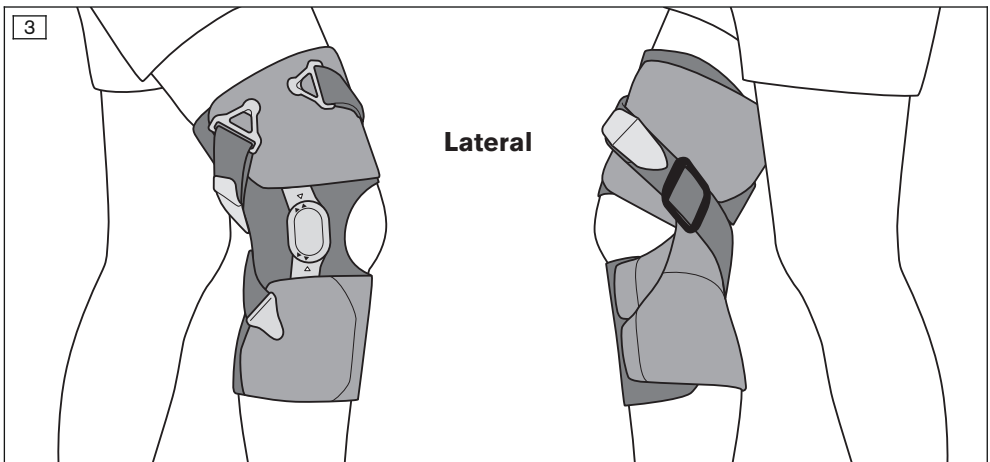
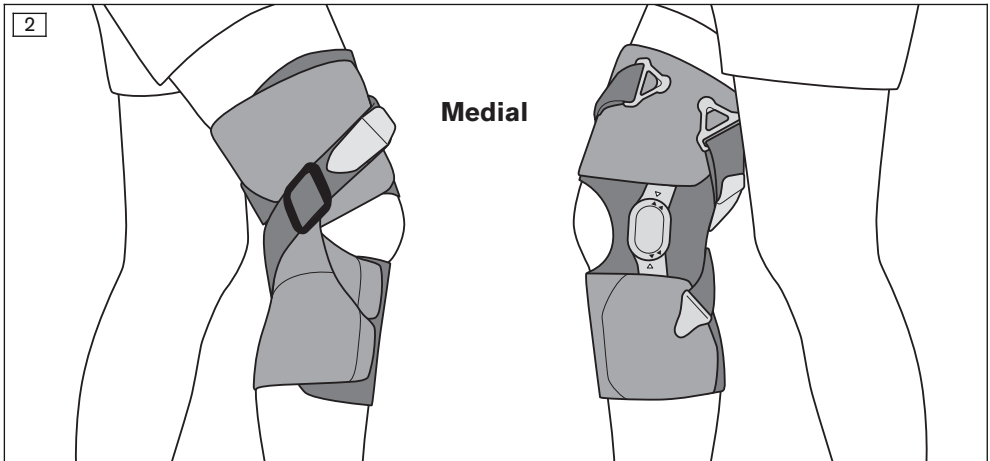
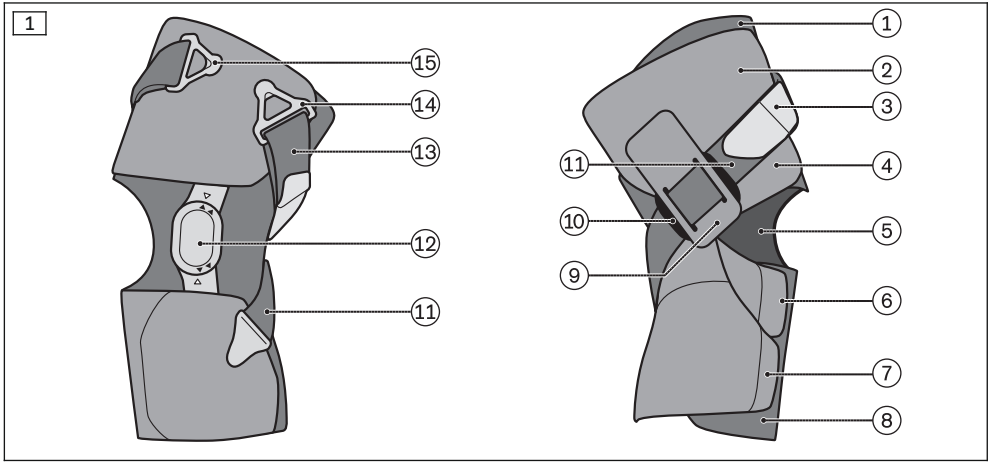
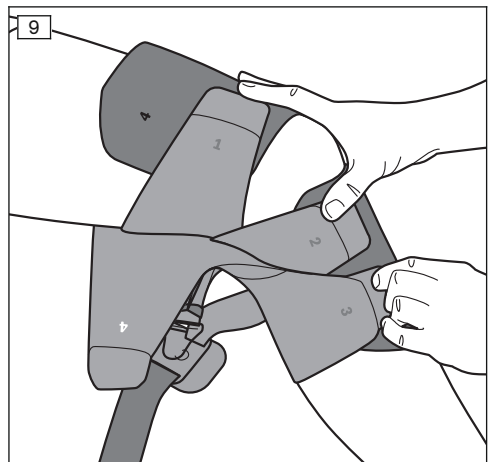
