

Instructions for Use

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.

Contraindications

Patients with severe arterial insufficiency and/or spider veins inducing skin at risk with the regular wearing of compression orthosis or a known reaction or allergy to any of the material ingredients

Warning and Precautions

Read all instructions prior to use. If increased pain, swelling, change in sensation, or any adverse reactions are experienced while using this product, immediately consult your medical professional. This product is intended to be applied by qualified clinician as directed by a physician or other qualified healthcare practitioner. For single patient use only.

Precautions

- Closely follow your healthcare professional's prescription and recommendations for use.
- Check the product is not damaged before use.
- Do not apply the product directly over broken skin or an open wound without an appropriate dressing.
- In the event of discomfort, significant restriction or unusual sensations, remove the product and seek the advice of a healthcare professional.
- In the event of a change in product performance, contact the healthcare professional who prescribed or supplied the product.
- This product is intended for the treatment of a given condition. Its duration of use is limited to this treatment only.
- For hygiene and performance reasons, do not re-use the product for another patient.
- Do not apply the device in direct contact with a greasy substance (ointment, cream, etc.).
- Remove the product before any imaging exams.
- Store at room temperature, preferably in its original packaging.
- The product should be disposed of as per local regulations.

Description

- **Purpose:** the product is aimed at patients with a moderate to severe knee ligament injury and/or in postoperative treatment. The patient's thigh and calf circumferences must correspond to the fitting range.
- **Properties/Mechanism of action:** Stabilization of knee joint ligaments provided by the rigid hinged side uprights.
 - Extension can be adjusted to 10° and 20°.
 - Flexion can be adjusted to 0°, 45°, 60° and 90°.
- **The product is available in 4 forms:** 2 versions (open and closed), each available in 2 lengths (short and long) to meet the needs of patients (example of open long version in **figure A** and closed short version in **figure B**). Each version is available in 7 sizes.
- **The product is composed of:**
 - a fabric part consisting of a 3D knit at the front and a thin, elastic knit at the back;
 - 2 rigid uprights providing knee stability ①;
 - the TM5+ hinge mimicking the knee's natural movements ②, protected by a cover;
 - 2 anterior half-straps and 2 posterior half-straps (including a suspension strap ⑤) for the short version;
 - 4 anterior half-straps and 3 posterior half-straps (including a suspension strap ⑤) for the long version;
 - a patellar insert to enable correct positioning of the product on the leg. The closed version has finger loops for easier fitting.
- The flexion/extension adjustment system ⑦ is designed to be used without tools.
- The design of the frame enables limitation of extension to 0° by default.
- A bag containing 4 metal pins ⑧, required to adjust the hinge of the knee brace, is included in the packaging.
- The product is made of aluminum, stainless steel, polyamide, elastane, polyester, synthetic rubber, polyoxymethylene, TPU, and PVC.

Unwanted side effects

- This device can cause skin reactions (redness, itching, blistering, burns, blisters, etc.)
- Any serious incidents occurring related to the device should be reported to the manufacturer and to the competent authority of the country in which the user and/or patient is resident.

Brace Components & Sizing

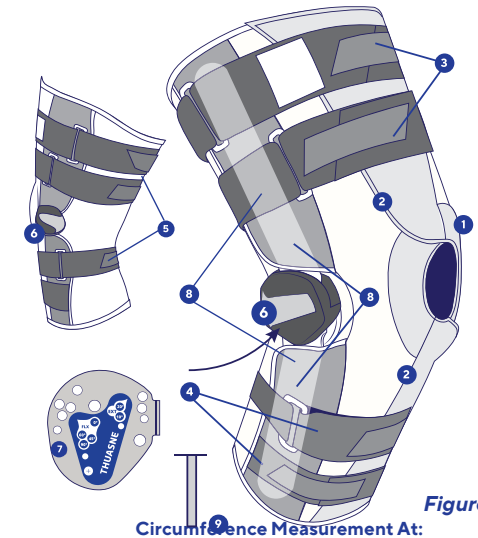


Figure A

Size	6" Above Knee Center	Knee Center	6" Below Knee Center
XS	13 - 15 ½"	11 ¼ - 13"	9 ¾ - 11 ¾"
SM	15 ¼ - 18 ½"	13 - 14"	11 ¼ - 14"
MD	18 ½ - 20 ¾"	14 - 15"	14 - 16 ¼"
LG	20 ¾ - 23 ¾"	15 - 17"	16 ¼ - 18"
XL	23 ½ - 23 ¾"	17 - 19"	18 - 20"
2XL	26 ½ - 29 ½"	19 - 21"	20 - 22"
3XL	29 ½ - 32"	21 - 23"	22 - 24"

Components

1. Patella buttress
2. Wrap opening
3. Upper straps
4. Lower straps
5. Posterior straps
6. TM5 hinge and metal uprights/stays
7. TM5+ ROM tool-less flexion/extension hinge
8. Metal uprights/stays
9. Flexion/Extension Pins (six included)

