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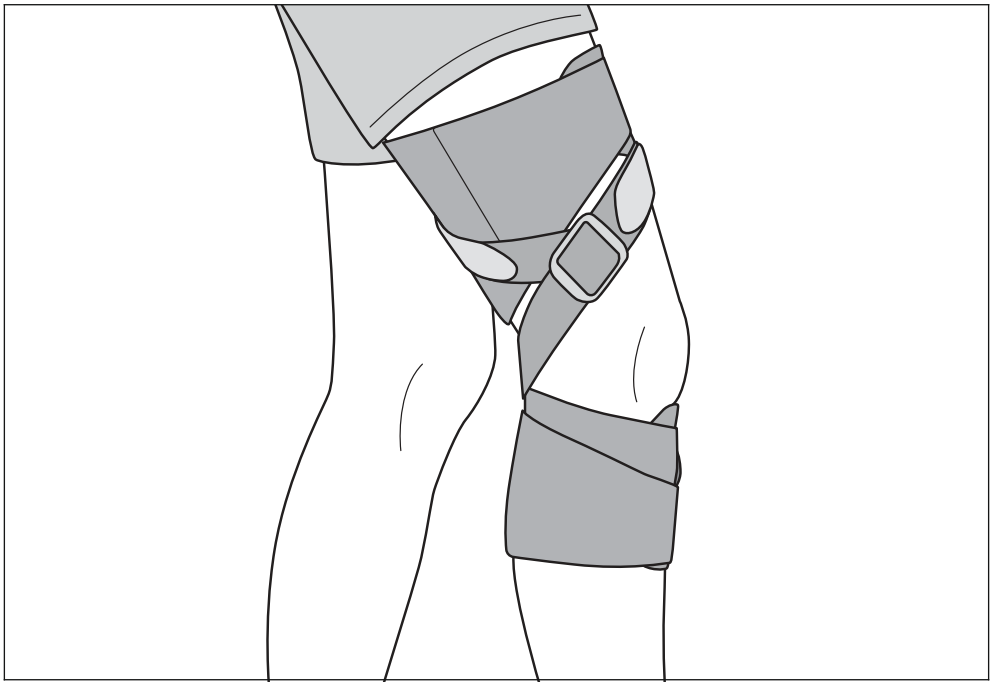
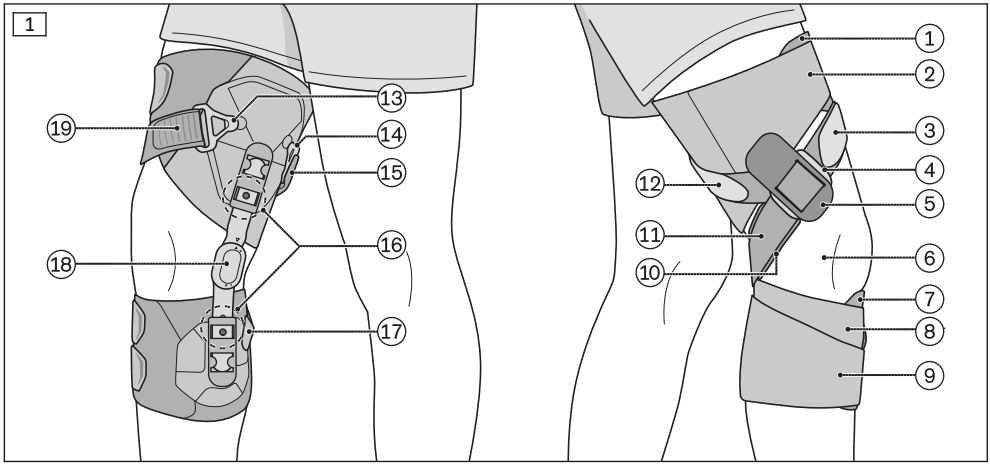