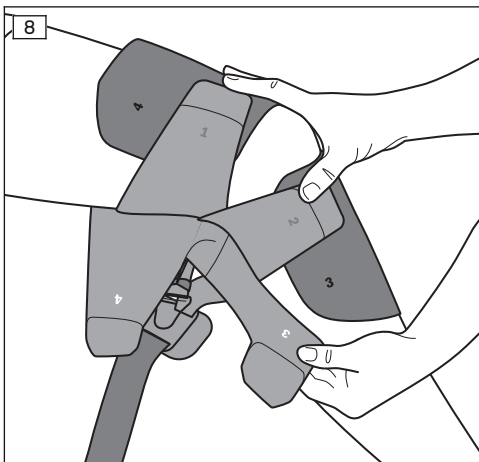
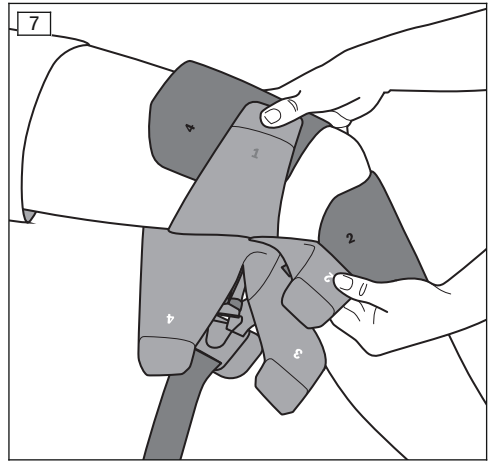
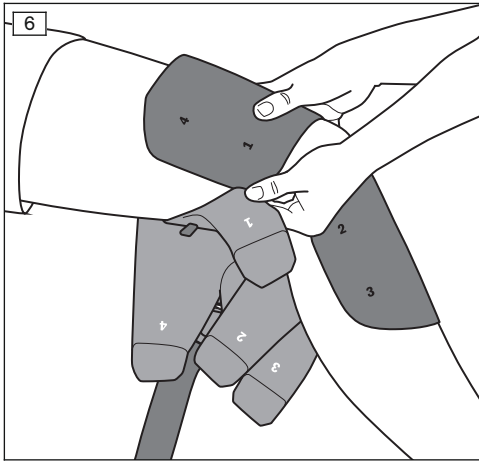
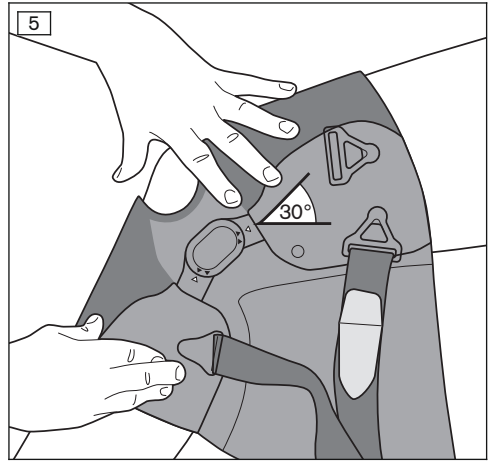
