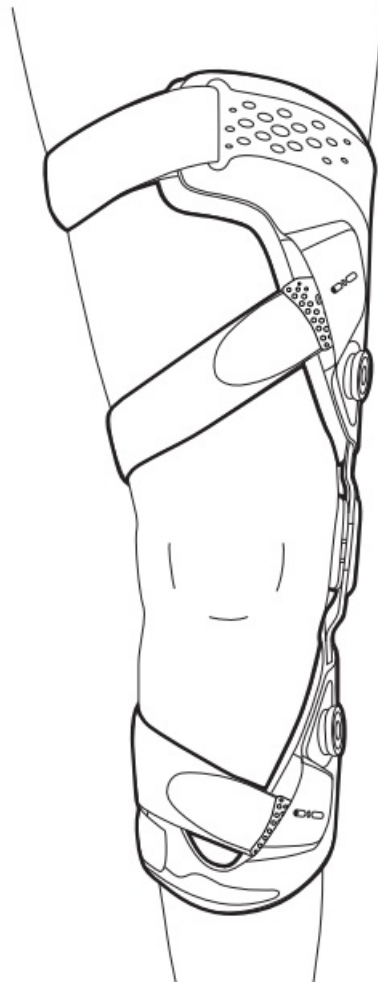


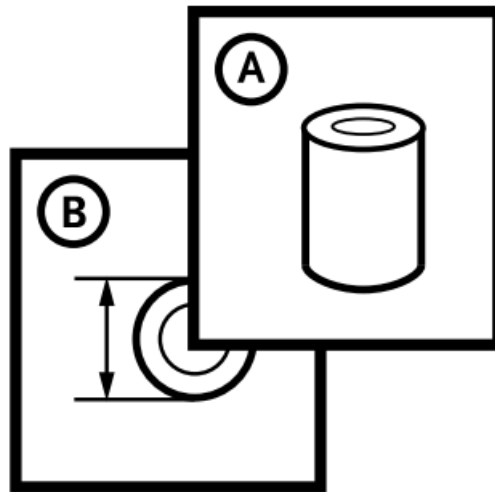


OSSUR Unloader One X, Unloader One Custom Knee Brace Instruction Manual

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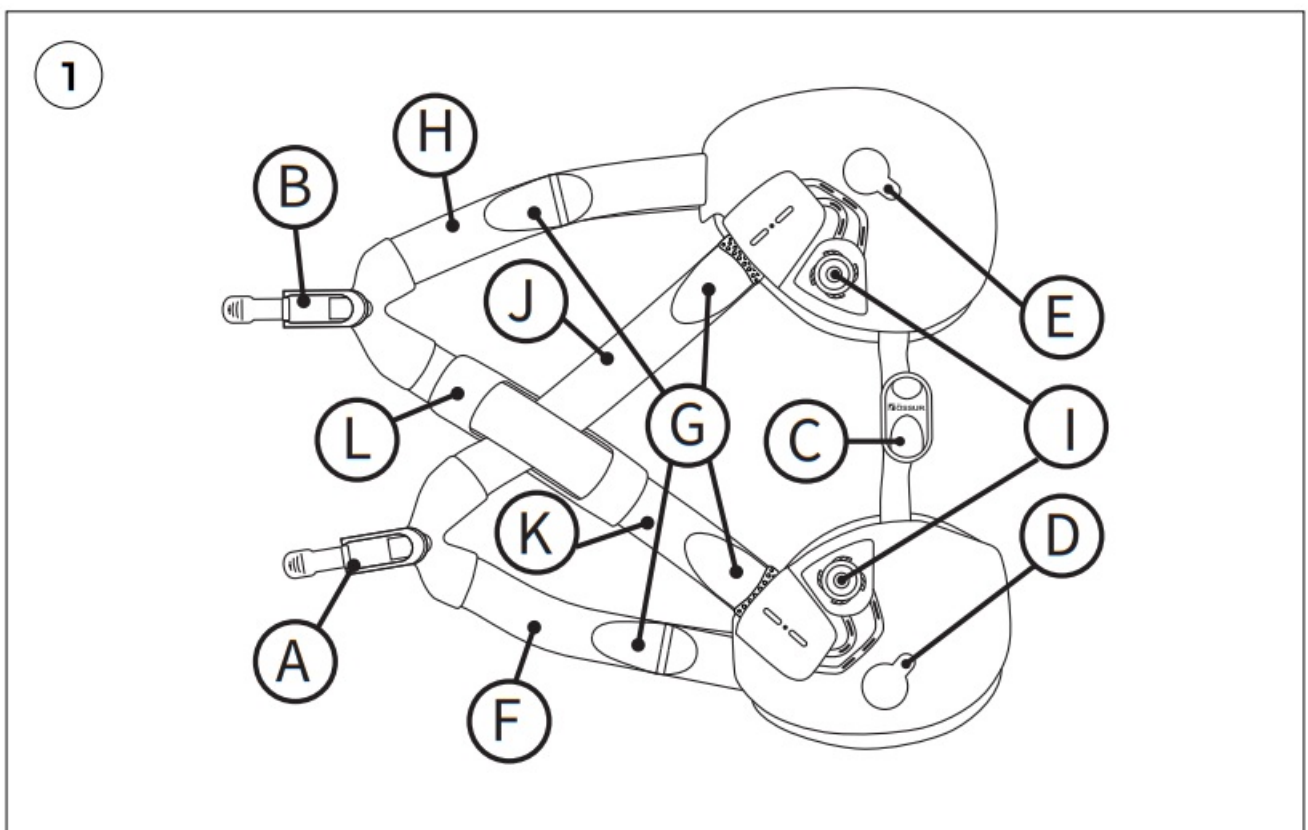
Instructions for Use
UNLOADER ONE®X
UNLOADER ONE®X CUSTOM

