

Rebel Lock

Description/Destination

Rebel® Lock

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.

Properties:

 Stabilization of knee joint ligaments provided by the rigid hinged side uprights

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.
- · Severe knee instabilities requiring a locking orthosis.

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.

$\label{thm:care professional instruction guide:} Healthcare professional instruction guide:$

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.

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 fitthe 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.



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, vinyl

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.

		Size in Inches	xs	s	М	L	XL
4	6 in	Thigh circumference	12 ½ - 15 ½"	15 ½ - 18 ½"	18 ½ - 21"	21 - 23 ½"	23 ½ - 25"
		Knee width	3 - 3 ½"	3 ½ - 4"	4 - 4 ½"	4 ½ - 5"	5 - 5 ½"
9) 6in	Calf circumference	11 - 12 ½"	12 ¼ - 13 ¼"	13 ¼ - 15"	14 ¼ - 15 ¾"	15 – 17"

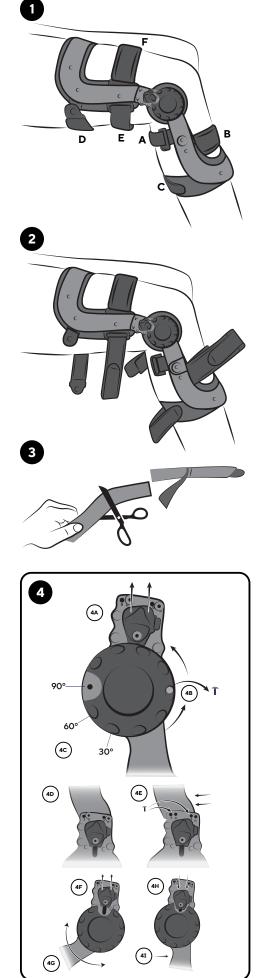


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How to fit the knee brace:

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. 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 ②. 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).

Step 3: Fitting the knee brace

- Fasten the suspension strap **① A** so it is above the calf muscle, just below the flexion fold on the back of knee.
- Next fasten the anterior tibia strap **③ 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**.

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, cut the strap to the desired length, and reattach the Velcro hook tab to the end of the strap ③. 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.

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.

Step 5: To set flexion at 30°, 60° or 90° remove screw using Allen wrench (included), pull lock to highest position A and rotate hinge cap to reveal flexion stops B. Place the screw through the washer and insert at desired setting C. Use Allen wrench to tighten. Repeat on opposite side.

Step 6: To change locking position from 0° to 5°, use the Allen wrench to remove both screws -**D**. Slide thigh shell backwards until both holes align at the 5 setting -**E**. Insert screw and tighten. Repeat on opposite side.

Step 7: To disengage drop locks pull up on the lock until it clicks into the unlocked position F. Hinge will move freely between extension and flexion settings G. To engage the hinges, press buttons at the front of lock H and straighten leg completely. Hinges will lock into place. I

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.

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 $(30^{\circ} \text{ to } 60^{\circ})$.

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 ②.

Step 3: The suspension strap **① A** should be position 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 $\bf C$, then the two straps behind the thigh $\bf D$ and $\bf E$. It should not normally be necessary to readjust the front straps $\bf B$ and $\bf F$.

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.

Distributed by Thuasne USA

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