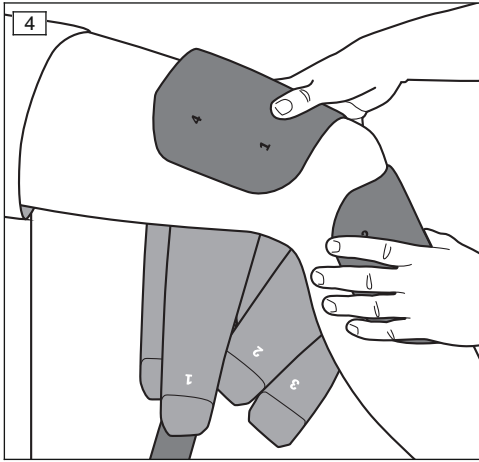
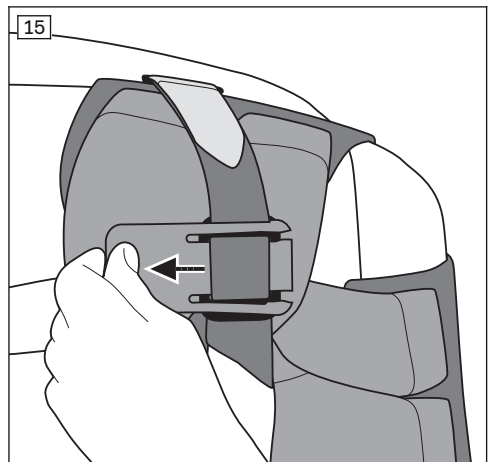
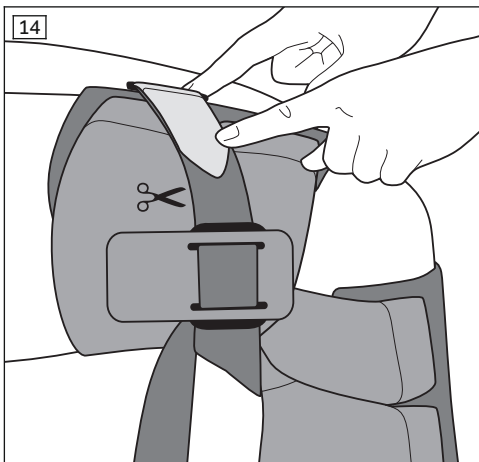
