ACTIMOVE INSTRUCTIONS FOR USE

Actimove® Post-Op ROM Knee Brace

Medical device, medical accessory.
Expiry date: see on the packaging.
Manufacturer: BSN Medical GmbH, Germany, Schützenstrasse 1-3 22761 Hamburg
Storage: at room temperature, protected from direct heat.
Distributed by Essity Hungary Ltd. Budakeszi Road 51. 1021 Budapest

Instructions for use

Dear Customer,

Thank you for choosing Actimove® Post-Op ROM Knee Brace. The Actimove® Post-Op ROM Knee Brace prevents knee movement or restricts range of motion as prescribed by a medical professional. It can be used after injury, post-surgery, and during rehabilitation. With the quick-locking keys of the swivel strap the knee can be held at 0°, 15°, and 30° angles. The range of motion can be adjusted in 10° increments for flexion between -10° and 120° and extension between -10° and 90°. The telescopic rods of the knee brace can be easily adjusted to most patients. The knee brace can be worn on the both left and the right knee.

Intended use and Indications: The post-operative use of the product is recommended after the following procedures or in cases:

- Injuries of the ACL (anterior cruciate ligament), PCL (posterior cruciate ligament), MCL (medial collateral ligament), and LCL (lateral collateral ligament).
- Fracture of the tibial joint surface
- Osteochondral (involving the cartilage and underlying bone) restoration
- Meniscus (cartilage ring) restoration
- Patellar realignment
- Condylar (bone joint end) fracture restoration
- Knee dislocation or sprain
- High tibial osteotomy (knee realignment surgery)

Application: Initial application should only be done by a healthcare professional. Before applying, carefully read the instructions.

1. Unlock the straps, open the telescopic rods of the swivel brace, then extend the knee brace (1)

2. Adjust the knee brace so that the patient's knee is positioned in the centre between the swivel straps. The swivel straps rods marked with "TOP" should be at the thigh. (2)

3. Adjust the knee brace to the length of the patient's leg by pushing the buttons on the rods in the release ("unlock") direction and holding them in place while sliding the rods to the desired length. When the button is released the rod will be placed in locked position. The length indicators on the swivel strap rods help that the adjustment is consistent in the medial and lateral directions. (3)

4. Fix the buckles in a loose position. Start with the closest ones to the knee. After all the buckles are fixed, please check that the lateral and medial position of the swivel strap rod is maintained, and the patient's knee is centred between the rods. (4)

5. Pull the straps through the buckles and fix them with the hook and loop fastener (5). If shorter straps are needed, remove the hook and loop fastener, cut or fold the strap accordingly, and then replace the hook and loop fastener. Adjust the straps sufficiently tight to be comfortable for the patient. (6)

The adjustments of the ROM swivel strap:

1. The swivel strap can be set to 0° (neutral), 15° and 30° using the colour-coded quick-release button in curved position. Before performing the fixation with the quick-release buttons, please make sure that the medial and lateral settings correspond.(7)

2. To set the extension and flexion limits, move the colour-coded quick-release button to the release ("unlock") position. (8) Before performing the fixation with the quick-release buttons, please make sure that the medial and lateral settings correspond.

The extension limit can be set between -10° and 90° by pulling out and sliding the tab to the desired position.

The flexion limit can be set between -10° and 120° by pulling out and sliding the tab to the desired position. (9)

After the initial application, the Actimove® Post-Op ROM Knee Brace can be easily removed and repositioned by releasing the buckles.

Remove only upon the instruction of your medical practitioner.

Contraindications: There are no contraindications for the use of the product.

Warnings and Precautions:

• The Actimove® Post-op ROM Knee Brace is designed for single-patient use. It is not intended for use by multiple patients.

• If you experience pain, swelling, or any other symptoms while use, please discontinue the device, and consult a medical practitioner.

• The device is intended to protect the injured area by restricting the range of motion in accordance with the rehabilitation program or other appropriate measures prescribed by a medical practitioner.

Warning:

• Generally there is no side effects when wearing a device recommended by your medical practitioner and properly fitting.
• In case of existing sensory disorders, numbness may lead to circulatory problems due to compression at the pressure points.
• In such cases, always check the position of the product and the strength of the fastening.
• Improper application and fastening of the device may cause skin changes and impairment of arterial blood supply.
•If the symptoms are unchanged, please consult your treating physician immediately.

Cleaning and care: Plastic parts (such as fastening straps), use a damp cloth soaked in gentle soapy water to clean the orthopedic frame.
Textile parts (foam inserts): Wash the foam inserts by hand in a mild soapy water, then rinse them thoroughly. Gently press out most of the water and lay them flat to air-dry. Avoid direct heat or sunlight exposure. Do not bleach, iron, or dry clean. Store in a dry, well-ventilated place at room temperature.

Note:

Any serious incidents related to the device must be reported to the company as well as the relevant authorities in your country.

Please immediately report any serious and unexpected events related to the use of the device to BSN medical GmbH (BSN Medical GmbH, Germany, Schützenstrasse 1-3, 22761 Hamburg) or Essity Hungary Ltd. (Budakeszi Road 51. 1021 Budapest), as well as to the relevant local authorities (National Institute of Pharmacy and Nutrition - OGYÉI, 1051 Budapest 3 Zrínyi str. Budapest, Tel: (1) 8869-300, E-mail: amd.vig@ogyei.gov.hu, 1372 P.O. Box 450).

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Closing date: July 22, 2022.