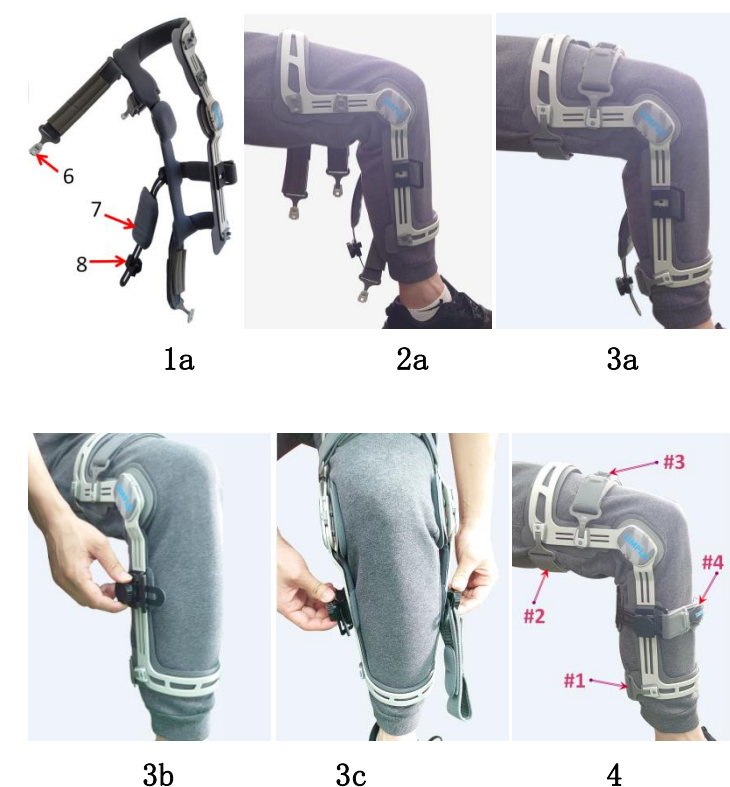


Simple Medical(Shenzhen)Limited Instruction For Use

SIMPLE Knee Brace H4 PCL

Model: 11049& 11050 Size: S, M, L, XL



APPLICATION INSTRUCTIONS

STEP 1. Release the Straps, hold the button 6 and remove the buckle from the buckle seat, and release the strap #4 synchronously. . Release the adjustment belt 7 (see step 1.1) and then release the adjustment seat 8 (the side with the Quick Release Buckle (Fig 1a).

STEP 1.1. Adjust the tightness of the push-back plate. Pull both sides of the rotating knob outward, both sides hear a sound that has unlocked the knob, push the plate back is loosened. Press both sides of the knob inward, both sides hear a sound indicating that the knob has been locked, clockwise of the knob is tightened.

STEP 2. Sit with your legs in the brace, knees slightly bent, center of hinge aligned with center of the knee (Fig 2a).

STEP 3. Tighten the straps. When fastening straps , the product and hinge remain supported to prevent movement. fix the strap #1/#2/#3 in turn. When fastening, the Quick Buckle will be fastened, and the buckle should be fastened in place to ensure the fastening position of the buckle. (Fig 3a) The sequence of tying straps is as follows:

Strap#1: Attach the lower calf position

Strap#2: Attach the upper thigh.

Strap#3: Tie the lower thighs, but not too tight. Excessive tightening may limit circulation or cause the frame to move downward.

STEP 3.1 Adjust the rear push plate. Adjust the seat to the guide rail mouth push back can be fixed. After fixing and locking the knob, rotate the knobs on both sides and adjust the back push plate until the level of the tibial tuberosity (the projecting bone at the upper tibia) is consistent with the level of the healthy leg (adjustment here is for professionals only) (Fig 3b~3c). After adjusting, fix strap #4

STEP 4. Adjust the tightness of each strap for comfort. (Fig 4).