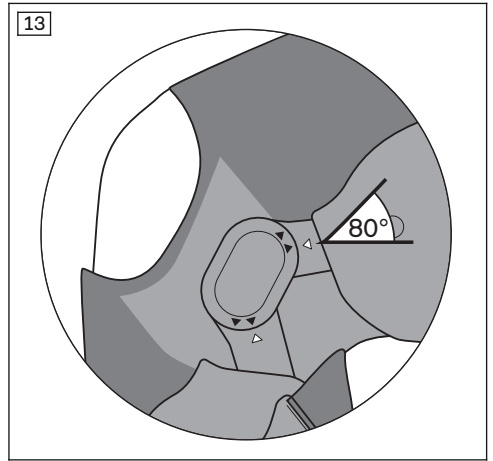
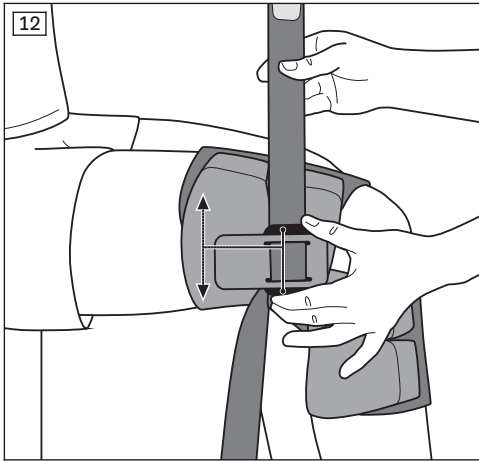
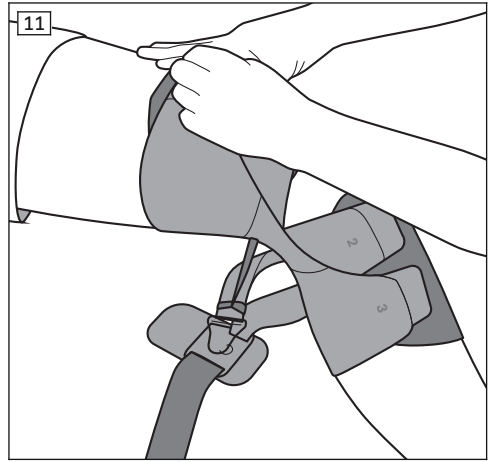
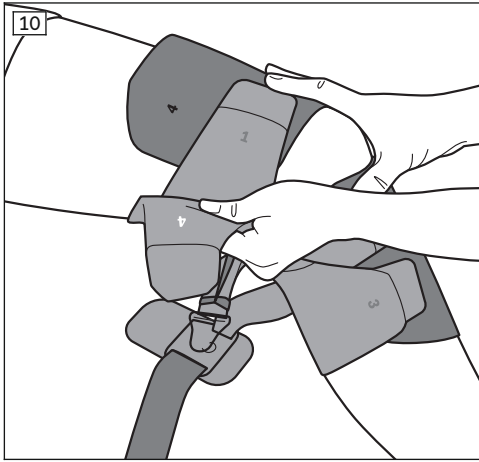


