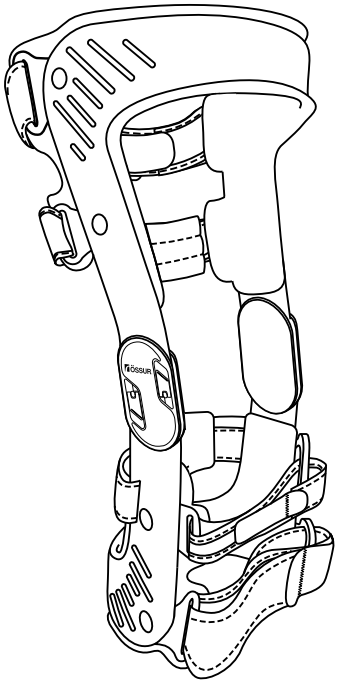
ÖSSUR®
LIFE WITHOUT LIMITATIONS



Instructions for Use

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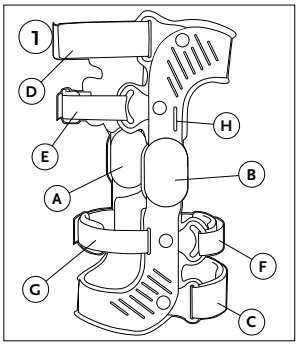
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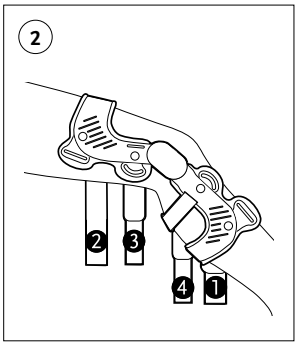
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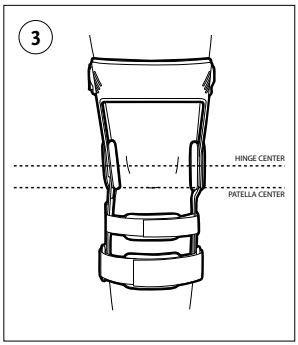
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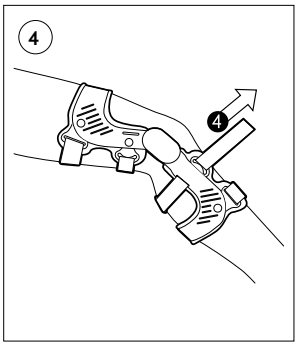
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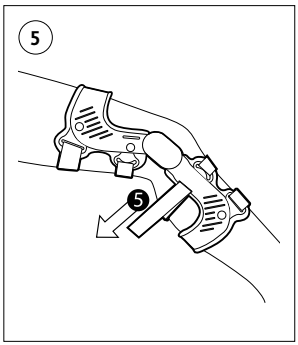
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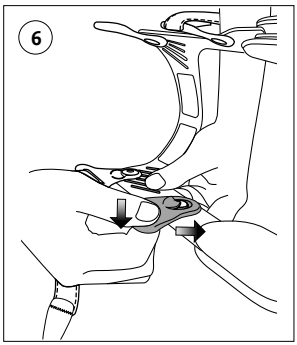
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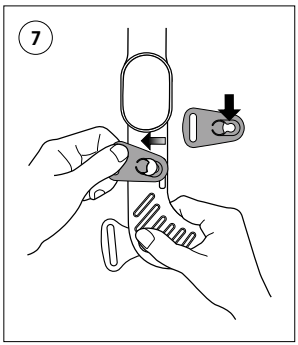
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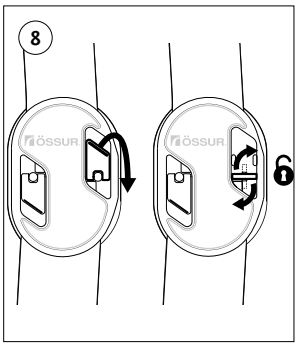
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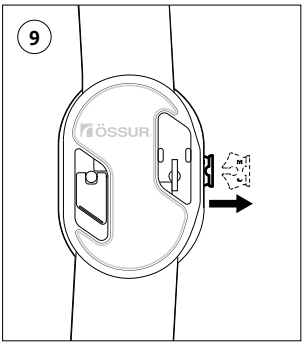
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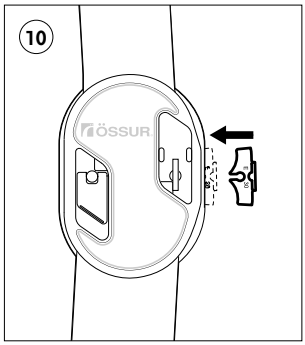
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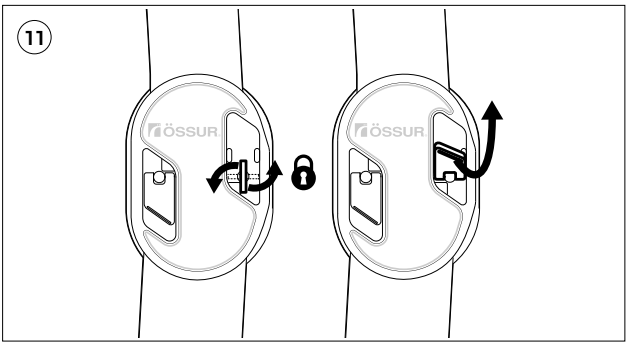
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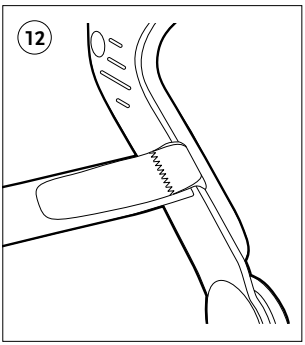
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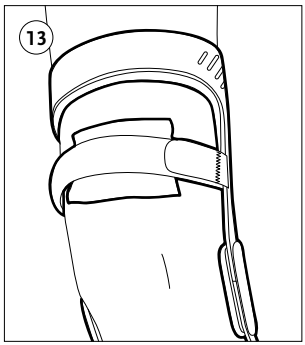
13

