6 / 7 / 8 around the legs through the strap buckle and fasten in the opposite direction, a properly applied POST-OP KNEE BRAC, To remove the brace, simply unfasten the straps and open the foam pads. The brace can then be removed and reapplied as a single unit. (Fig. 4d~4e)

NOTICE:

Fasten the strap on upper thigh, not too tight. Too tight may lead to slow blood circulation or downward movement of the bracket..From the side view, the hinge should be slightly behind the midline of the knee. In order to ensure good movement, it is normal for the brace to drop during walking. Adjust the position of the straps and bracing if necessary.

STEP 5. Adjust the scope of activity.

Press and move the angle adjustment key for flexion, extension or extension, and move to the marked angle scale as needed (Fig 5f)

Post-operative wearing:

It is up to the doctor to set the angle of hinge brace and the angle of flexion and extension as well as the amount of time to wear each day until your attending physician agrees that you can remove the bracing.

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

* IMPORTANT :

- 1) Products are for individual patients and are not recommended for multiple patients.
- 2) Both hinges must be set to the same extension and / or flexion settings.
- 3) Before adjusting the brace, the patient should consult his own doctor.
- 4) This product shall be purchased and installed on prescription by a medical practitioner.
- 5) This device will not prevent or reduce all injuries .Proper rehabilitation and activity improvement are also indispensable processes in safe treatment planning.

Foam length adjustment

Determine the required gasket length, and then cut it from the side where there is no magic sticker to the desired length.

LOCKING INSTRUCTION

- 1) By adjusting the key and sliding to the desired position, you can select the angle limit setting between -10 ° and 30 °.
- 2) The bending limit setting can be selected from -10 ° to 120 °.
- 3) The hinge may be locked by sliding the quick lock button into the locked position at any one of 5 positions: -10° of hyperextension, 0° (neutral), 10°, 20° and 30°.

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. Hinges can be lubricated with dry silicone spray

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) Metal bracket: aluminum alloy/stainless steel
- 2) plastic bracket: polyamide
- 3) buckle: nylon
- 4) Accessories: nylon glass fiber
- 5) Strap/pad: nylon / polyurethane / polyester / EVA/ magic paste

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: 5 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

EC REP
SUNGO Europe B.V.

Fascinatio Boulevard 522 ,Unit1.7,2909VA Capelle aan den IJssel ,The Netherlands
Tel : +31(0)10-3034500

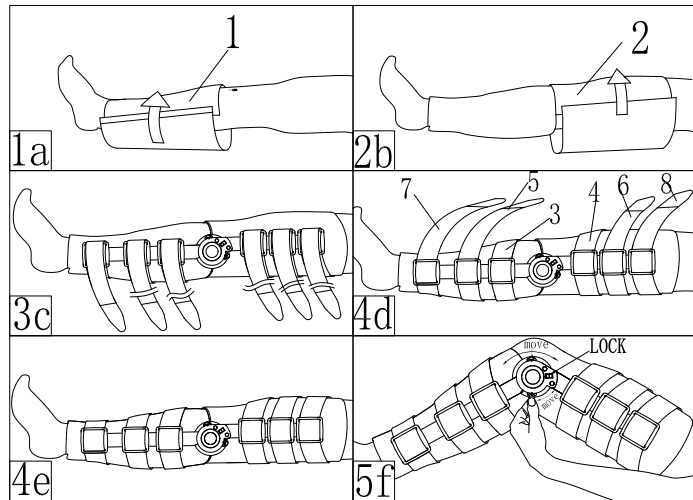
*Please refer to the Instructions before usage



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：11015 产品规格：L&S



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。产品用于限制屈伸和伸展，控制膝盖创伤后以及手术后修复的活动范围。产品采用流线型轻量化的设计。设置有支撑器和舒适的防滑衬里，通过支撑器使得膝关节与大/小腿有妥帖的保护，特别的轮廓设计，为腿部提供顺畅的流动性和提高患者的韧带保护性。

二. 预期用途

用于膝部部位的外固定或支撑。

三. 适应症

- 前交叉韧带 (ACL), 后十字韧带 (PCL), 内侧副韧带 (MCL), 外侧副韧带 (LCL) 修复/损伤
- 胫骨平台骨折
- 骨软骨修复
- 半月板修复
- 髌骨肌腱修复
- 髌突骨折
- 胫骨高位截骨术
- 急性扭伤/扭伤膝盖

四. 应用说明

注意:

本产品须由医生或专业人员来安装和调整。长款与短款穿戴方法相同，长款与短款的区别仅是长款比短款多了绑带#7 和绑带#8。

步骤 1:

松开固定带，将泡沫垫 1 包裹膝盖中心以下的小腿部分并固定住（图 1a）。

步骤 2:

将泡沫垫 2 包裹膝盖中心以上的大腿部分并固定住（图 2b）。

步骤 3:

把腿放进支具内，两边支架应在腿部两侧相对应且铰链中心位置与膝盖中心位置对齐（图 3c）。

步骤 4:

紧固绑带。用手固定住支具防止移动。并依次将绑带 3-4-5-6-7-8 环绕腿部穿过绑带扣并紧固在相反的方向上，请正确使用术后膝盖支撑。（图 4d~4e）

要拆卸支架，只需解开带子，打开衬垫 1&2 将支架拆下并可作为一个单元重新应用。

重要: 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或支架向下移动。注意：从侧面看，铰链应在膝盖中线稍靠后一点。为了确保适当的活动，在行走时，支架下降是正常的。必要时进行绑带和位置调整。

步骤 5. 调整活动范围

按下并移动屈伸或伸展的角度调整键，根据需要移动到标示的角度刻度上。（图 5f）。

术后穿戴时间：支具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) 两个铰链必须设置为相同的扩展和/或屈曲设置。
- 3) 在调整固定器之前，患者应咨询自己的医生。
- 4) 本产品须由执业医师开处方购买并安装。
- 5) 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。

锁紧说明

- 1) 通过角度调整键并滑动到所需位置，可以在 -10° 到 30° 之间选择角度限制设置。
- 2) 弯曲极限设置可以选择在 -10° 到 120° 。
- 3) 铰链可通过滑动快速锁紧按钮进入锁紧位置，锁紧位置为 5 个位置中的任意一个：拉伸 -10° 、 0° （中间）、 10° 、 20° 、 30° 。

保养与维护

衬里可以用中性洗涤剂和 30°C 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，铰链可用干硅胶喷雾来润滑。

警告: 如果您在使用此产品时感到疼痛，肿胀，发生变化，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) 金属支架：铝合金/不锈钢
- 2) 塑胶支架：聚酰胺
- 3) 绑带扣：尼龙
- 4) 配件：尼龙/玻纤
- 5) 绑带/衬垫：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：5 年。
- 2) 产品的保管：未使用前请放置在干燥、清洁的室内，保证室内通风。
- 3) 运输：本产品存储及运输的过程，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 5 年
-  参考使用说明

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。

金属支架----- 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

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【说明书修订日期】2023 年 06 月 30 号

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