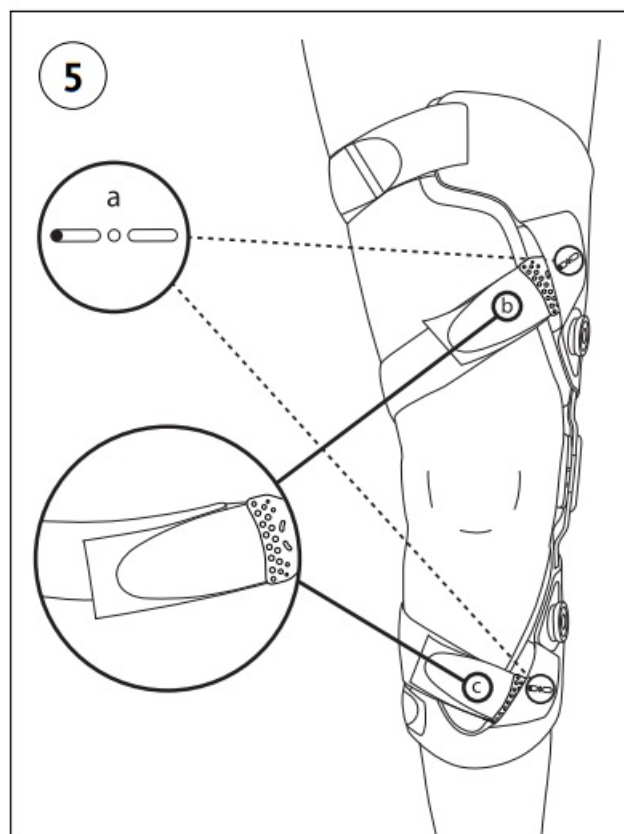
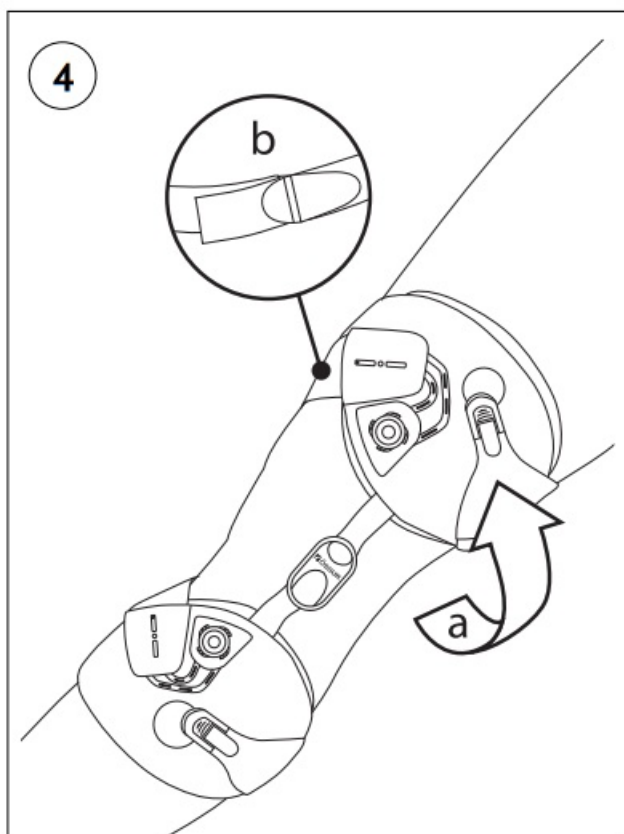
