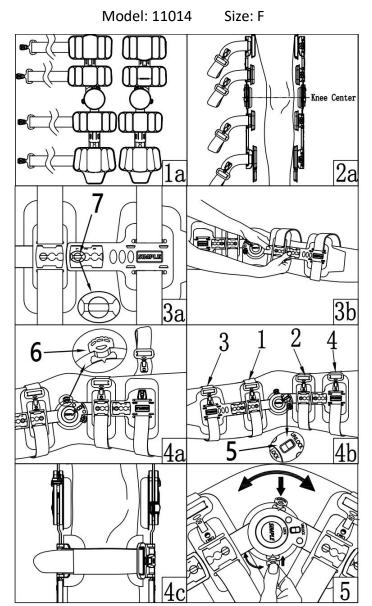


Simple Medical (Shenzhen) Limited **Instruction For Use**

SIMPLE Premium Post-Op Knee Brace K1



Product Structure and Performance

The brace is mainly composed of aluminum metal bracket, polymer material fittings, straps, liners and accessories. The products are designed to limit flexion and extension and control the range of post-traumatic and post-operative repair of the knee. The product adopts streamlined lightweight design with support and comfortable non-slip lining. With the support device, the knee joint and the large / lower leg are properly protected, and special contours are designed to provide smooth mobility for the legs and to improve the protection of the patient's ligaments.

INDICATIONS

- •ACL, MCL, PCL, LCL repairs/injuries
- Meniscal repairs
- •Tibial plateau fractures
- Osteochondral repairs •Sprains/strains of the knee
- Patellar tendon repairs
- Condylar fractures
- HTOs(High Tibial Osteotomy)

APPLICATION INSTRUCTION

NOTICE: This product must be installed and adjusted by a doctor or professional.

STEP 1. Loosen the fixing straps, take the quick buckle out of the buckle seat in turn, and straighten the knob of the Angle adjustment button 6 (Fig 1a).

STEP 2. 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. 2a)

STEP 3. Adjust the length of the connecting rod. Press down the adjustment key 7 on the bracket and push the bracket to the required length, and then release it to lock the plastic bracket. (Fig 3a~3b).

IMPORTANT 1: Doctors should adjust the length of the hinge to provide optimal knee stability. The height of the hinge wall of the thigh should be less than 5 cm from the groin, and the height of the hinge wall of the calf should not be lower than that of the joint of the calf and the Achilles tendon.

STEP 4. Fasten the straps. Hold the brace by hand to prevent it from moving. And buckle the buckles in turn, and the buckles should be buckled in place. After fastening the buckle position, adjust the length of the strap and the comfort of the cushion before fastening the strap. The length of the strap can be trimmed as required (Figure 4a~4c)Fasten the straps in the following order:

. Strap#1: Fasten the strap on upper calf

Strap#2: Fasten the strap on lower thigh

Strap#3: Fasten the strap on lower calf

Strap#4: Fasten the strap on upper thigh, not too tight. Too tight may lead to slow blood circulation or downward movement of the

NOTICE: 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. After the setting is completed, the braces can be taken off by the quick buckles without relaxing and tightening each fixed strap. (Fig 4a).

STEP 5. Adjust the range of activities. Press and hold down the Angle adjustment button 6, move it to the marked Angle scale as needed, and press the knob of the Angle adjustment button 6 to the inside of the leg to 90°. Then push the LOCK button on the chuck 5 in the direction of "LOCK" to prevent the hinge wall from moving (Fig 5).

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

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

* IMPORTANT 2:

- 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
- 3) Before adjusting the brace, the patient should consult his own
- 4) This product shall be purchased and installed on prescription by a medical practitioner and worn.
- 5) Proper rehabilitation and activity improvement are also indispensable processes in safe treatment planning.

Strap length adjustment

Determine the required length, open the Velcro at the strap end, separate the Velcro at the strap end stick and strap, cut strap to the desired length, and then stick the Velcro at the strap end back to the end of the strap

LOCKING INSTRUCTION

- 1) Determine the desired locking angle
- 2) Slide the adjustment button toward the center of the hinge to lock the hinge angle.
- 3) The knob of Angle adjustment button 6 is pressed to the inside of the leg to 90°.

CARE AND MAINTENANCE

Liners can use neutral detergent and 30 $^{\circ}\mathrm{C}$ water washed by hand, and natural dry. Do not use clothes dryer or other heat source for

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 \sim 60 $^{\circ}$ C
- 2)Relative humidity: ≤ 80%

Product materials

- 1)Metal bracket: aluminum alloy/stainless steel
- 2) plastic bracket: polyamide
- 3)Button / buckle: poly formaldehyde
- 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

LOT

Batch Code



medical device





Protect from sunlight

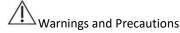


Hand wash only



Do not use when the packing is damaged







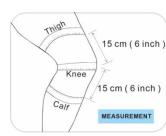
Reference instructions

Accessories list

Instructions ----- 1 copy

Selection

	Item	REF. 110	REF. 11014		
	Size	F			
	Colour	Grey			
	Size	Thigh	Knee	Calf	
	F	15.5-26.5"	13-19"	12-20"	
		(39-67.25cm)	(33-48.25cm)	(30.5-50.75cm)	



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).



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*Please refer to the Instructions before usage.

11014 V0.3