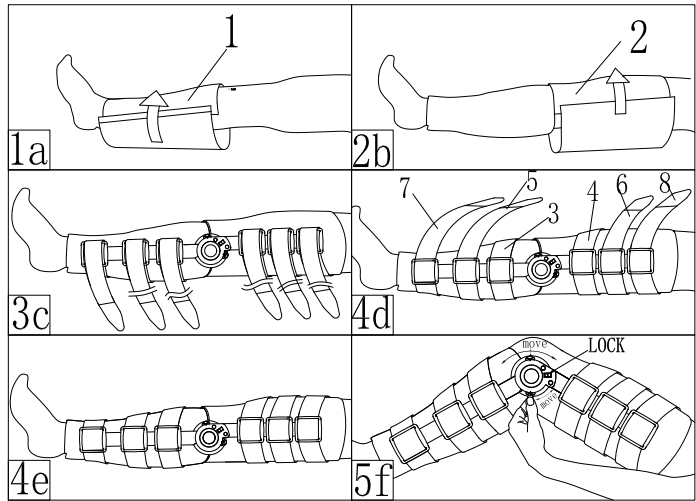


Simple Medical(Shenzhen)Limited Instruction for Use

SIMPLE Post-Op Knee Brace K2

Model: 11015 Size: L&S



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:

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

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) Thise 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
- Expiry Date
- Protect from sunlight
- Hand wash only
- Do not use when the packing is damaged
- Warnings and Precautions
- Reference instructions

Accessories list

Instructions ----- 1 copy

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

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

11015 V0.2