NOTICE:

From the side, the hinge should be slightly behind the midline of the knee. The strap #1, #2 and #4 will affect the tightness of the whole product. 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. After the setting is completed, the braces can be taken off by buckles without relaxing and tightening each fixed strap. (Fig 4).

"WEARING TIME"

:Gradually increase the wearing time of the brace and adjust the wearing time of the brace if the body allows.

POSTOPERATIVE WEARING:

The standard of wearing should be determined by the doctor, including the angle of flexion and extension and the time of wearing every day.

The pain caused by osteoarthritis takes time to subside. Wearing a brace regularly for weight-bearing activities (such as walking) will start to feel lighter as it will reduce joint load. This may require wearing it for weeks or more to reduce joint load until your primary care physician allows you to remove the brace.

RANGE OF MOTION ADJUSTMENTS

Start from the standard 0°.Additional flexion and extension angle accessories can be installed and they shall be fitted by the doctor as required. Optional extension angles include 5°, 10°, 15°, 20°, and 25°; Optional flexion angles include 30°, 45°, 60°, 75°, and 90°.

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

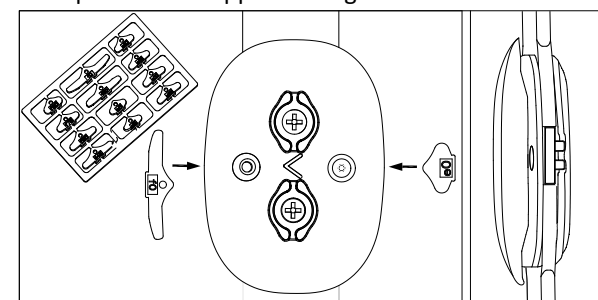
IMPORTANT: Both hinges must be set to the same extension and/or flexion settings. For 0° extension limiting, 0° extension stops must be used.

STRAP LENGTH ADJUSTMENT

To determine the required length, open the strap pad, open the end of the binding strap, separate the velcro and the binding strap, cut to the required length, and then attach the strap pad to the end of the binding strap.

TO CHANGE AN EXTENSION STOP:

Unscrew from the front of the hinge cap. Shake out the extension stop. Insert another extension stop into the front of the hinge and replace the screw. Repeat for the opposite hinge. Insert a flexion stop into the back of the hinge and use the extra screw that is attached to the flexion/extension stop tree to secure. Repeat for the opposite hinge.



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 sources for drying. Metal parts should not be washed with water. Hinges can be lubricated with dry silicone spray.

WARNINGS:

If you experience pain, swelling, sensory changes, or discomfort with this product, please contact your doctor.

For Single Patient Use Only

NOTICE: The device is a one-element holistic treatment program managed by medical professionals. There is no guarantee that damage can be prevented by using the device.

BASIC PRODUCT ENVIRONMENT

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

PRODUCT MATERIALS

- 1)Metal support: aluminum alloy/stainless steel
- 2) Buckle: ABS/ polyester thermoplastic elastomer
- 3) Angle adjustment accessories: nylon + glass fiber
- 4) Strap/pad: nylon/polyurethane/polyester /EVA/ Velcro

CONTRAINDICATION

⚠ Use with caution for unstable fractures;

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

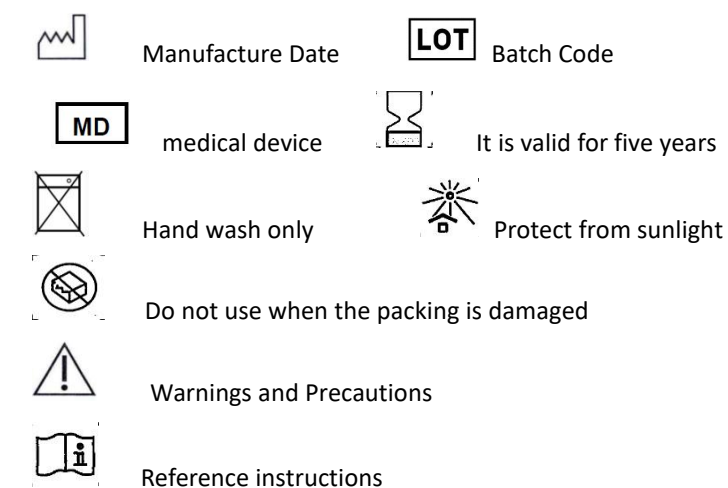
Storage, transportation and expiry date of products

- 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 the Packaging of this product according to the local laws.

