



OSSUR Unloader One Smartdosing Unloader One Custom Smartdosing Instruction Manual

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OSSUR Unloader One Smartdosing Unloader One Custom Smartdosing



Product Information

The product is a medical device intended for unicompartmental unloading of the knee. The device must be fitted and adjusted by a healthcare professional. There are no known contraindications for using the device. The device should be washed with the soft goods detached for thorough cleaning. It is important to note that the device should not be machine-washed, tumble dried, ironed, bleached, or washed with fabric softener. Additionally, it is recommended to avoid contact with salt water or chlorinated water.

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

Product Usage Instructions

Device Application:

1. Open Upper (A) and Lower (B) Buckles.
2. Ask the patient to sit down and extend their leg.
3. Place the device on the affected knee, ensuring that it is properly aligned.
4. Fasten the Upper (A) and Lower (B) Buckles securely.

5. Turn both Smart Dosing Dials clockwise until the indicator is at the starting position.

Device Removal

1. Ask the patient to sit down with their leg extended.
2. Turn both SmartDosing Dials counterclockwise until the indicator is at the starting position.
3. Open the Upper (A) and Lower (B) Buckles.

Cleaning and Care

Washing the device with the soft goods detached allows for a more thorough cleaning. Do not machine-wash, tumble dry, iron, bleach, or wash with fabric softener. 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.

Medical Device

INTENDED USE

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

Indications for use

- Mild to severe unicompartmental knee osteoarthritis
- Degenerative meniscal tears
- Other unicompartmental knee conditions that may benefit from unloading such as:
- Articular cartilage defect repair
- Avascular necrosis
- Tibial plateau fracture
- Bone marrow lesions (bone bruises)
- 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.
- If any pain or excessive pressure occurs with the use of the device, the patient should stop using the device and contact a healthcare professional.
- Care should be taken not to overtighten the device.
- Make sure the device fits properly to achieve effective pain relief.

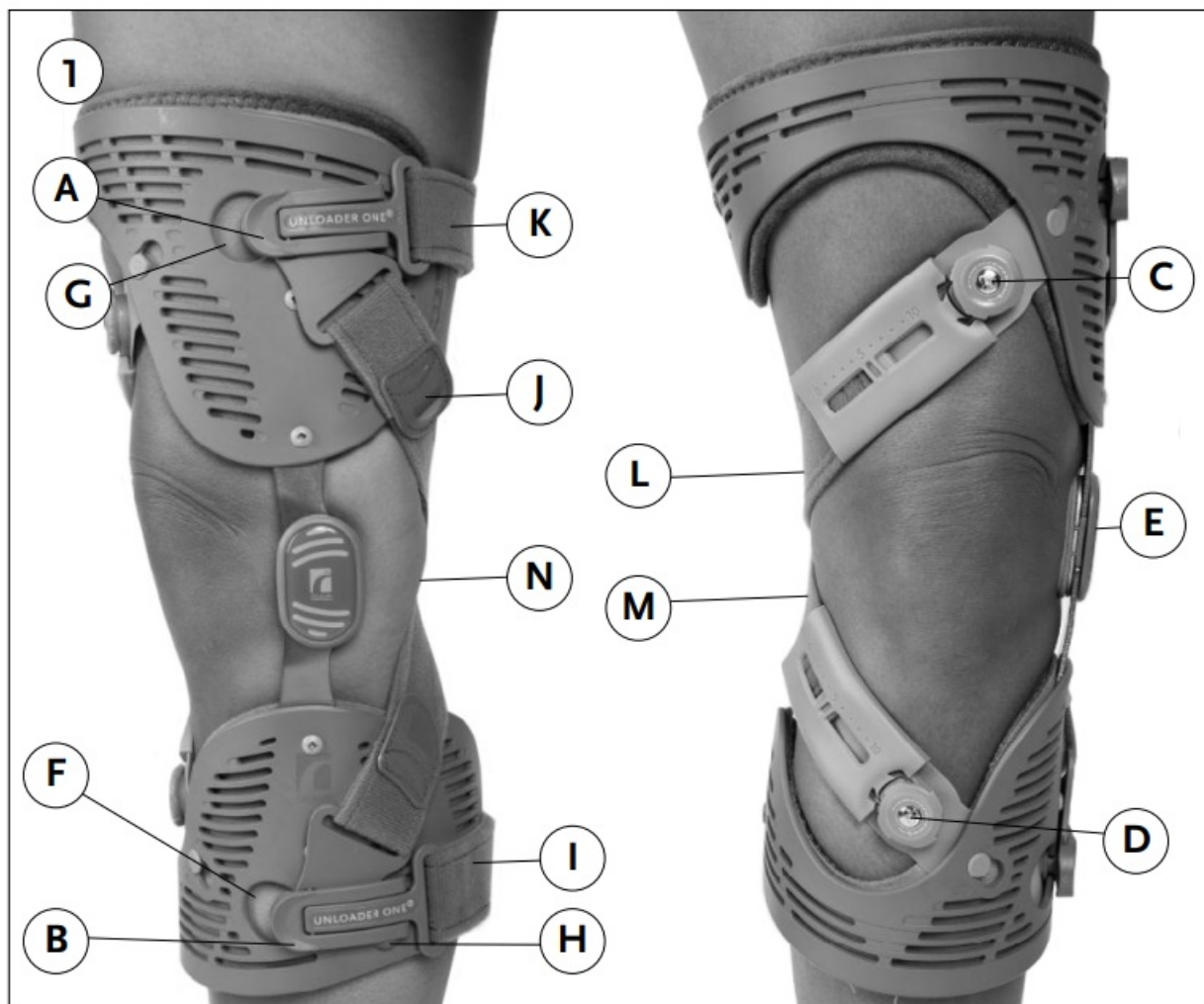
- The use of the device may increase the risk of deep vein thrombosis and pulmonary embolism.

