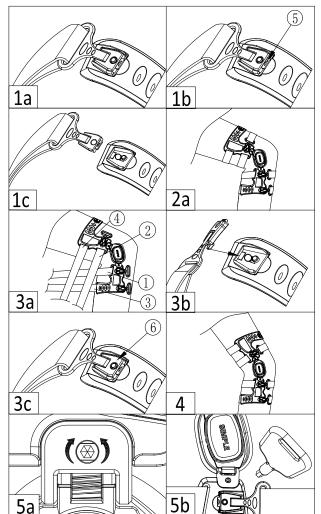


Simple Medical (Shenzhen) Limited Instruction For Use

SIMPLE Premium OA Knee Brace S2

Model: 11007&11011 Size: F



Product Structure and Performance

The Product is mainly composed of plastic shells, metal bracket, straps, liners and accessories. It is designed to be lightweight, with a built-in brace and non-slip liner for proper protection of thigh/calf. The unique patented hinge technology can effectively reduce the load of knee varus or valgus. Through the optimization of single column support and unique knee varus or valgus angle adjustment, it helps to relieve the pain and pressure points of the knee joint. Special profile design provides smooth flow of the legs and improves ligament protection. Patented fast fastening system, which can quickly wear and take off the product. The truss pad adopts a mesh system, which allows air circulation to keep the skin away from heat and humidity and improves the comfort of wearing. The product is suitable for a variety of uses, so that patients get a good recovery.

Indications:

- Mild to severe unicompartmental knee osteoarthritis
- Medial or lateral compartment

Application instructions

NOTICE: Before use, please set the hinge of 0°on horizontal position. The setting of the support angle should be performed by a trained professional in accordance with the doctor's instructions for inner and outer unloading, which will be adjusted in step 5.

STEP 1. Loosen the fastening strap and press and hold button 6 to remove the buckle from the base in turn (Fig 1a~1c).

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

STEP 3. Tighten the straps when fastening the straps the hinge should be kept in a supporting state to prevent movement. Click the buckles in place to ensure that the position of the straps is tight(Fig 3a~3c).The sequence of fixed straps is as follows:

Strap#1: Fasten the upper part of the calf.

Strap#2: Fasten the lower thigh.

Strap#3: Fasten the part of the lower calf..

Strap#4: Fasten your upper thigh, not too tight. Too much tightness can result in slow circulation or a downward movement of the stent. **STEP4.**Adjust the tightness of each strap, which should be tightened comfortably to ensure safety support and provide unloading.

NOTICE: From the side, the hinge should be slightly behind the midline of the knee (fig 3a~3c). 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).

STEP 5.Product initial installation: knee bend30 °, turn hinge center screw 1 / 8 (important) clockwise with adjustment tool to increase unloading on the outer side or unclockwise 1 / 8 turn to the center. This is the best starting point for initial use (fig 7 \sim 8).

STEP 5-1. Stand and walk short distances to ensure comfort after each adjustment and adjustment of support. If there is any discomfort in the knee or leg, adjust the angle slightly back.

If more unloading is required, turn hinge center screws no more than 1/8 turn. Walk after adjustment and check for comfort.

* Important: Excessive adjustment of hinge center screws may cause discomfort or skin pressure problems. Please adjust carefully "Wearing time":

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

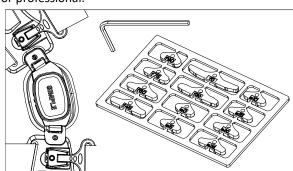
Preoperative wearing time: The first wearing time starts from 30 minutes and gradually increases to no less than 2 hours per day according to the degree of body adaptation. The supporting angle of hinge can be adjusted again in condition of no discomfort.

Postoperative wearing: The standard of wearing should be decided by the doctor, including the angle of hinge support, 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.



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 pad back to the end of the binding strap.

CARE AND MAINTENANCE

Liners can wash by hand using neutral detergent and 30 $^{\circ}$ C water, 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 experience pain, swelling, sensory changes, or discomfort with this product, please stop using and 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) Plastic shell: polyester resin
- 2)Metal support: aluminum alloy/stainless steel
- 3) Buckle: ABS/ polyester thermoplastic elastomer
- 4) Angle adjustment accessories: nylon + glass fiber
- 5) 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;

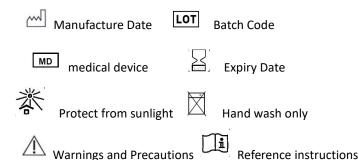
Storage, transportation and expiry date of products

- 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 dust-proof, 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



Accessories list

Instructions ----- 1 COPY

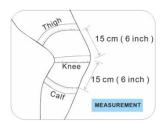
Angle adjusting accessories ---- 1SET

Angle adjustment key ---- 1PCS

Condyle pad ---- -- 1PCS

Selection

Item		REF. 11007 (Left) REF. 11011 (Right)		
Size		F		
Colour		Grey		
Size		Thigh	Knee	Calf
F	1	5.5-26.5"	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 11007&11 V0.2