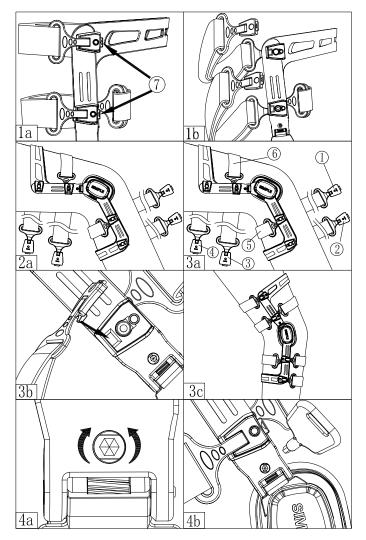


Simple Medical(Shenzhen)Limited **Instruction For Use**

SIMPLE Dual Upright OA Knee Brace M1

Model: 11018 & 11019 Size: S, M, L, XL



PRODUCT STRUCTURE AND PERFORMANCE

The support is mainly composed of aluminum alloy bracket, macromolecule material fittings, band, lining and fittings. The product has a streamlined lightweight design with support and a comfortable non-slip lining. 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. The special contour design provides smooth mobility for the legs, improves the protection of the ligaments, and the patented fast fastening system can be applied quickly

INDICATIONS:

• Patients with knee varus support and mild to severe osteoarthritis and ligament instability on one knee.

APPLICATION INSTRUCTIONS

STEP 1: Loosen the fastening belt and press and hold button 7 to remove the buckle from the base in turn (figure 1a~1b).

STEP 2: Sit with your legs in the brace, knees slightly bent, center of hinge aligned with center of knee (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:Attach the upper calf position

Strap#2: Attach the lower leg.

Strap#3: Attach the lower leg of the thigh.

Strap#4: Tie the upper thighs, but not too tight. Excessive tightening may limit circulation or cause the bracket to move

Strap#5: Fasten the back strap and tighten it.

Strap#6: Fasten the front strap and tighten it.

STEP 3.1. Adjust the tightness of each strap for comfort.

NOTICE: From the side, the hinge should be slightly behind the midline of the knee. The band #1, #3 and #5 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 belt. (Fig 3c)

STEP 4. 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 4a ~4b).

STEP 4-1. 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 are 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 same extension and/or flexion settings. For 0° extension limiting, 0° extension stops must be used

STRAP LENGTH ADJUSTMENT

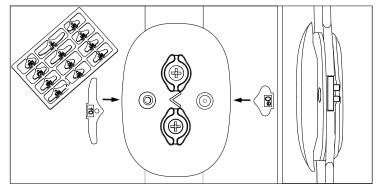
To determine the required length, open the cushion belt, open the end of the binding belt, separate the Velcro and the binding belt, cut to the required length, and then attach the cushion to the end of the binding belt.

TO CHANGE AN EXTENSION STOP:

Unscrew the screw on 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.

TO INSERT A FLEXION STOP:

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

Lining 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 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) 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

riangle 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

Hand wash only





Expiry Date





Protect from sunlight



Do not use when the packing is damaged



Reference instructions

Warnings and Precautions

ACCESSORIES LIST

Instructions ----- 1 copy

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

Angle adjusting accessories ---- PCS (sets)

Angle adjustment key ---- 1PCS

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

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