50K305 Agilium® Forte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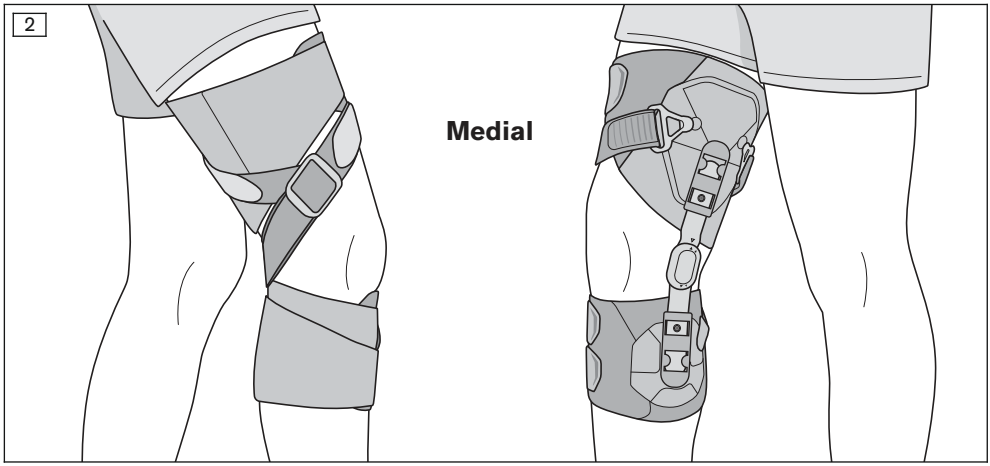
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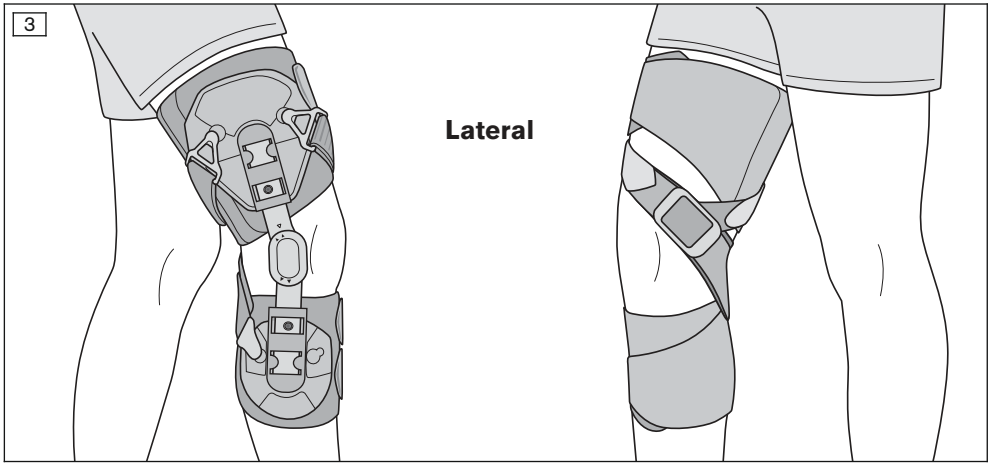
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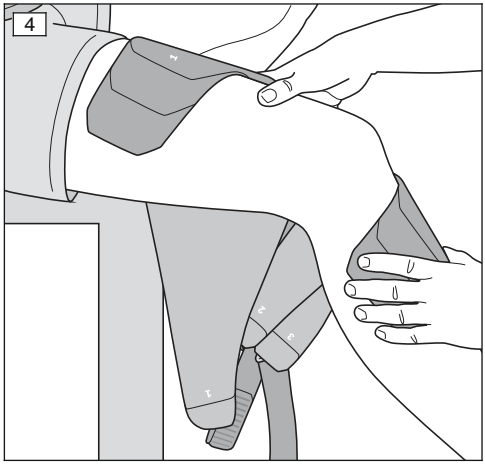
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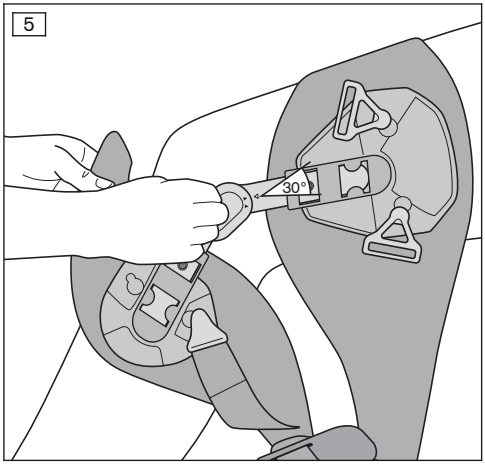
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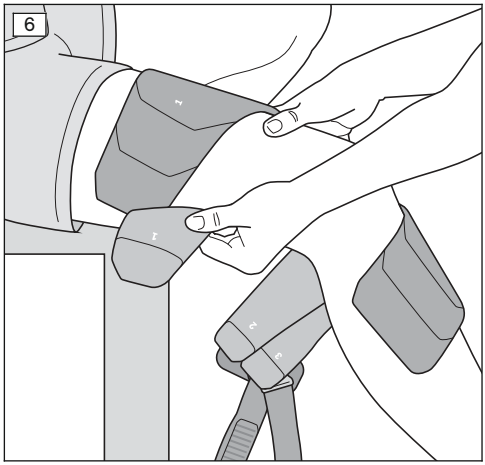
30°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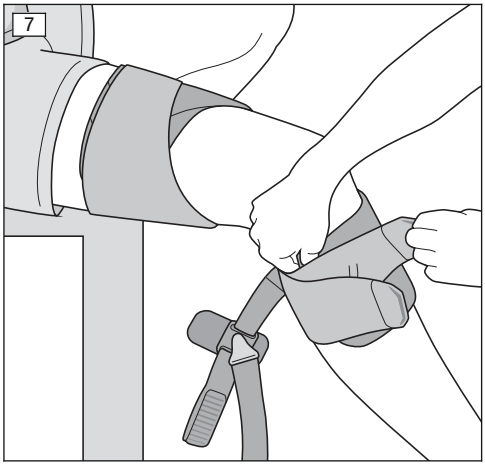
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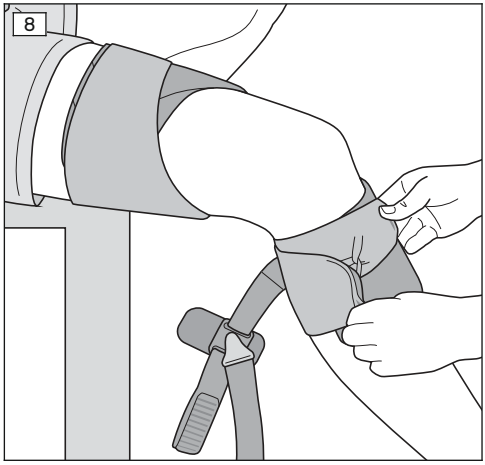