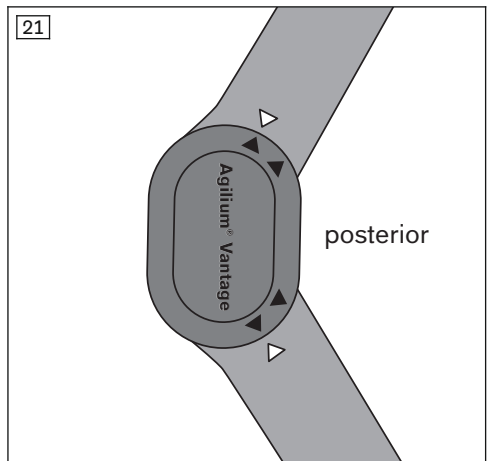
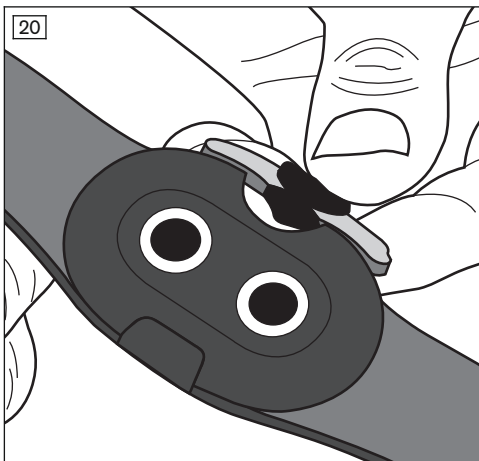
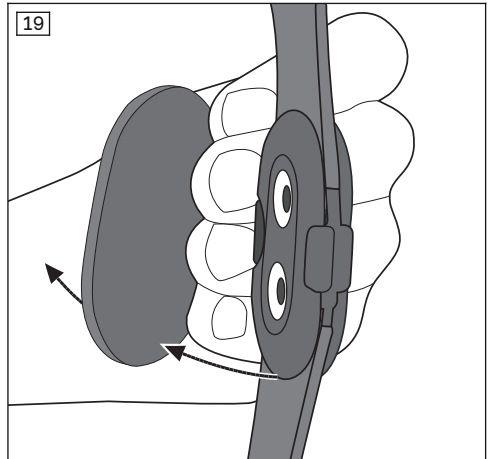
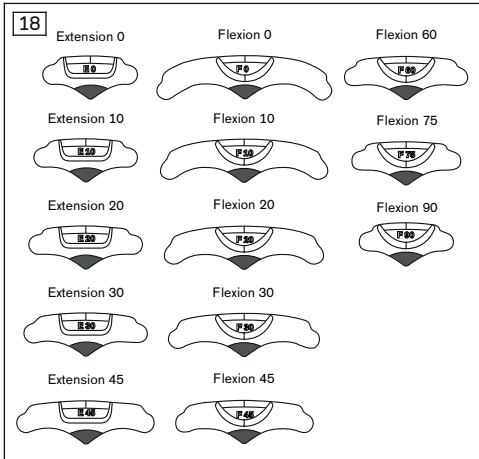
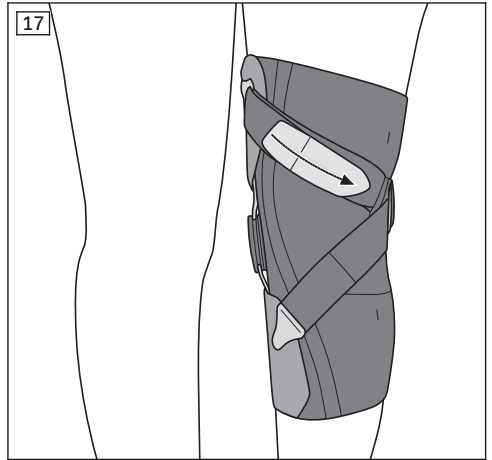
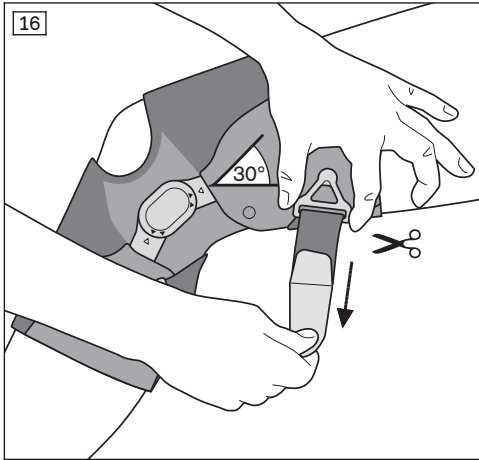
## 50K306 Agilium® Vantage