Also available in short length and/or sleeve style application

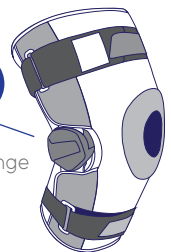
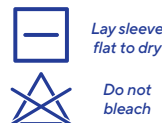
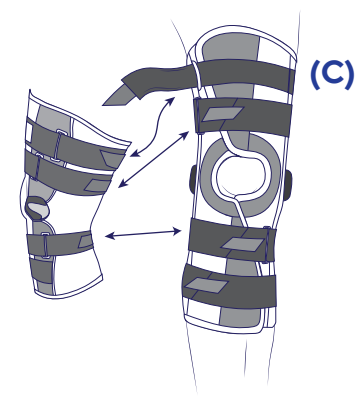
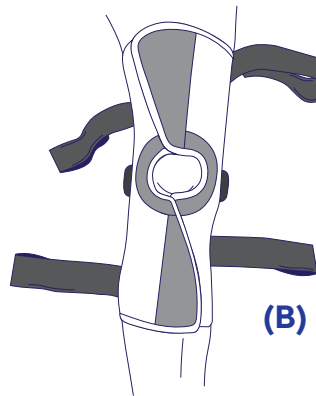
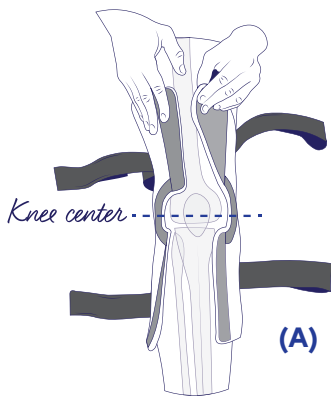


Figure B



Fitting Instructions

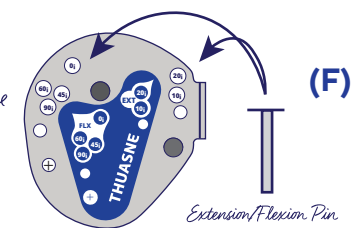
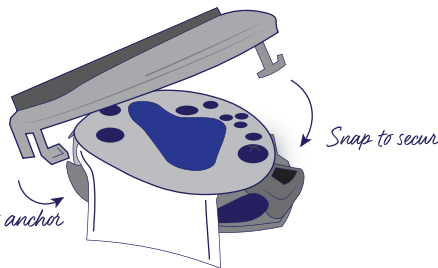
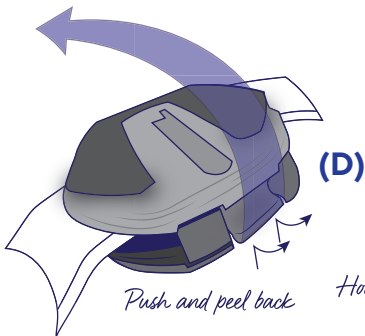
For optimum wear and fit it is recommended to apply the brace against bare skin (except in the case contraindicated). To improve comfort and fit, the metal uprights/stays may be formed to more closely align with patient anatomy. Choose the appropriate size to fit the patient, referring to the size chart (available on the box and at the start of the instruction sheet). If the measurements taken do not correspond to the same size, favor the size corresponding to thigh circumference measurement.



1. Unfasten all anterior and posterior straps and open anterior Velcro closure. Position open brace under leg (A) with patella buttress at knee center.

2. Wrap the sleeves around the thigh and calf, stretching the material until the Velcro adheres (B). Your knee cap should fit snugly in the patella buttress and the hinges should be at knee center.

3. Individually tighten each anterior and corresponding posterior strap, starting with the lower straps and finishing with the upper straps (C). The brace should be snug, but not so tight your circulation is restricted. If you feel any tingling or severe discomfort remove and contact the medical professional who fit the brace.



3. To remove hinge-cap, push the fastener from underneath the hinge and peel back upon release (D).

4. To replace the hinge-cap, hook the anchor under the front of the hinge and snap the fastener back in place (E).

5. Six flexion/extension pins are included with the brace. To set flexion/extension, insert pin into desired degree (F). Be sure both hinges are set to match. Extension can be limited to 10° and 20°. Flexion can be limited to 0°, 45°, 60° and 90° Pins can be removed at any time to adjust settings.

** The product's default position is limitation of flexion to 90°. Additional pins are supplied with the product.*

Warranty: Aluminum hinge, straps and sleeve are covered under standard warranty for six months from date of purchase. If you experience a problem with the fit or function of the brace, please call the medical provider who fit your brace.

Limited Warranty: Thuasne USA warrants to the original purchaser that this product is free from defects in materials and workmanship. Normal wear and tear during the use of a product is not considered a defect.

This warranty does not apply if this product; (1) has been altered in any way; (2) was not purchased from Thuasne USA or one of its authorized distributors; (3) is not used in accordance with Thuasne USA's Instructions for Use (IFU). Under this Limited Warranty

Thuasne USA's sole obligation shall be to repair or replace the defective product or associated part(s) at no charge. This Limited Warranty does not cover damage as a result of mishandling, accidents, improper use or alteration of the product. This is in place of all other warranties, either express or implied, including but not limited to warranties of merchantability or fitness for a particular purpose. Thuasne USA shall not be liable under this or any implied warranty for any personal injury, property damage, or special, incidental, or consequential damages arising out of, related, or incidental to the use of the product even if Thuasne USA has been informed of the prospect of such possible loss or damage, unless state law otherwise prohibits this exclusion.

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