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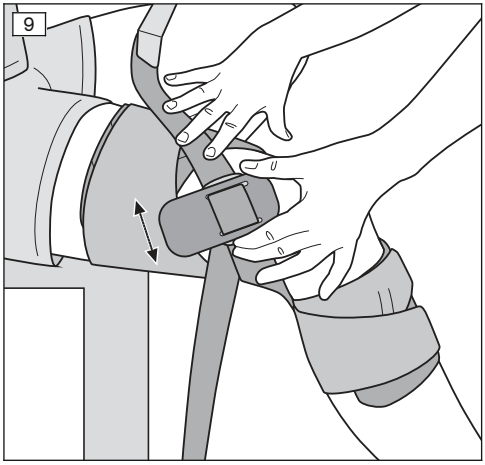
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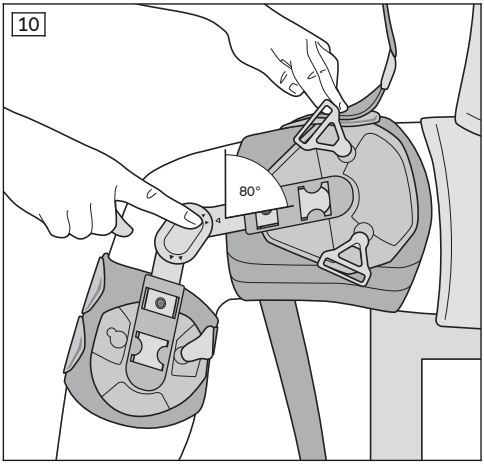
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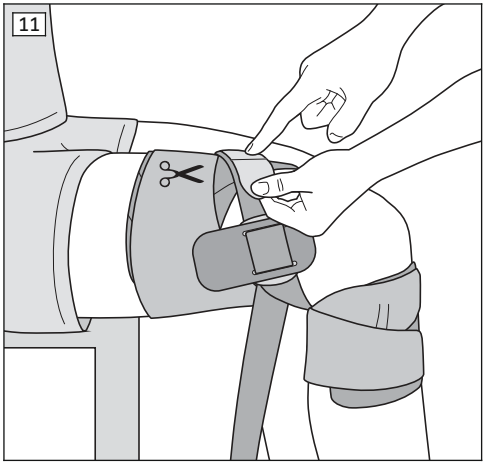
80°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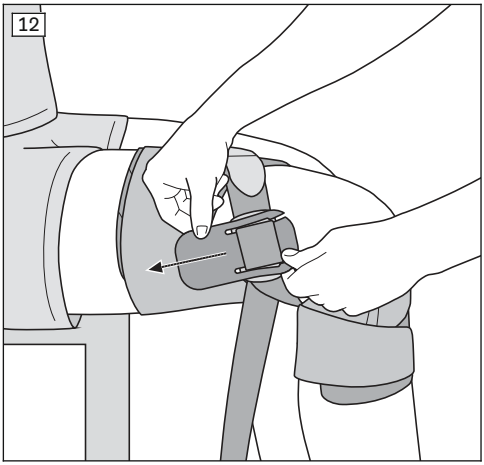
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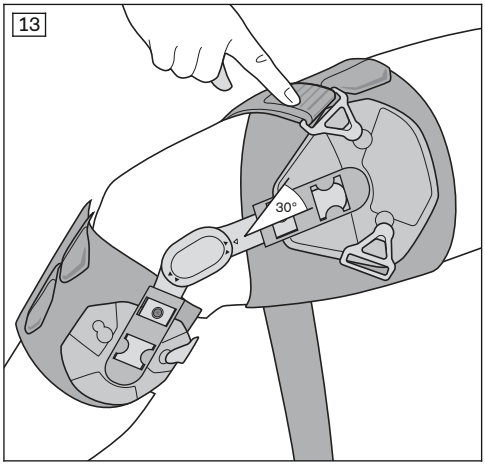
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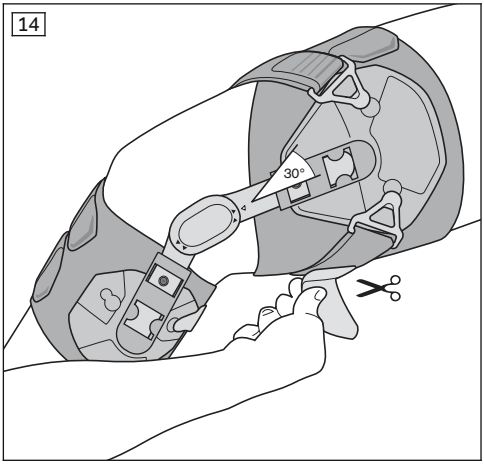
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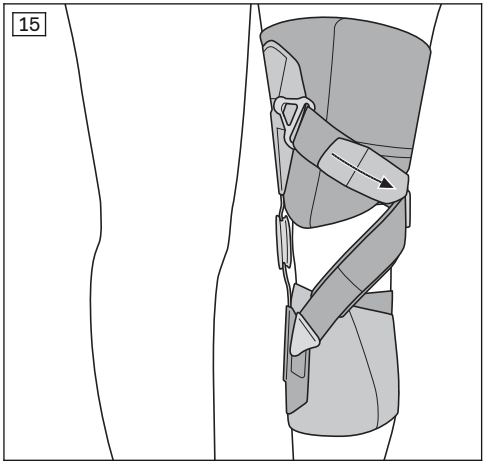
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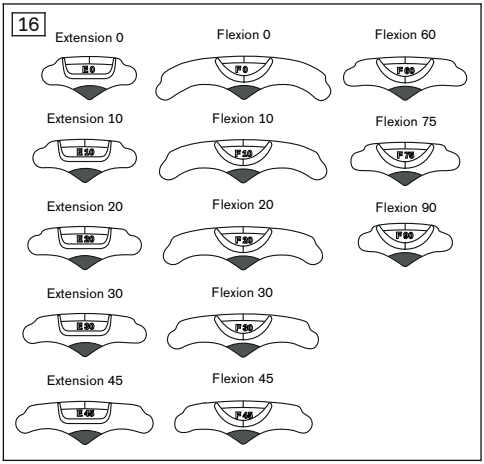

