



Ligament Description

This brace is effective for the treatment of ligament injuries and/ or rehabilitative use post reconstructive knee surgery.

This device is intended only for the treatment of the indications listed and for patients whose measurements correspond to the sizing table.

Ligament Indications:

- Functional treatment of the knee during the pre- or post-operative period, as well as the rehabilitation period (including following moderate or severe cruciate ligament and/or collateral ligament sprains).
- Conservative treatment of knee ligament injuries and/or ruptures.
- Knee instability

OA Description

This brace is effective treatment for unicompartmental OA (Medial or Lateral).

OA Indications:

- Moderate to severe unicompartment femoral-tibial osteoarthritis of the knee.
- Unicompartment knee joint degeneration requiring offloading.
- Post-operative offloading of a single compartment (articular or meniscus cartilage defect or osteochondral defect).

Properties:

- Stabilization of knee joint ligaments provided by the rigid hinged side uprights
- Extension stops available: 0°, 5°, 10°, 15°, 20°, 30°.
- Flexion stops available: 0°, 30°, 45°, 60°, 75°, 90°, 110°

Contraindications:

- Patients with severe arterial insufficiency and/or varicose veins resulting in a risk to skin, with regular wear of compression garments.
- Known allergy to any of the components.

Adverse effects:

This device can cause skin reactions (redness, itching, burns, blisters...) or wounds of various degrees of severity. Any serious incident that occurs in connection with the product must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient are/is domiciled.

Precautions:

- Follow the recommendations of the healthcare professional who prescribed or supplied the product. In case of discomfort or hindrance, or any unusual reaction during the use of the product, remove the knee brace and consult this healthcare professional.
- Restrict yourself to physical activities authorized by the doctor who is responsible for evaluation your physical condition prior to defining the activities that are safe and appropriate for you to do while wearing the brace.
- The use of rigid orthotics is not recommended during sports or other activities giving rise to shocks.
- Store the brace at normal room temperature, and don't expose the brace to extreme temperatures, especially very hot temperature. To protect the cosmetic finish, when not in use, keep the brace in the original packaging or a small bag. For reasons of hygiene, performance and safety, this brace should only be used by the original users, and should not be worn by any other person.

Care and warranty:

Care of the knee brace

- **Hinges:** The hinges on the brace are pre-lubricated in the factory. If sand, dirt or water gets inside the hinges, they may require lubricating again. If you notice the hinges not gliding smoothly, a few drops of a synthetic lubricant can be applied. Wipe off any excess lubricant before wearing the brace to prevent stains on clothing.
- **Straps:** After prolonged use, if the fibres on your strap do not adhere as well to the Velcro tab, cut the strap shorter so the Velcro tab adheres to a section of the strap that has fresher fibres. If this is not possible, you should contact the medical provider who fit your brace.
- **Pads:** The brace is lined with padding that provides a comfortable interface between the leg and the shells. The straps also have pads. Do not remove these pads from the brace or straps. Wipe the pads after each use to remove any moisture and let the pads air dry. You can also clean the pads with a mild anti-bacterial soap and rinse them off with fresh water. Do not wash the pads in a machine and do not dry in a tumble dryer.



Washing instructions:

- Do not use detergents, fabric softeners or aggressive products (products containing chlorine).
- Squeeze out excess water.
- Dry away from heat sources.

Composition:

Aluminum, stainless steel, nylon, polyurethane, polyamide vinyl

PA12 3D printed upper, lower cuffs, and d-rings

Upper and Lower cuffs available in length of 180mm or 150mm

PA12 3D printed d-rings

Disposal:

Dispose of in accordance with local regulations.

Parts and after sales service:

Comfort pads, condylar pads, hinge caps, straps and other parts of the knee brace may need to be repaired or replaced due to normal wear or damage. If this is the case, you should contact the professional who assisted you in ordering and fitting your brace. Certain parts are covered by a limited warranty (see information below).

Warranty:

Under normal use and conditions, the shells and hinges of the brace are covered by a one year warranty against defects or breaking. Straps, hinge caps, and other replaceable parts are covered for six months. If you experience a problem with the fit or function of the brace, please call the medical provider who fit your brace.

Product disclaimer:

This knee brace is a product prescribed by a physician and should be used in accordance with his or her instructions, as part of a treatment plan for global health. Due to variations in age, health and physical condition, Thuasne does not make any specific recommendations regarding appropriate activities for the user of this knee brace. As the manufacturer has no role in patient selection, or fitting and adjusting the knee brace, or any role in instructing the patient and/or monitoring the use of the knee brace, Thuasne cannot be held responsible for the results arising from the use of the knee brace.

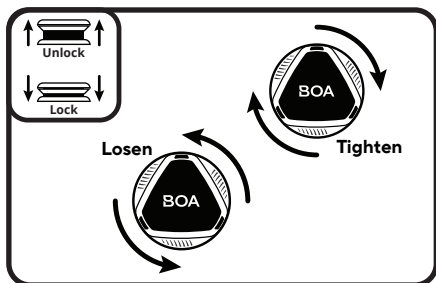
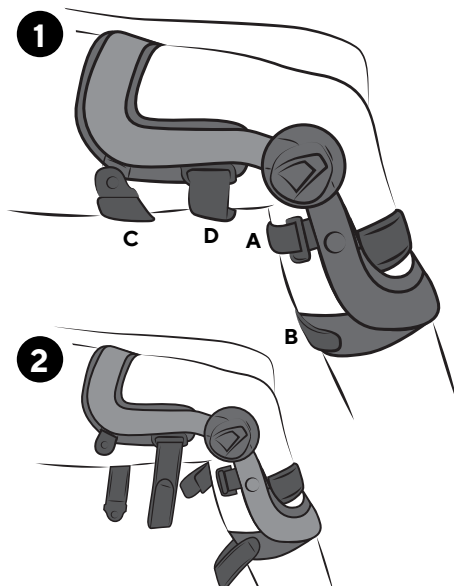
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Foreword(?)