ENGLISH

MD Medical Device

INTENDED USE

The device is intended for external support or stabilization of the knee. The device must be fitted and adjusted by a healthcare professional.

Indications for use

- ACL, MCL, LCL, PCL and combined instabilities.
- Conditions requiring unicompartmental load control (Acculign slider configuration).

No known contraindications.

Warnings and Cautions:

- 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, or unusual reaction occurs with the use of the device.

The device is for single patient – multiple use.
This device is a supportive brace only and is not intended or guaranteed to prevent injury.

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. Unfasten the posterior straps on the upper frame and the anterior straps on the lower frame of the device **(Fig. 2)**.
2. Bend the knee to between a 30° - 45° angle, step through the device, and then slide it up on the leg such that the patella is centered between the Condyle Pads (A) **(Fig. 2)**. Ensure proper alignment of the device on the leg:

- Height positioning: Align the center of the Hinge (B) slightly above the middle of the patella **(Fig. 3)**.

3. The device is pre-assembled with medium Condyle Pads. There are also thin and thick Condyle Pads, as well as a hook-and-loop shim, included with the device. Use any combination of the Condyle Pads and shim to widen or narrow the width of the device at the knee.

- Fasten the straps in the following order. All straps can be adjusted and/or trimmed to length.

4. Fit the Lower Shin Strap (C) first by inserting it through the D-Ring.
5. Next, snugly fasten the Upper Thigh Strap (D) and continue with the Lower Thigh Strap (E).
   Note: Overtightening the top two straps can cause the device to migrate.

6. Fasten the Upper Shin Strap (F) **(Fig. 4)**.
7. Last, snugly fasten the Calf Strap (G) **(Fig. 5)**.

- If the device frame is too far anterior, loosen the Upper and Lower Shin Strap and tighten the Calf Strap.
- If the device frame is too far posterior, loosen the Calf Strap and tighten the Upper and Lower Shin Strap.

Device Adjustments

Adjusting the Device Contouring

The device can be adjusted to individual anatomies. Use bending irons to cold form the aircraft-grade aluminum frame to fit different thigh and calf shapes.

How to Replace or Move the Field-Serviceable D-Rings

D-Rings can be moved from the interior to the exterior or replaced if broken. Moving a D-Ring from the interior to the exterior:

1. Remove strap from D-Ring.
2. Bend D-Ring mounted on the device interior, push it inwards to release it from the keyhole lock and remove it from the rivet **(Fig. 6)**.
3. Attach D-Ring to the device exterior by pushing down onto the rivet through the keyhole lock. Slide and click D-Ring into place. Place keyhole lock with indented side facing up **(Fig. 7)**.
4. Replace strap. If needed, repeat steps for other D-Rings.

Range of Motion (ROM) Adjustment

The device has 0° extension stops attached to the hinges. If needed, the range of motion can be adjusted using the extension and flexion stop kits.

1. Lift and turn tab 90° **(Fig. 8)**.
2. Remove existing stop if necessary, by pulling on the lower edge of the installed stop **(Fig. 9)**.
3. Insert desired flexion/extension stop with the number facing the opposite direction of leg **(Fig. 10)**.
4. Return tab to initial position and press downward to lock in place **(Fig. 11)**.
5. Follow the same procedure to change any additional stops and repeat on the opposite hinge.

PCL Strap Attachment

The PCL kit is designed to counteract posterior subluxation of the tibia.

1. Take the end of the PCL strap with the alligator clip and loop it through the PCL Slot (H) on the device's upper frame **(Fig. 12)**. The alligator clip will close on the inside of the strap. Trim strap if necessary.
2. Loop the other end of the PCL Strap through the device frame. Fasten the strap and secure it onto the outside of the strap.
   Note: Trim and adjust the PCL strap for proper fit.
3. Place the adjustable pad in the middle of the strap **(Fig. 13)**. Trim the strap pad if needed.
4. Fully extend the leg. Tighten the strap, securing the pad.

Device Removal

1. Sit down and bend the knee to between a 30° - 45° angle.
2. Unfasten the posterior straps on the upper frame and the anterior straps on the lower frame of the device and attach the straps back to themselves. This will make it easier to put the device on next time and will also prolong the life of the straps.
3. Slide the device off the leg.

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

USAGE

Cleaning and care
Washing Instructions
Washing the device with the soft goods detached allows for more thorough cleaning.
- 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.
- Do not disassemble the hinge.

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.