GENERAL SAFETY INSTRUCTIONS

- Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.
- The healthcare professional should inform the patient about everything in this document that is required for safe use of this device.
- **Warning:** If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact a healthcare professional.
- 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 Upper (A) and Lower (B) Buckles. Ask patient to sit down and extend leg while fitting the device. Ensure that the Upper (C) and Lower (D) SmartDosing® Dials are set to the “0” position. Place the device on the patient’s leg with the Hinge (E) on the affected side of the knee.
 - Ensure proper alignment of the device on the leg (fig. 2).



- **Height positioning:** Align the center of the Hinge slightly above the middle of the patella.
- **Side positioning:** Center of the Hinge should be at midline of leg.

2. Fasten the Buckle buttons to their color-matched Keyholes (F, G). Place the blue Lower Buckle button into the blue Calf Shell Keyhole (F) above Buckle Stability Shelf (H) and use the palm of the hand to snap the Lower Buckle closed (Fig. 3). Adjust the Calf Strap (I) to the appropriate length by tensioning around the calf and folding into the Alligator Clip (J) so that it keeps the device securely and correctly positioned on leg.



- Bend the patient's knee to 80°. Place the yellow Upper Buckle button into the yellow Thigh Shell Keyhole (G) and use the palm of the hand to snap the Upper Buckle closed (Fig. 4). Adjust Thigh Strap (K) to appropriate length by tensioning around leg and folding into Alligator Clip.

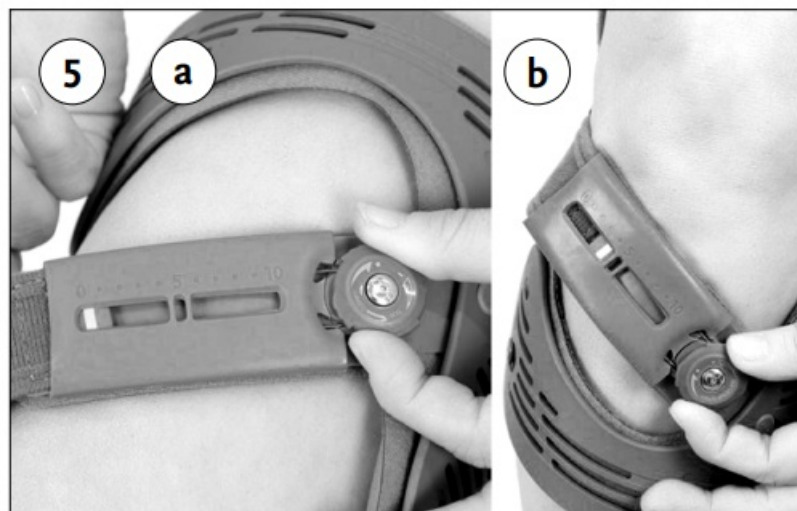


3. Adjust the length of the Dynamic Force System™ (DFS) Straps (L, M).

- With the patient's knee fully extended, adjust the Upper DFS Strap (L) length until it sits firmly against the leg, and then fold it into Alligator Clip. At this point, patient should not experience any tension or unloading.

4. Adjust the Lower DFS Strap (M) in the same way.

- Ask the patient to bend knee with the foot flat on the floor. Turn Upper (5a) and then the Lower (5b) SmartDosing Dial clockwise until indicators are in the "5" position.



- 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 the "5" position, adjust the length of the DFS Straps accordingly.
 - Aim for final SmartDosing Dial setting at the "5" position since this will give patient the ability to adjust dosing during daily life activities.
5. When final fit has been confirmed, trim the straps to the appropriate length starting with the Calf Strap so that device sits correctly on leg while trimming other straps.
- Ensure that the Strap Pad (N) is not wrinkled and positioned where the DFS straps cross in the popliteal fossa (Fig. 6).



- Trim back the straps sufficiently so that the alligator clips are positioned away from the popliteal area. This reduces the bulk behind the knee.

Device Removal

1. Ask patient to sit down with the leg extended.
2. Turn both SmartDosing Dials counterclockwise until the indicator is at the “0” position to release tension on the DFS Straps.
3. Bend the patient’s knee to 90° and open both Lower and Upper Buckles.
4. 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

- Washing the device with the soft goods detached allows for more thorough cleaning.

Washing Instructions

- Hand-wash using mild detergent and rinse thoroughly.
- Air dry.
- **Note:** Do not machine-wash, 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.

Hinge

- Remove foreign materials (e.g., dirt or grass) and clean using fresh water.

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

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Documents / Resources

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References

-  [Össur. Life Without Limitations.](#)