Healthcare Professional: Please read these instructions with the patient when fitting the brace for the first time and make sure that he/she understands how to position the knee brace.

Patients: The medical professional who performed the initial fitting of your brace should have made all the necessary modifications to the corrective force applied by the knee brace, selected the appropriate hinge pads, and adjusted the length of the straps. The fitter should have also explained how to put on your brace. While the process is relatively simple, you are encouraged to refer to the instructions below to ensure you are putting the brace on correctly.

If you feel the need for additional correction in the future, or if you are feeling any discomfort, or are experiencing any other issue with the fit, function or suspension of the brace, stop wearing your brace until you can see your physician or the medical professional who fit the brace. The manufacturer cannot be held responsible for problems or injuries resulting from any unsupervised adjustments.

Fitting instructions

Step 1: Positioning the brace on the leg

Sit on the edge of a chair and slightly bend your leg (30° to 60°).

Step 2: Positioning the brace on the leg

Healthcare professional: Loosen all the straps of the knee brace. For optimal fit, place the knee brace on the bare leg, not on top of clothing.

Patient: Place the knee brace on your leg so that the oval shaped pads attached to the inside of the hinges press against both sides of the knee. The middle of the pads should line up between the middle and the upper third of your knee cap and should also be centered on the side of your leg ②.

Step 3: Fitting the knee brace

Healthcare professional: Fasten the suspension strap A, so it is above the calf muscle, just below the flexion fold on the back of knee.

Next fasten the lower strap B, and then the two straps behind the thigh C and D, and finish by fastening the anterior thigh strap F (if applied*).

Optional: If one or more of the knee brace straps is too long, each strap can be cut to the desired length. To do this, remove the Velcro hook tab from the end of the strap on the anchor side next to the frame of the brace, cut the strap to the desired length, and reattach the Velcro hook tab to the end of the strap ①. Take care to not cut any strap too short. The comfort pads fixed inside the straps may need to be removed for this operation and repositioned after the strap is cut to avoid any interference when the strap is tightened.

Patient: The suspension strap A should be positioned above the natural contour of the upper calf. This strap should be tightened (with the BOA) in the flexion fold behind the knee. It is the most important strap for preventing the brace from slipping down your leg. By tightening the suspension strap A above the calf muscle below the flexion fold behind the knee you will ensure that the hinges are at the correct level on the leg.

Next fasten and tighten the lower strap B, then the two straps behind the thigh C and D. Carefully follow your physician's instructions regarding physical activities and the specific use of this product.

Step 4: Check the fit, suspension and pain level

Healthcare Professional: Ask the patient to stand and walk, taking normal steps and looking straight ahead. Confirm the brace fits and suspends properly on the leg and does not cause the patient any discomfort.

Control of flexion/extension:

During the fabrication of the knee brace, the hinges are set at 0° extension and maximum flexion. To adjust and/or reduce the range of motion of the hinges, follow these instructions and make the adjustments to BOTH hinges. The extension and flexion stops are supplied on a plastic tree in the box (figure 4A, 5A).

Extension stops available: 0°, 5°, 10°, 15°, 20°, 30°.

Flexion stops available: 0°, 30°, 45°, 60°, 75°, 90°, 110°.

Instructions For Adjusting The Extension Stops

At the time of fabrication, zero degree extension stops have been installed in each TM5+ Hinge. To install a different pair of extension stops, follow these instructions :

1. Detach the pair of stops required from the plastic support with all the stops available. You must install identical extension stops in both hinges.
2. Remove the screw located on the side of each hinge ④.
3. After removing the screws, flex the brace and remove the zero degree stop from each hinge. Note the direction each stop is facing.
4. Insert the desired stops, hole end first, with the hook end at the top and facing forward. Straighten the brace to full extension to push the stops down into position. The small hole in each stop must be aligned and visible through the screw hole so the screw will thread into the stop.
5. Reinsert and tighten the screw. Flex and extend the brace several times to ensure the stop is locked into position and functioning properly.

Instructions For Adjusting The Flexion Stops (Optional)

1. To limit flexion, detach the stops required from the two metal uprights with all the stops available. Each stop has the degree etched into the surface. You must install the same degree stop in both hinges.
2. If you are installing the 110° flexion stops, remove the two screws from the posterior aspect of each hinge cover ⑤ and take out the spacer that was installed at the factory. There is only one hole in the 110° stop. Insert the stop, with the flat end facing up, and position it so the hole in the stop is visible through the lower screw hole in the cap. The screw must thread through the cap and stop to secure the stop in the proper position. The second (top) screw can be reinserted back into the hinge cap to fill the empty hole.
3. If you are installing the 0°, 30°, 45°, 60°, 75° or 90° flexion stops, remove both screws from the posterior aspect of each hinge cap and take out the spacer that was installed at the factory. Insert the stop with the flat end facing up and position it so that both holes in the stop are visible through the screw holes in the cap. Thread and tighten the screws through the cap and into both holes in the stop.
4. Flex the brace until the upright contacts the stops to ensure they are functioning properly.



Extension Stop Kit



Flexion Stop Kit

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