

Simple Medical(Shenzhen)Limited Instruction For Use

SIMPLE Knee Brace H4 PCL

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



PRODUCT STRUCTURE AND PERFORMANCE

The product is mainly made up of aluminum alloy bracket, knob adjusting system, patented fastener system, straps, polymer material accessories, linings and accessories. The product adopts streamlined and lightweight design, the set knob adjustment system and the patented fast buckle system can be adjusted and worn accurately and quickly. Special contour design provides smooth flow for legs and improves the protection of ligaments. With the support device and comfortable non-slip lining, the knee joint and lower leg are properly protected and comfortable to wear and help relieve pressure points, helping the patient to get a good recovery.

INDICATIONS:

- Conservative adjuvant treatment after posterior cruciate ligament injury
- Postoperative adjuvant therapy after posterior cruciate ligament reconstruction

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.

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**

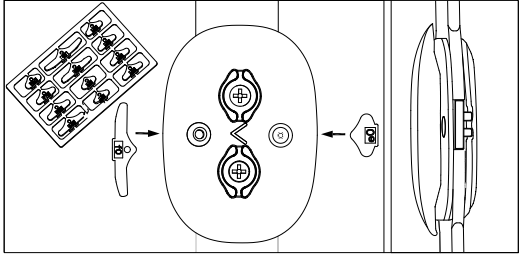
IMPORTANT: Both hinges must be set to the same extension and/or flexion settings. For 0° extension limiting, 0° extension stops must be used.

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 bend adjustment fitting behind the hinge and secure it using screws attached to the bend adjustment fitting. Repeat for another 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

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

	Manufacture Date		Batch Code	
	medical device		Expiry Date	
	Hand wash only		Protect from sunlight	
	Do not use when the packing is damaged			
	Warnings and Precautions			Reference instructions

ACCESSORIES LIST

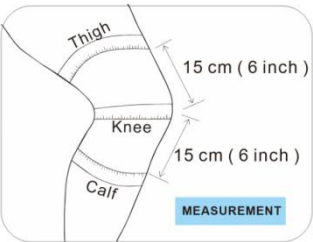
Instructions ----- 1 copy

Angle adjusting accessories ----2 PCS (sets)

Knee pad ---- - 2 PCS (sets)

Selection

Item	REF. 11049 (Left)		REF. 11050 (Right)
Size	S, M, L, XL		
Colour	Grey		
Size	Thigh	Knee	Calf
S	15.5-18.5" (39-47cm)	13-14" (33-35.5cm)	12-14" (30.5-35.5cm)
M	18.5-21" (47-53.25cm)	14-15" (35.5 -38cm)	14-16" (35.5-40.5cm)
L	21-23.5" (53.25-59.5cm)	15-17" (38-43 cm)	16-18" (40.5-47cm)
XL	23.5-26.5" (59.5-67.25cm)	17-19" (43-48.25 cm)	18-20" (47-50.75 cm)



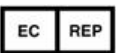
WARRANTY

Simple Medical (Shenzhen) Limited warrants to the user who originally purchases this product that it is free from defects in material and workmanship. The sole obligation of Simple Medical (Shenzhen) Limited in the event of breach of warranty shall be to repair or replace the defective product or part(s).



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.

Fascinatïo Boulevard 522 ,Unit1.7,2909VA Capelle aan den IJssel ,The Netherlands

Tel : +31(0)10-3034500

***Please refer to the Instructions before usage. 11049&50 V0.2**