SYMBOL AND PICTURE DESCRIPTION



ACCESSORIES LIST

- Instructions ----- 1 copy
- Angle adjusting accessories ----2 PCS (sets)
- Knee pad ---- - 2 PCS (sets)

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 are any material or process defects, please contact your seller directly. The manufacturer will completely or partially repair or replace the equipment and /or accessories.

Metal support ---- -- 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



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

产品说明书

膝部固定器

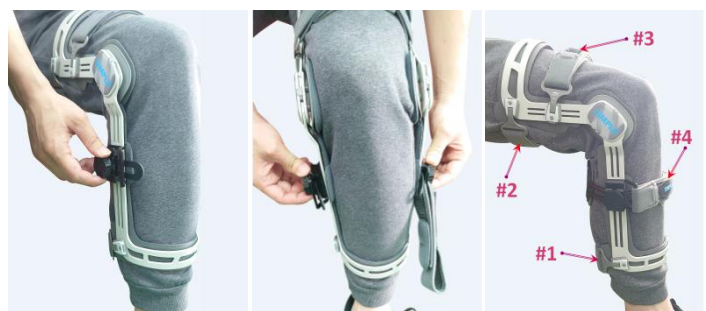
产品型号：11049&11050 产品规格：S, M, L, XL



1a

2a

3a



3b

3c

4

一. 产品结构及性能

采用高分子材料、织物、皮革、金属等材料制成。产品采用流线型轻量化的设计，设置的旋钮调节系统和专利技术的快速搭扣系统可精准快速调节与穿戴。特别的轮廓设计，为腿部提供顺畅的流动性，提高韧带的保护性。通过设置的支撑器支撑和舒适的防滑衬里，使得膝关节与大/小腿有妥帖的保护和舒适的穿戴感且有助于缓解压力点，帮助患者得到良好的恢复。

二. 适应症

用于膝部部位的外固定或支撑。

三. 适应症

- 后十字韧带受伤后的保守治疗
- 后十字韧带重建后的术后治疗

四. 应用说明

步骤 1: 松开固定带，按住按钮 6 依次将快速扣从扣座上取出，绑带#4 同步松开。小腿后推板松开前先将调节带 7 松开（松开与收紧方法见步骤 1.1）再将调节座 8（有快速绑带扣那一侧）往前推松开即可（图 1a）。

步骤 1.1: 后推板松紧度调节。将两侧旋转钮往外拉，两侧听到咔哒声即已解锁，将两边旋钮往里按，两侧听到咔哒声即已上锁。将推板往后拉即是松开，顺时针旋转旋钮即是收紧。

步骤 2: 坐着把腿放进支具内，膝盖稍微弯曲，铰链中心位置与膝盖中心位置对齐（图 2a）。

步骤 3: 紧固绑带。在紧固绑带时，产品与铰链处保持支撑状态防止移动。依次将绑带#1/#2/#3 固定住。紧固时快速扣要扣到位，保证快速扣位置紧固（图 3a）。系绑带的顺序如下：

绑带#1：系上小腿下部。

绑带#2：系大腿上部。

绑带#3：系大腿下部，不要过紧。过紧可能会导致血液循环缓慢或支架向下移动。

步骤 3.1: 调节后推板和固定绑带#4。将调节座对准导轨口往后推即可固定。固定后使旋钮处于上锁状态，旋转两侧旋钮，调节后推板直到胫骨结节骨（胫骨上端的突出骨）的水平高度与健康腿高度一致（此处调节仅限专业人士操作）（图 3b-3c）。调节好后再固定绑带#4。

