

Rebel Reliever

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).
- Knee joint instability after injury or surgery on the cruciate and/or collateral ligaments (*ACL, PCL, LCL, MCL*).

Contraindications:

- Do not place the product directly in contact with damaged skin.
- Patients with severe arterial insufficiency.
- Patients with severe varicose veins preventing the regular use of an offloading brace.
- Allergy to one of the components.
- Severe cognitive and/or psychiatric disability.
- Patients with severe genu recurvatum.
- Patients presenting with significant genu varum or genu valgum.

Adverse effects:

There are no known adverse effects when the product is used correctly.

Healthcare professional instruction guide:

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.

How the RebelReliever® works:

The RebelReliever® knee brace is primarily designed to apply corrective forces and alignment support to your leg by means of a three-point pressure offloading system. These corrective forces help distribute excessive load away from the damaged knee compartment. By helping to keep your leg in a normal alignment, and by redistributing weight throughout your knee joint, the brace will routinely help reduce compression, pain and inflammation. Although the RebelReliever® cannot definitively cure osteoarthritis, by reducing the pain and symptoms, the brace can enable you to resume your physical activities and mobility. The brace may also slow down the progression and increasing severity of your knee OA.

Adjusting the correction:

During your initial fitting, the healthcare professional should have made any necessary adjustments to obtain a base level of corrective force. 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.

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 authorised 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 paint 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.

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 RebelReliever® knee brace.

Warning:

The adjustment of the flexion/extension must be decided and performed by the healthcare professional, not by the patient. Both hinges **MUST** be adjusted to the same angle. There can be damage to the hinges, and compromises (including injury) to the patient, if the settings are not the same on both hinges.

The adjustment of the correction must be decided and performed by the healthcare professional, not by the patient.




Fitting videos

For the healthcare professional



For the patient

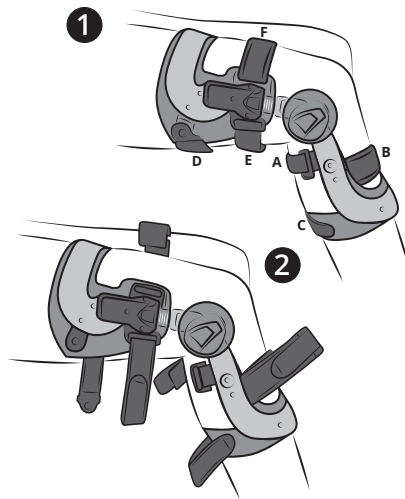


Size in Inches	XS	SM	MD	LG	XL	2XL
 6in Thigh circumference	12 ½ - 15 ½"	15 ½ - 18 ½"	18 ½ - 21"	21 - 23 ½"	23 ½ - 25"	25 - 28"
 Knee width	3 - 3 ½"	3 ½ - 4"	4 - 4 ½"	4 ½ - 5"	5 - 5 ½"	5 ½ - 6"
 6in Calf circumference	11 - 12 ½"	12 ½ - 13 ½"	13 ½ - 15"	14 ½ - 15 ½"	15 - 17"	17 - 19"



Composition : Inner layer = Nylon

Distributed by
Thuasne USA
4615 Shepard Street,
Bakersfield, CA 93313
United States
Tele: 800.432.3466
Fax: 800.798.2722
ThuasneUSA.com



How to fit the knee brace:

Step 1: Evaluation of initial pain

Assess the level of pain felt by the patient to be able to assess the function and efficacy of the knee brace after it is fitted.

Step 2: Positioning the brace on the leg

Loosen all the straps of the knee brace and confirm the LOADSHIFTER Mechanism above each knee joint are in the factory-set neutral position (same height on both sides of the thigh shell). Have the patient sit on the edge of a chair, and have the patient bend his/her knee to a position of approximately 30-60° of flexion. Place the knee brace on the bare leg, not on top of clothing (●). Ensure that the brace size is appropriate by checking that there is no space between the brace and the leg. If there is any gapping, or if the brace is too tight, if possible, manipulate the frame of the brace or retake measurements of the leg and select the appropriate size (see size table on page 1 of this instruction leaflet).

Step 3: Fitting the knee brace

- 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 anterior tibia strap **B** (●). In addition to helping secure the brace to the tibia, the secondary function of this strap is to pre-set the anterior-posterior position of the hinges and uprights, so they align with the midline of the sides of the leg, or just posterior to midline (2nd third of the leg in the sagittal plane).
- The anterior-posterior position of the hinges can be modulated by adjusting straps **A** & **B**. After you pre-set the anterior strap, instruct the patient to leave it closed when putting on or taking off the brace.
- Next fasten the lower strap **C**, and then the two straps behind the thigh **D** and **E**, and finish by fastening the anterior thigh strap **F**.

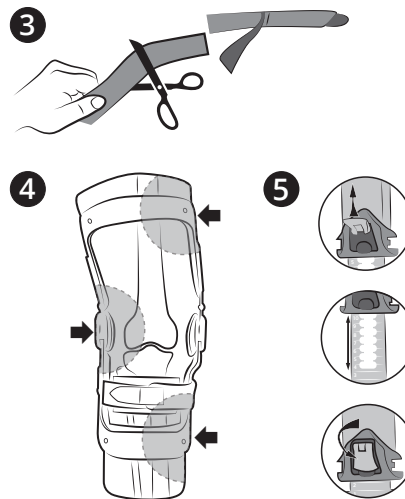
Optional: If one or more of the knee brace straps is too long, each strap can be cut to the desired length. To do this, remove the Velcro hook tab from the end of the strap on the anchor side next to the frame of the brace, cut the strap to the desired length, and reattach the Velcro hook tab to the end of the strap ●

Step 4: Check the fit, suspension and pain level prior to adjusting the corrective force

Ask the patient to stand and walk, taking normal steps and looking straight ahead. Confirm the brace fits and suspends properly on the leg. Ask the patient if the pain level with the brace on (and with the dual LOADSHIFTER Mechanisms still in the neutral position) is the same or less than without the brace.