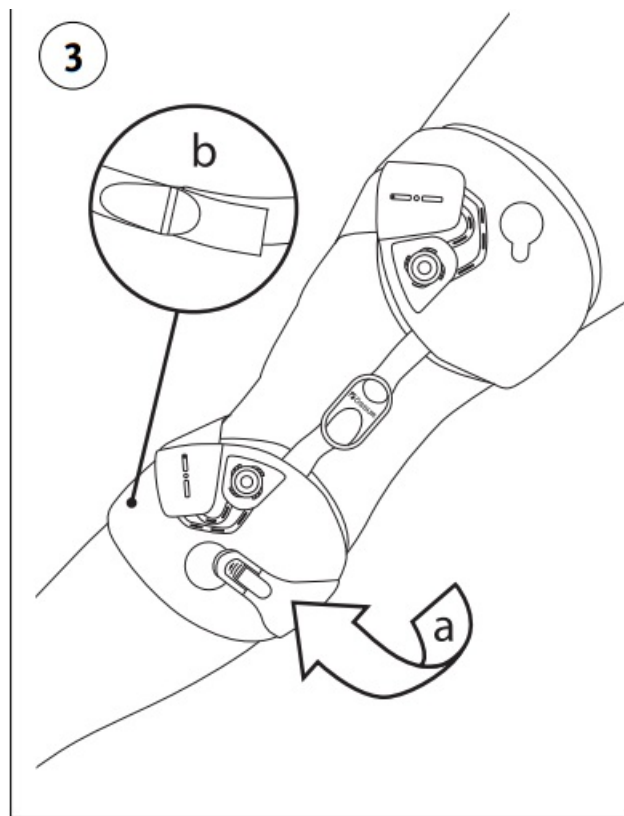
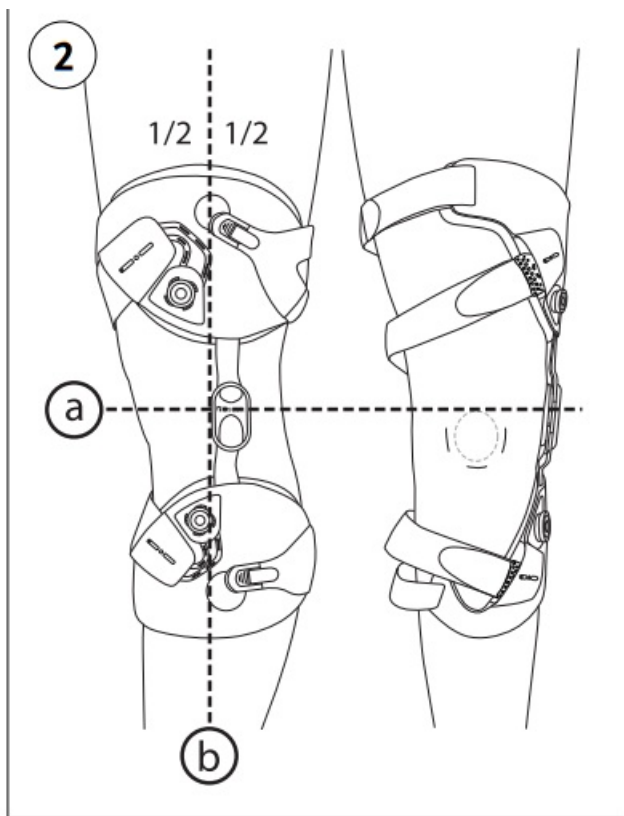