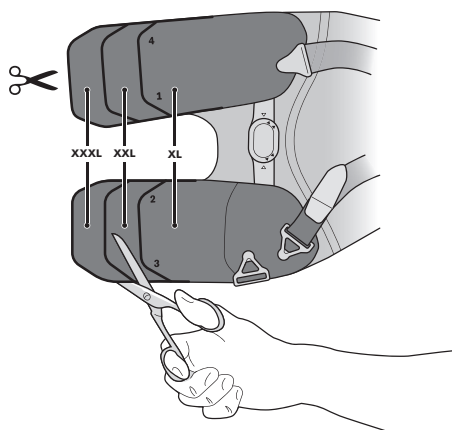
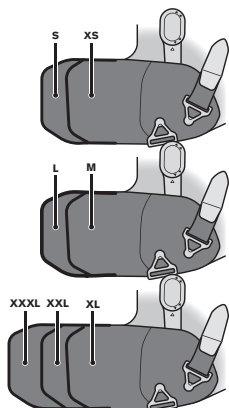
EN Instructions for use .....







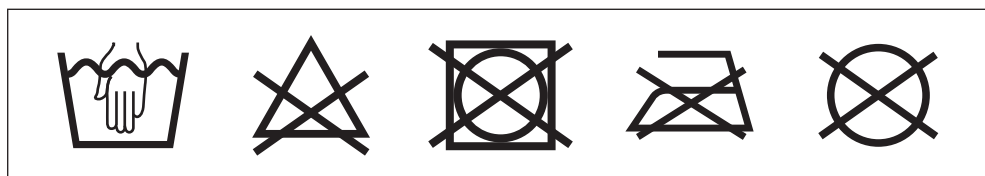




	Size	A		B	
		Lower leg circumference		Thigh circumference	
		[cm]	[inch]	[cm]	[inch]
	<b>XS</b>	28–32	11–12.5	36–41	14–16
	<b>S</b>	32–36	12.5–14	41–46	16–18
	<b>M</b>	36–41	14–16	46–53	18–21
	<b>L</b>	41–46	16–18	53–60	21–23.5
	<b>XL</b>	46–51	18–20	60–67	23.5–26.5
	<b>XXL</b>	51–56	20–22	67–75	26.5–29.5
	<b>XXXL</b>	56–61	22–24	75–81	29.5–32

Combined Sizes	Medial compartment osteoarthritis		Lateral compartment osteoarthritis	
	Left	Right	Left	Right
	50K306*			
<b>XS/S</b>	*=L-XS-S-MO	*=R-XS-S-MO	*=L-XS-S-LO	*=R-XS-S-LO
<b>M/L</b>	*=L-M-L-MO	*=R-M-L-MO	*=L-M-L-LO	*=R-M-L-LO
<b>XL/XXL/XXXL</b>	*=L-XL-3XL-MO	*=R-XL-3XL-MO	*=L-XL-3XL-LO	*=R-XL-3XL-LO

<b>Material</b>	Aluminium, Steel, ABS, Nylon, PU foam, Spandex
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## 1 Foreword

### INFORMATION

Last update: 2019-09-03

- ▶ Please read this document carefully before using the product.
- ▶ Follow the safety instructions to avoid injuries and damage to the product.
- ▶ Instruct the user in the proper and safe use of the product.
- ▶ Please keep this document in a safe place.

These instructions for use provide important information on the fitting and application of the 50K306 Agilium® Vantage.

## 2 Product description

50K306 Agilium® Vantage (see fig. 1)			
Item	Description	Item	Description
1	Thigh pad	9	Positioning aid
2	Flap 4	10	Clip
3	Y-hook-and-loop	11	Release strap
4	Flap 1	12	Brace joint
5	Patella cutout	13	Anti-rotation strap
6	Flap 2	14	D-ring for anti-rotation strap
7	Flap 3	15	D-ring for release strap
8	Calf pad	–	Extension and flexion stops (see fig. 18)

## 3 Intended use

### 3.1 Indications for use

The brace is intended **exclusively** for orthotic fittings of the lower limbs and **exclusively** for contact with intact skin.

The brace must be used in accordance with the indications.

### 3.2 Indications

- Unicompartmental knee osteoarthritis
- Conditions/injuries requiring unicompartmental relief (e.g. post-operative treatment following meniscus reconstruction or ligament injuries which require unilateral relief)
- Rheumatoid arthritis

The indication must be determined by the physician.

### 3.3 Contraindications

#### 3.3.1 Absolute Contraindications

None known.

#### 3.3.2 Relative Contraindications

The following indications require consultation with a physician: skin diseases/injuries; inflammation; prominent, swollen scars; reddening and hyperthermia of the treated limb; pronounced varicose veins, especially with impaired return flow; lymphatic flow disorders, including unclear soft tissue swelling distal to the body area where the device will be applied; sensory and circulatory disorders in the legs, e. g. associated with diabetic neuropathy.

- Bicompartamental osteoarthritis of the knee

### 3.4 Mechanism of Action

The brace provides relief for the affected compartment by means of the 3-point principle and stabilizes the knee joint.