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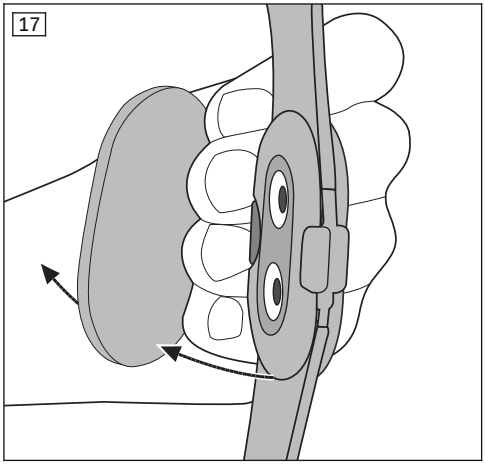

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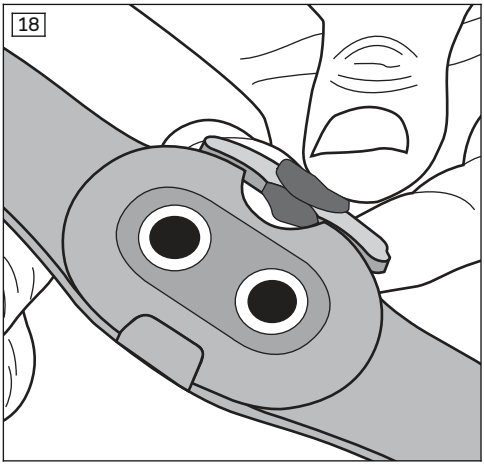