步骤 4: 调整各个绑带的松紧度，直到舒适为止（图 4）。注意：从侧面看，铰链应在膝盖中线稍靠后一点。绑带#1, #2 和#4 将影响整个产品的穿戴松紧度。为了确保适当的活动，在行走时，支架下降是正常的。必要时需进行绑带和位置的调整。设置好后，支具佩戴可使用快速扣（图 4）穿脱，不需要放松和收紧每条固定带。

“穿戴时间”：

逐渐增加支架的穿戴时间，在身体允许的状态下调整支具的穿戴时间。

术后穿戴：

支具穿戴的标准应由医生来制屈伸的角度和每天的穿戴时间。

骨关节炎引起的疼痛需要时间来消退。经常穿戴支具负重活动（例如：步行），会让你开始感觉轻松，因为它会减轻关节负荷。这可能需要佩戴几个星期或以上来减轻关节负荷，直至你的主治医生同意你取下支具。

运动调整范围：

支撑从标准 0° 延伸。额外的屈伸档可以安装，他们是由医生按规定或需要来安装适合的支撑。延长挡位可选 5°，10°，15°，20°，和 25° 屈曲挡位可选 30°，45°，60°，75° 和 90°。

*请在医生或专业人士指导下购买和使用。

*重要事项：两个铰链必须设置为相同的扩展和/或屈曲设置。对于 0° 扩展限制，必须使用 0° 扩展停止。

绑带长度调整：

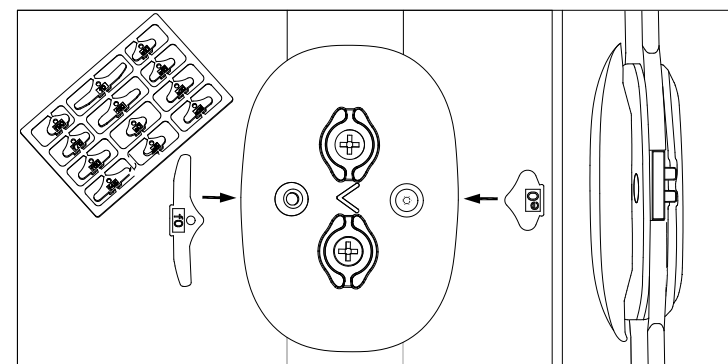
确定所需长度，打开软垫带，打开绑带尾端，分开魔术贴和绑带，剪切至所需长度，再将软垫贴至绑带尾部。

更改延伸限制：

松开铰链前面的螺丝，在铰链的前部插入另一个延伸限制调整配件，并更换螺丝。重复另一个铰链。

插入弯曲限制：

在铰链后面插入一个弯曲调整配件，并使用附加到屈曲/扩展调整配件啊的螺钉来固定。重复另一个铰链。



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，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，感觉变化，或有不适的反应，请停止使用联系您的医生。仅适用于单例患者。

注意：该设备是只有一个元素的整体治疗方案由医疗专业人员管理。不能保证通过使用该装置可以防止损伤。

五. 产品基本环境

- 1) 环境温度：-15~60℃
- 2) 相对湿度：≤80%

六. 产品材料

- 1) 金属支架：铝合金/不锈钢
- 2) 搭扣：ABS/聚酯型热塑性弹性体
- 3) 角度调整配件：尼龙+玻纤
- 4) 绑带/衬垫：尼龙/聚氨酯/聚酯/EVA/魔术贴
- 5) 旋钮调节系统：PE/POM/不锈钢丝/铝合金

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 5 年
- 📖 参考使用说明

十一. 配件清单

说明书----- 1 份
角度调整配件----- 2 个（套）
膝衬垫----- 2 个（套）

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
【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
【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】2023 年 06 月 30 号
【网址】www.simplemedical.cn