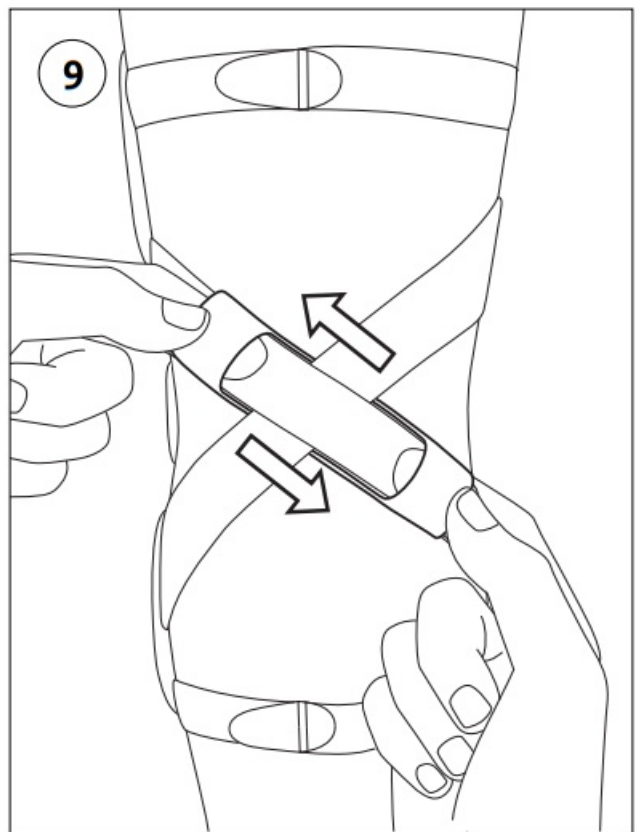
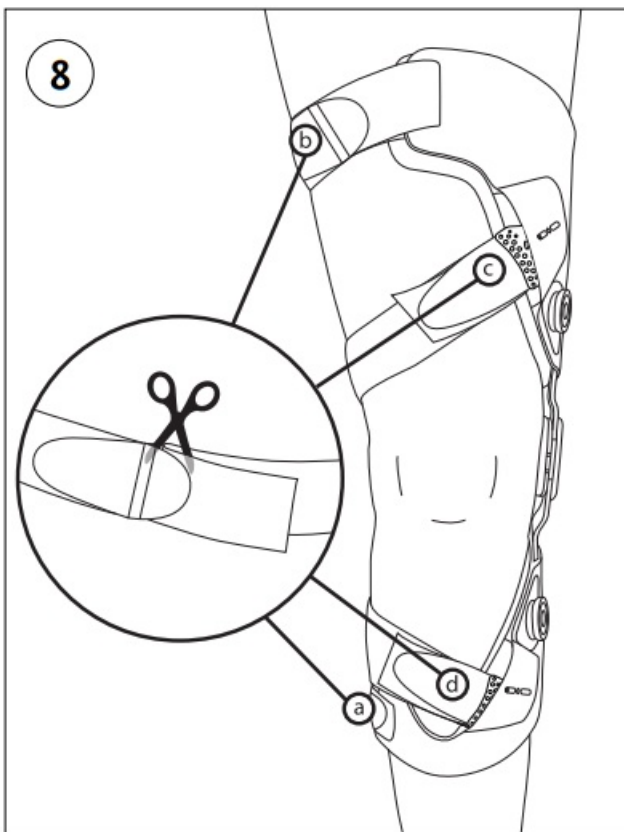
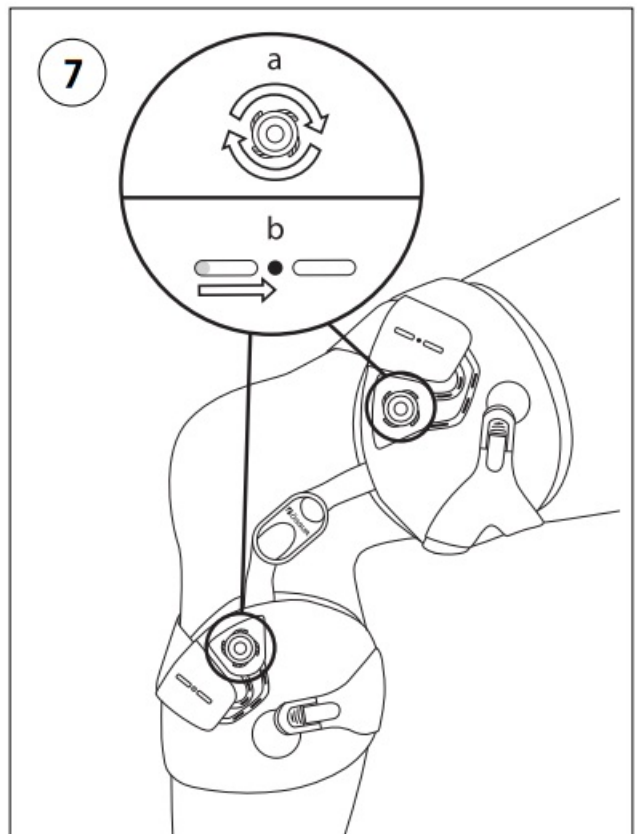
