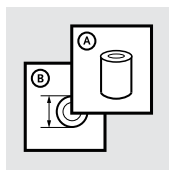


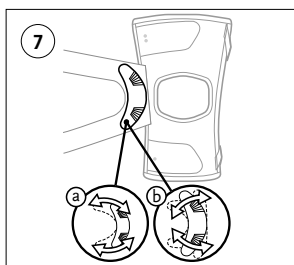
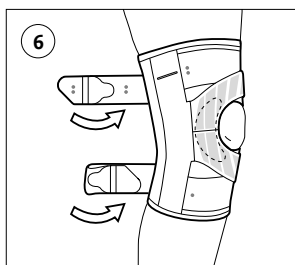
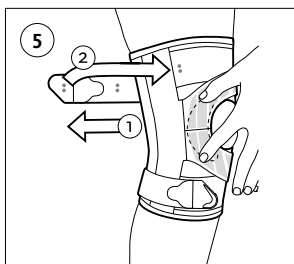
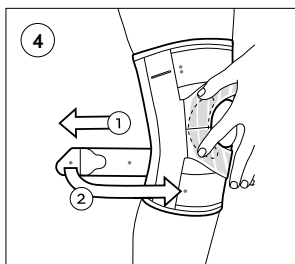
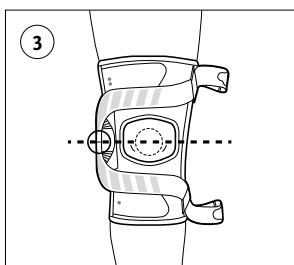
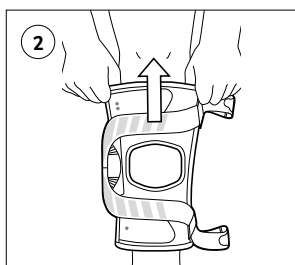
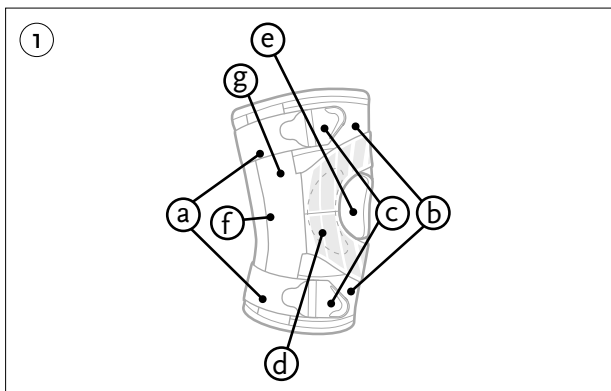
Instructions for Use

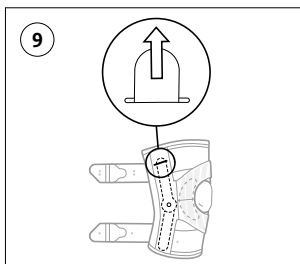
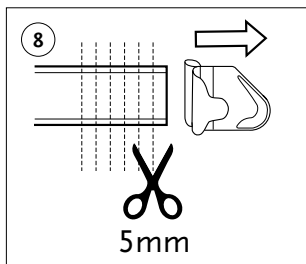
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FORMFIT<sup>®</sup> TRACKER



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Medical Device

## PRODUCT DESCRIPTION

Formfit Tracker is a brace that provides lateral support to your kneecap (patella). The strap tightly fastens the buttress next to your kneecap. The buttress can be adjusted to the shape of your kneecap.

You can also find two thermoformable hinges on each side. A CPO can remove the two hinges if necessary.

Overview (**Figure 1**):

- a. PowerLock™ strap
- b. Hook and loop surfaces
- c. Strap ends
- d. ReflexWing™ buttress
- e. Kneecap opening
- f. CustomFit™ hinges
- g. Hinge pocket

## INDICATIONS FOR USE

For knee conditions that may benefit from realignment of the patella and/or patients that would benefit from an added lateral support of the patella, such as:

- lateral patellar subluxation or dislocation
- lateral maltracking

## CONTRAINDICATIONS

None known.