## 4 Safety

### 4.1 Explanation of warning symbols

**CAUTION** Warning regarding possible risks of accident or injury.

**NOTICE** Warning regarding possible technical damage.

### 4.2 General safety instructions

#### **CAUTION**

##### **Reuse on other persons and improper cleaning**

Skin irritation, formation of eczema or infections due to contamination with germs

- ▶ The product may be used by one person only.
- ▶ Clean the product regularly.

#### **CAUTION**

##### **Use with heat-sensitive skin**

Skin irritation due to overheating

- ▶ Do not use the product in case of a known heat allergy.
- ▶ Do not continue to use the product if skin irritation occurs.

#### **CAUTION**

##### **Contact with heat, embers or fire**

Risk of injury (such as burns) and risk of product damage.

- ▶ Keep the product away from open flames, embers and other sources of heat.

#### **NOTICE**

##### **Contact with oils, salves, lotions or other products that contain oils or acids**

Insufficient stabilization due to loss of material functionality

- ▶ Do not expose the product to oils, salves, lotions or other products that contain oils or acids.

## 5 Use

#### **INFORMATION**

- ▶ The daily duration of use and period of application are generally determined by the physician.
- ▶ The initial fitting and application of the product must be carried out by qualified personnel according to the instructions of the treating physician.
- ▶ Consult a physician if any exceptional changes are noted (such as worsening of the complaint).



## 5.1 Size selection

- 1) Measure the circumference of the lower leg **15 cm** below the center of the patella (circumference A).
- 2) Measure the circumference of the thigh **15 cm** above the center of the patella (circumference B).
- 3) Determine the size of the brace (see size chart).

## 5.2 Adapting the size

Trim the product to use it in sizes XS, M, XL and XXL (see fig. 22).

- ▶ Use scissors to cut the thigh and calf pads (item 1, item 8) to the desired size at the marks.
- Trim size S to XS.
- Trim size L to M.
- Trim size XXXL to XXL or XL.

## 5.3 Fitting and application

### CAUTION

#### **Incorrect or excessively tight application**

Risk of local pressure and constriction of blood vessels and nerves due to improper or excessively tight application

- ▶ Ensure that the product is applied properly and fits correctly.

### NOTICE

#### **Use of a worn or damaged product**

Limited effectiveness

- ▶ Before each use, check the product for functional reliability and for possible wear or damage.
- ▶ Do not continue using a product that is no longer functional, or that is worn or damaged.

- > **Prerequisite:** The patient should be seated on the edge of a chair.
- > **Prerequisite:** The knee joint should be relieved of pressure and slightly bent.
- 1) Open all hook-and-loop closures on the brace.
- 2) Center the patella cutout (item 5) over the patella (see fig. 4).
- 3) Bend the leg to a flexion position of **30°** with the foot flat on the floor (see fig. 5).
- 4) Place the brace joint (item 12) medially (MO) or laterally (LO) on the side being treated, positioning the center of the brace joint at the height of the middle of the patella.
- 5) Use one hand to hold the brace on the leg (see fig. 6).
- 6) Use the other hand to tighten flap 1 (item 4) and attach it to mark 1 on the thigh pad (item 1) with the hook-and-loop closure. The hook-and-loop sections should overlap (see fig. 7).
- 7) Then, tighten flap 2 (item 6) and attach it to mark 2 on the calf pad (item 8) with the hook-and-loop closure (see fig. 8).
- 8) Tighten flap 3 (item 7) and attach it to mark 3 on the calf pad (item 8) with the hook-and-loop closure (see fig. 9).
- 9) Tighten flap 4 (item 2) and attach it to mark 4 on the thigh pad (item 1) with the hook-and-loop closure (see fig. 10).
- 10) Check the fit of the brace and adjust the flap positions, if necessary.
- 11) **Optional:** Use scissors to change the size or fit of the thigh and calf pads.
- 12) **Optional:** Use bending irons to change the fit of the brace joint bars. **INFORMATION: The joint bars are permanently integrated in the brace and cannot be removed from the brace. The brace joint must not be bent, as this results in loss of function of the brace joint.**