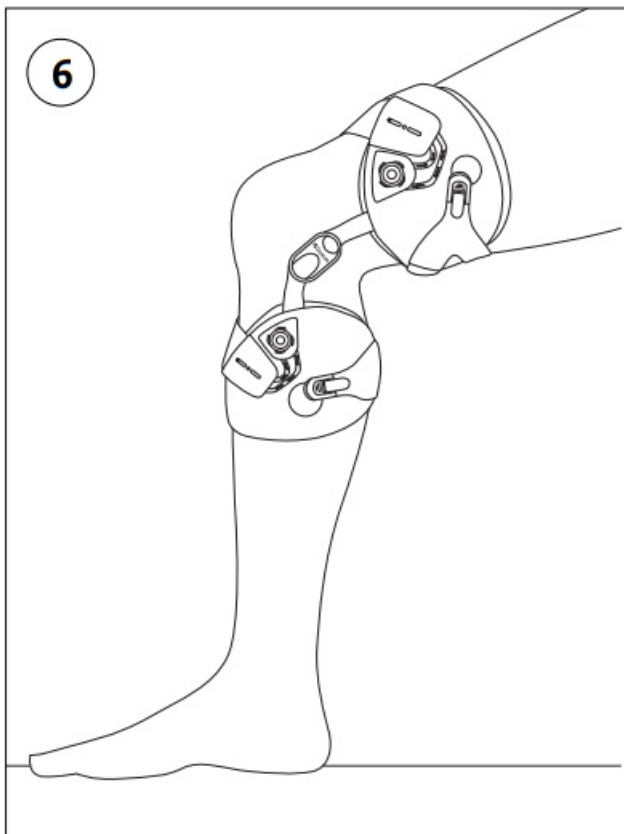
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Unloader One X, Unloader One Custom Knee Brace