## INTENDED USE

Formfit Tracker is intended to be used for lateral support of the kneecap during everyday activities of all activity levels.

## GENERAL SAFETY INSTRUCTIONS

### WARNINGS:

- This product is designed and tested based on single patient use. Do not use for multiple patients.
- In cases of functional change or functional loss, the patient should stop using the device and contact a healthcare professional.
- 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.

## USING THE BRACE

### **Fastening dots**

Dots show you where to fasten the strap ends.

Fasten parts of the brace with two vertical dots in the same area. Fasten parts with single dots in the same area.

**NOTICE:** Make sure to fasten the strap ends when the brace is not in use. If you do not fasten the strap ends, they can damage the brace.

### ***Putting the brace on***

1. Hold the brace by the hinge pockets and pull it up over your knee (**Figure 2**).
2. Make sure your kneecap is in the middle of the opening (**Figure 3**).
3. Use fingers to keep the buttress pushed against the side of your kneecap (**Figure 4**). Pull the bottom strap around the back of your knee to tighten it first. Then fasten the bottom strap as the dots show you.  
**CAUTION:** Do not tighten too much. If you tighten too much, you can cut off your blood flow.
4. Repeat for the top strap (**Figure 5**).
5. The buttress is now in position and pushes tightly against the side of your kneecap.

### ***Taking the brace off***

1. Pull the strap ends off of the brace and fasten them to the strap (**Figure 6**). Fasten as the dots show you.
2. Hold the brace by the hinge pockets. Then pull it down to take it off.

## **USING THE BUTTRESS**

If necessary, you can bend and move the buttress to adjust it to your patella (**Figure 7**).

### ***Moving the buttress***

1. Pull the buttress off of the loop material (**Figure 7a**).
2. Put it in the correct position for your patella.

### ***Bending the buttress***

1. Pull the strap ends off of the brace. Then fasten the strap ends as the dots show you.
2. Fully open the brace.
3. Push the middle of the buttress down with your index finger (**Figure 7b**).
4. Lift the end you want to adjust.
5. Bend it to agree with the shape of your patella.
6. Push the end back down again.

## **SHORTENING THE STRAPS**

If the straps are too long, you can make them shorter.

**NOTICE:** Only shorten the strap in single steps of 0,5 cm/ ¼". If you cut off too much, you may not be able to use the brace correctly.

1. Fully remove the strap end from the strap.
2. Then use scissors to cut off a short piece of the strap (**Figure 8**).
3. Put the brace on again to check how it fits. If the strap is too long, repeat steps 1) and 2). If the strap length is good, move to step 4).
4. Put the strap end back on the strap again.

## **USING THE HINGES**

### ***Removing the hinges***

If necessary, the hinges can be heated and bent by a certified prosthetist orthotist (CPO) to agree with the shape of your leg. To remove the hinges, do as follows:

1. Pull the strap ends off of the brace and fasten them to the strap (**Figure 6**). Fasten as the dots show you.

2. Push the hinges out of the brace through the openings on the hinge pockets (**Figure 9**).

### ***Putting the hinges back***

To put the hinges back into the brace, do as follows:

1. Pull the strap ends off of the brace and fasten them to the strap (**Figure 6**). Fasten as the dots show you.
2. Push the hinges into the brace through the openings on the hinge pockets (**Figure 9**).

### **PRODUCT CARE**

You can wash the brace without removing its components.

Wash on a delicate cycle at max 30 °C with a mild detergent. Leave to air dry. Do not tumble dry.

**NOTICE:** Make sure to fasten the strap ends before washing. If you do not fasten the strap ends, they can damage the brace materials.

### **REPORT A SERIOUS INCIDENT**

#### **Important notice to users and/or patients established in Europe:**

The user and/or patient must report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

### **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.