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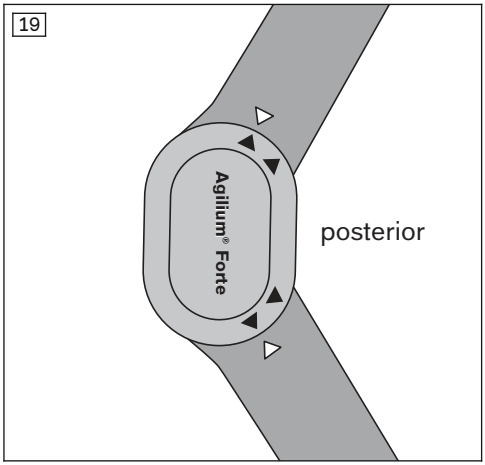

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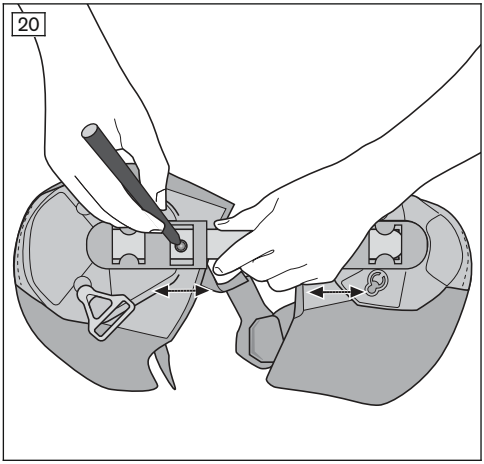

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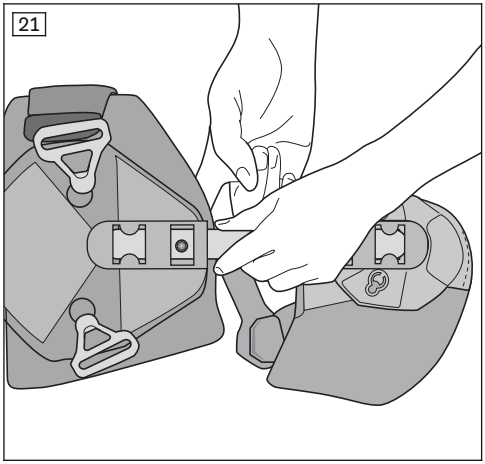