## Adjusting the straps

- 1) Use one hand to tighten the release strap (item 11) and the other hand to slide the clip (item 10) on the strap.
- 2) Position the clip so it is centered on the side of the thigh (see fig. 12).
- 3) Guide the strap through the D-ring (item 15) of mark 5 and move the leg to a flexion position of **80°** with the foot flat on the floor (see fig. 13).
- 4) Hold the thigh pad (item 1) in place with one hand and fasten the strap with the other hand (see fig. 14).
- 5) Remove the positioning aid (item 9) from the clip; this fixes the clip to the strap (see fig. 15).
- 6) Move the leg back to a flexion position of **30°**.
- 7) Thread the anti-rotation strap (item 13) through the D-ring (item 14) (see fig. 16).
- 8) Tighten the strap and fasten the strap to itself (see fig. 17). **INFORMATION: Tighten the strap until maximum pain relief is achieved.**
- 9) **NOTICE! Once the straps have been shortened, this cannot be undone. Proceed with care!** Ensure an optimal fit by removing the Y-hook-and-loop from the respective strap and using scissors to shorten the end of the strap to the required length.
- 10) Reattach the Y-hook-and-loop to the strap end.

## Optional: limiting the knee flexion and extension

The extension limitation at delivery is **0°**. The flexion is not limited.

Available extension stops (square grip):	0°, 10°, 20°, 30°, 45°
Available flexion stops (round grip):	0°, 10°, 20°, 30°, 45°, 60°, 75°, 90°

- ▶ Change the extension and flexion limits only if advised to do so by the attending physician.
- 1) Remove the cover (item 12) from the brace joint (see fig. 19).
  - 2) Remove the placeholder from the brace if present.
  - 3) Insert the required extension stop, alternatively the flexion stop (see fig. 18).
    - The stop will engage with slight resistance.
  - 4) Place the cover on the brace joint, ensuring that the arrows are pointing in the correct direction on the cover. The arrows should point in the posterior direction (see fig. 21).
  - 5) Move the brace joint and check the position of the stops.

## 5.4 Delivery

### NOTICE

#### Incorrect setting

Damage to the brace due to overloading of the material and improper fit of the brace due to breakage of load-bearing components

- ▶ The brace may only be adjusted by qualified personnel.
- ▶ Do not make any improper changes to the settings.

- 1) Check the product fits properly on the leg when handing the brace over to the patient.
- 2) Ask the patient to sit down, stand up and walk a few steps.
  - The center of the brace joint should be at the height of the middle of the patella.
  - The brace should not be twisted on the leg.
  - The straps should be tight but not impair the patient's comfort.

Inform the patient:

#### Inspect the brace for damage

- ▶ Inspect the brace for damage daily. Contact the qualified personnel promptly if changes are noted.

## 5.5 Removal

- 1) Open both straps at the hook-and-loop closures and remove them from the D-rings.

- 2) Open flaps 1 to 4, one after the other, and remove the brace from the leg.

## 6 Cleaning

### NOTICE

#### Use of improper cleaning agents

Damage to the product due to use of improper cleaning agents

- ▶ Only clean the product with the approved cleaning agents.

Clean the product promptly after contact with water containing salt or chlorine, or if it gets dirty.

#### Cleaning the brace joint

- ▶ The brace joint may only be dismantled by qualified personnel.
- 1) Rinse the brace joint with clean, fresh water and remove dirt.
  - 2) Dry with a cloth or allow to air dry.

#### Cleaning the brace

- 1) **Hand wash** the brace in warm water at **30 °C** with standard mild detergent. Do not use fabric softener. Rinse thoroughly.
- 2) Allow to air dry. Do not expose to direct heat sources (e.g. sunlight, stove, or radiator).
- 3) Do not tumble-dry or bleach.

## 7 Disposal

Dispose of the product in accordance with national regulations.

## 8 Legal Information

All legal conditions are subject to the respective national law of the country of use and may vary accordingly.

### 8.1 Liability

The manufacturer shall be liable in the event that the product is used in accordance with the descriptions and instructions in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorized modification of the product.

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