INTENDED USE

The device is intended for uni compartmental unloading of the knee
 The device must be fitted and adjusted by a healthcare professional.

Indications for use

For knee conditions that may benefit from uni compartmental load reduction, such as:

- Mild to severe uni compartmental knee osteoarthritis
- Degenerative meniscal tears
- Articular cartilage defect repair
- Meniscal repair
- Avascular necrosis
- Condylar bone marrow lesions (bone bruises)
- Tibial plateau fractures

No known contraindications.

Warnings and Cautions:

- Regular healthcare professional supervision is recommended for patients with peripheral vascular disease, neuropathy, and sensitive skin.
- Make sure the device fits properly to minimize the possibility of skin irritation. Increase usage time gradually as the skin adapts to the device. If redness appears, temporarily decrease the usage time until it has subsided.
- Care should be taken not to overtighten the device.
- Make sure the device fits properly to achieve effective pain relief.
- The use of the device may increase the risk of deep vein thrombosis and pulmonary embolism.

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.

Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

The patient should stop using the device and contact a healthcare professional:

- If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions.
- If any pain, skin irritation, excessive pressure, or unusual reaction occurs with the use of the device.

The device is for single patient – multiple use.

FITTING INSTRUCTIONS

While carrying out the following instructions, please refer to the overview figure for locating components mentioned in the text (Fig. 1).

Device Application

1. Open Lower (A) and Upper (B) Buckle. Ask patient to sit down and extend leg while fitting the device. Place the device on patient's leg with the Hinge (C) on the affected side of the knee.
Ensure proper alignment of the device on the leg (Fig. 2).
 - Height positioning (2a): Align Össur logo on the Hinge with upper edge of the patella.
 - Side positioning (2b): Front edge of the Hinge cap should be at midline of leg.
2. Fasten the Buckle buttons to their color-matched Keyholes (D, E).
 - Place the blue Lower Buckle button into the blue Calf Shell Keyhole (D) and use the palm of the hand to snap the Lower Buckle closed (3a). Position Calf Strap (F) above widest part of gastroc, fold strap at appropriate length into Alligator Clip (G) and fasten strap (3b) so that it keeps device securely and correctly positioned on

leg.

- Place the yellow Upper Buckle button into the yellow Thigh Shell Keyhole (E) and use the palm of the hand to snap the Upper Buckle

closed (4a). Adjust Thigh Strap (H) to appropriate length by tensioning around leg and folding into Alligator Clip (4b).

3. With the patient's leg extended and both SmartDosing® Dials (I) at lowest setting (5a), adjust the length of the Dynamic Force System™ (DFS) Straps (J, K).
 - Adjust the Upper DFS Strap (J) length until it sits firmly against the leg, and then fold it into Alligator Clip (5b). At this point, patient should not experience any tension or unloading.
 - Adjust the Lower DFS Strap (K) in the same way (5c).
4. Ask patient to bend knee with the foot flat on the floor (Fig. 6). Turn upper and lower SmartDosing Dials clockwise (7a) until indicators are in the middle slot (7b). Have the patient stand up and take a few steps to verify correct positioning of the device and tightness of the straps.
 - Determine optimal DFS Strap tension based on patient's pain relief feedback.
 - If patient requires more or less tension with indicator at mid setting, adjust the length of the DFS Straps accordingly.
 - Aim for final SmartDosing Dial setting at middle indicator slot since this will give patient the ability to adjust dosing during daily life activities.
5. When final fit has been confirmed, trim the straps (Fig. 8) to the appropriate length starting with the Calf Strap (8a) so that device sits correctly on leg while trimming other straps (8b, 8c, 8d).
6. With patient in standing position, insert fingers into Popliteal Pad (L) openings and move to an ideal position in popliteal area (Fig. 9).

Device Removal

1. Ask patient to sit with knee bent and foot flat on floor (Fig. 6).
2. Open both Lower and Upper Buckles.
3. Pull the Buckle buttons out of Keyholes.

Accessories and Replacement Parts

Please refer to the Össur catalog for a list of available replacement parts or accessories.

USAGE

Cleaning and care

- Insert the entire device into a washbag, without removing soft goods.
- Machine-wash with a mild detergent at cold temperature (30°C).
- Air dry.

Note: Do not tumble dry, iron, bleach, or wash with fabric softener.

Note: Avoid contact with salt water or chlorinated water. In case of contact, rinse with fresh water and air dry.

DISPOSAL


The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

LIABILITY

Össur does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

Documents / Resources

	<p>ÖSSUR Unloader One X, Unloader One Custom Knee Brace [pdf] Instruction Manual Standard Unloader One X, Short Unloader One X, Unloader One X Custom, Unloader One X Unloader One Custom Knee Brace, Unloader One X, Unloader One Custom, Unloader One X Knee Brace, Unloader One Custom Knee Brace, Knee Brace, Brace</p>
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