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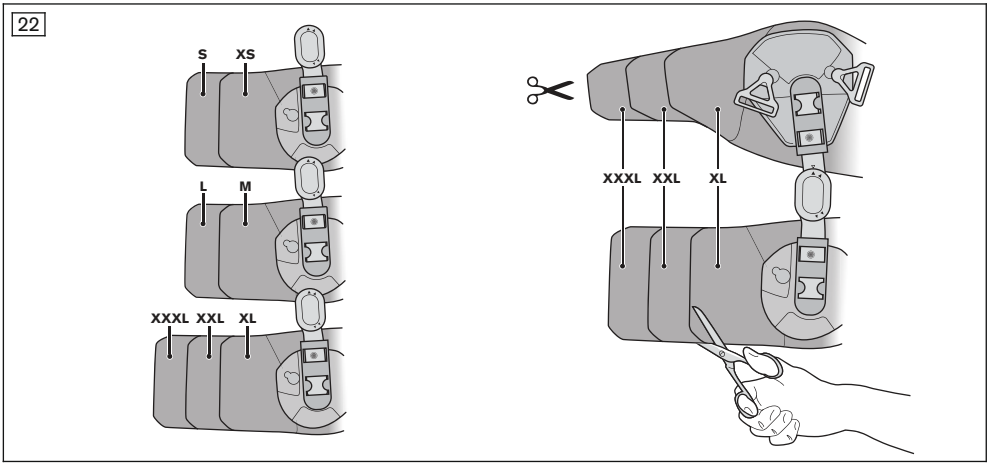
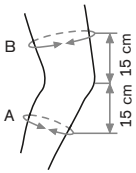
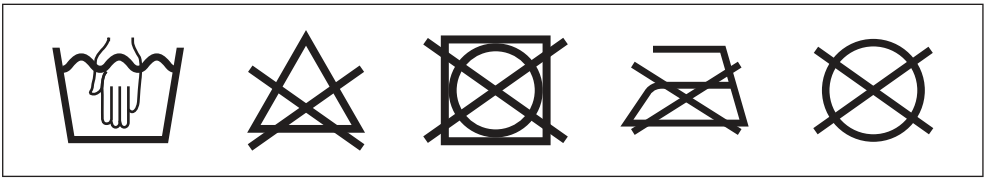


	Size	A Lower leg circumference		B Thigh circumference	
		[cm]	[inch]	[cm]	[inch]
	**XS**	28–32	11–12.5	36–41	14–16
	S	32–36	12.5–14	41–46	16–18
	M	36–41	14–16	46–53	18–21
	L	41–46	16–18	53–60	21–23.5
	XL	46–51	18–20	60–67	23.5–26.5
	XXL	51–56	20–22	67–75	26.5–29.5
	XXXL	56–61	22–24	75–81	29.5–32

Combined Sizes	Medial Compartment osteoarthritis		Lateral Compartment osteoarthritis	
	Left	Right	Left	Right
	50K305*			
XS/S	*=L-XS-S-MO	*=R-XS-S-MO	*=L-XS-S-LO	*=R-XS-S-LO
M/L	*=L-M-L-MO	*=R-M-L-MO	*=L-M-L-LO	*=R-M-L-LO
XL/XXL/XXXL	*=L-XL-3XL-MO	*=R-XL-3XL-MO	*=L-XL-3XL-LO	*=R-XL-3XL-LO

Material	Aluminium, Steel, ABS, Nylon, PU foam, Spandex



1 Foreword

INFORMATION

Date of last update: 2020-10-26

- ► Please read this document carefully before using the product and observe the safety notices.
- ► Instruct the user in the safe use of the product.
- ► Please contact the manufacturer if you have questions about the product or in case of problems.
- ► Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ► Please keep this document for your records.

These instructions for use provide important information on the fitting and application of the 50K305 Agilium® Forte.