Step 5: Adjusting the corrective force

The dual LOADSHIFTER Mechanisms enables you to change the angle of the femoral shell of the knee brace to increase the corrective 3-point force and offload the compromised (degenerated, compressed) medial or lateral compartment of

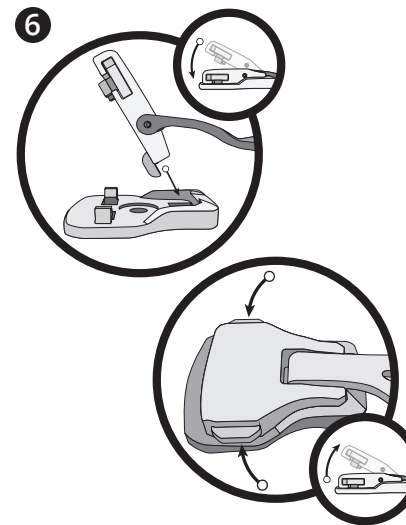


the knee (●). Both LOADSHIFTERS are set during fabrication in a neutral position at mid-height. The optimum way to adjust the correction is by lengthening the upright on the affected side. This produces more leverage force. If the patient is short, you can also increase correction of lowering the upright on the unaffected side of the knee. For severe OA and/or severe varus or valgus deformities, you may need to adjust both LOADSHIFTERS. Collectively, the angle of the Rebel Reliever thigh shell can be adjusted by up to 18°.

Medial Compartment Femoral-Tibial Osteoarthritis of the Knee: This brace is effective for the treatment of unicompartement internal/medial femoral-tibial osteoarthritis of the knee. A thicker condylar pad should be positioned on the external/lateral hinge (on the side opposite the affected compartment). To increase corrective force, the internal/medial upright (affected side) can be lengthened compared with the external/lateral upright, or the external/lateral upright can be shortened compared to the internal/medial upright.

Lateral Compartment Femoral-Tibial Osteoarthritis of the Knee: This brace is also effective for the treatment of unicompartement external/lateral compartment femoral-tibial osteoarthritis of the knee. A thicker condylar pad should be positioned on the internal/medial hinge (on the side opposite the affected compartment). To increase corrective force, the external/lateral upright (affected side) can be lengthened compared with the internal/medial upright, or the internal/medial upright can be shortened compared to the external/lateral upright (●).

- There are lines and numbers on each of the uprights. Beginning with the LOADSHIFTERS in the neutral position, you can raise the LOADSHIFTER above the affected compartment, or lower the LOADSHIFTER on the upright opposite the affected compartment. The initial adjustment should create a 1-3 number/line difference between the two sides of the brace, shifting the angle of the femoral shell to create a corrective force at the top end of the brace on the same side of the leg of the affected compartment, which will create a corresponding increase to the corrective force applied by the thicker condylar pad that should be positioned on the inside of the hinge on the unaffected side of the knee. To adjust the LOADSHIFTERS, lift the black plastic SNAP LOCK lever located above the hinge, on the side of the brace you want to lengthen or shorten (●). After adjusting the angulation of the upper shell of the brace.
- Ask the patient to walk again and assess his/her pain level.
- Repeat the operation, increasing or reducing the correction until it is satisfactory and optimal for the patient.
- If the patient feels any discomfort, reduce the angle of the thigh shell which will reduce the corrective force.
- For conservative treatment, start with a small amount of correction and let the patient wear the knee brace for one or two weeks. If it is necessary to increase the correction, see the patient again.



- A bag containing an additional set of condylar pads is provided in the box with the brace. If necessary, use the set of thicker pads to increase the compression on the sides of the knee. The pad on the unaffected side should routinely be thicker than the pad on the affected side.
- Once the adjustment of the knee brace is finalized, it is possible to trim any excess padding at the lower end of the pads, just above both hinges. There are a series of serrated depressions in the pads to indicate where to cut the pads.

Optional: When ordering a brace with quick release buckles depress side buttons to disengage buckle from it's fixed position. (●) and to reengage insert into slot and press until you hear an audible «click». This should ensure the buckle is secured and fastened. (●)

Patient Instruction Guide:

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.

Fitting instructions:

Step 1: Sit on the edge of a chair and slightly bend your leg (30° to 60°).

Step 2: 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 centred on the side of your leg (●).

Step 3: The suspension strap **A** (●) should be positioned above the natural contour of the upper calf. This strap should be tightened 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 in the flexion fold behind the knee you will ensure that the hinges are at the correct level on the leg.

Step 4: Next fasten and tighten the lower strap **C**, then the two straps behind the thigh **D** and **E**. It should not normally be necessary to readjust the front straps **B** and **F**.

Carefully follow your physician's instructions regarding physical activities and the specific use of this product. It may take several weeks to feel comfortable with the brace on your leg. We recommend that you initially wear the brace for only a few hours a day. Some patients feel immediate pain relief. For others, it can take several weeks to notice measurable benefits.

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 ●A, ●A).

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

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

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 ●.
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.

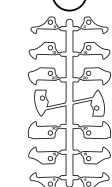
Instructions For Adjusting The Flexion Stops (Optional)

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 ● and take out the spacer that was installed at the factory. 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.

7



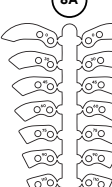
7A



8



8A



Distributed by
Thuasne USA

4615 Shepard Street,
Bakersfield, CA 93313
United States
Tele: 800.432.3466
Fax: 800.798.2722
ThuasneUSA.com