2 Product description

50K305 Agilium® Forte (see fig. 1)			
Item	**Designation**	**Item**	**Designation**
1	Thigh pad	11	Release strap
2	Flap 1	12	Y-hook-and-loop
3	Y-hook-and-loop	13	D-ring release strap
4	Clip	14	D-ring anti-rotation strap
5	Positioning aid	15	Anti-rotation strap
6	Patella cutout	16	Height adjustment, joint bars
7	Calf pad	17	Anti-rotation strap, bottom attachment
8	Flap 2	18	Brace joint
9	Flap 3	19	Marking strip for strap tightening
10	Strap pads	–	Extension and flexion stops (see fig. 16)

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.

- Bicompartmental 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

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

► Use scissors to cut the thigh and calf pads to the desired size at the marks.

- Shorten size S to XS.
- Shorten size L to M.
- Shorten size XXXL to XXL or XL.

5.3 Adapting the height

The product is set to the standard height on delivery. **Optional:** The height position of the upper and lower leg shells can be adapted to the needs of the patient.

1) Use a pen to push inwards the plastic button inserted into the hole on the joint bar of the upper or lower leg shell (see fig. 20).
2) Move the joint bar to the desired position.
3) Push the plastic button from inside to outside using your finger so it fully engages in the hole on the joint bar (see fig. 21).

5.4 Adaptation

⚠ 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.
2) Center the patella cutout 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 medially or laterally 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.
6) Use the other hand to tighten flap 1 and attach it to mark 1 on the thigh pad with the hook-and-loop closure. The hook-and-loop sections will overlap (see fig. 6).
7) Then tighten flap 2 and attach it to mark 2 on the calf pad with the hook-and-loop closure (see fig. 7).

8) Tighten flap 3 and attach it to mark 3 on the calf pad with the hook-and-loop closure (see fig. 8).
9) Check the fit of the brace and optionally adjust the flap positions.
10) **Optional:** Use scissors to change the size or fit of the thigh and calf pads.
11) **Optional:** Use bending irons to change the fit of the brace joint bars. **NOTICE! 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 and the other hand to slide the clip on the strap (see fig. 9).
2) Position the clip so it is centered on the side of the thigh.
3) Guide the strap through the D-ring of mark 4 and move the leg to a flexion position of **80°** with the foot flat on the floor (see fig. 10).
4) Hold the thigh pad in place with one hand and fasten the strap with the other hand.
5) Adjust the length of the release strap (see fig. 11).
6) Remove the positioning aid from the clip; this fixes the clip to the strap (see fig. 12).
7) Align the hook-and-loop marking strip for strap tightening on the release strap (see fig. 13).
8) Move the leg back to a flexion position of **30°** (see fig. 14).
9) Thread the anti-rotation strap through the D-ring.
10) Tighten the strap and fasten the strap to itself. **INFORMATION: Tighten both the release strap and anti-rotation strap until maximum pain relief is achieved, using the marking strip on the release strap for orientation.**
11) Ensure an optimal fit by removing the Y-hook-and-loop from the strap and using scissors to shorten the end of the strap to the required length.
12) Attach the Y-hook-and-loop to the strap end (see fig. 15).

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 from the brace joint (see fig. 17).
2) Remove the placeholder from the brace if present.
3) Insert the required extension stop, alternatively the flexion stop (see fig. 16, 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. 19).
5) Move the brace joint and check the position of the stops.

5.5 Application

> **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.
2) Center the patella cutout 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 medially or laterally 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.
6) Use the other hand to tighten flap 1 and attach it to mark 1 on the thigh pad with the hook-and-loop closure. The hook-and-loop sections will overlap (see fig. 6).
7) Then tighten flap 2 and attach it to mark 2 on the calf pad with the hook-and-loop closure (see fig. 7).

8) Tighten flap 3 and attach it to mark 3 on the calf pad with the hook-and-loop closure (see fig. 8).
9) Guide the release strap through the D-ring of mark 4 and move the leg to a flexion position of **80°** with the foot flat on the floor (see fig. 10).
10) Hold the thigh pad in place with one hand and fasten the strap with the other hand using the marking strip as guidance.

5.6 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.

5.7 Removal
1) Open the release strap at the hook-and-loop closure and remove it from the D-ring. **INFORMATION: The anti-rotation strap should not be opened and closed by the patient once that strap has been fit by qualified personnel.**
2) Open flaps 1 to 3 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 (86 °F) 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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