Verwendung oder unerlaubte Veränderung des Produkts verursacht werden, haftet der Hersteller nicht.

7.2 CE-Konformität

Das Produkt erfüllt die Anforderungen der europäischen Richtlinie 93/42/EWG für Medizinprodukte. Aufgrund der Klassifizierungskriterien nach Anhang IX dieser Richtlinie wurde das Produkt in die Klasse I eingestuft. Die Konformitätserklärung wurde deshalb vom Hersteller in alleiniger Verantwortung gemäß Anhang VII der Richtlinie erstellt.

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1 Foreword

English

INFORMATION

Last update: 2016-06-22

- ► 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 contain important information for fitting and applying the 50K4-1 Agilium Freestep knee osteoarthritis brace.

2 Product description

2.1 Components (see Fig. 1)

Item:	Description	Item:	Description
1	Bars	2	Foot stirrup
3	Foot component	4	Brace ankle joint
5	Allen head screws	6	Strap

Components not illustrated	
Heel raiser	Allen wrench

2.2 Design

The brace consists of a foot component and a lower leg component. These components are connected via a freely movable brace ankle joint (sagittal plane) (4).

The foot component consists of a foot component (3) that can be cut to size and the foot stirrup (2).

The lower leg component consists of the brace ankle joint, two adjustable bars (1) and the strap (6). 2 Allen head screws (5) are used to adjust the lower leg component.

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
- Pre-operative: Checking the indication of a valgizing corrective osteotomy in case of varus gonarthrosis (brace test)
- Post-operative: After intervention in the cartilage structure and meniscus surgery requiring unilateral relief

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.

3.4 Mechanism of Action

The brace reduces or increases the varus moment on the knee joint depending on the chosen brace.
In the treatment of medial knee osteoarthritis (brace bar lateral), two mechanisms cause a reduction in varus moment. Initially the rigid bridging of the ankle joint in the frontal plane reduces eversion in the lower ankle joint. At the same time, forces that can be adjusted at the lateral contact point of the brace are transferred in the area of the lower leg. This effect shifts the ground reaction force laterally. Immediate consequences are the reduction of varus moment and relief for the medial compartment. In the treatment of

lateral knee osteoarthritis (brace bar medial), the force transmission point is shifted in the medial direction. This increases the varus moment, relieving the lateral compartment. Strain can be relieved on either the lateral or medial compartment depending on the brace selection.

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

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 ointments, lotions, or other products that contain oils or acids

Insufficient stabilization due to loss of material functionality

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

5 Handling

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.
- ► Instruct the patient in the handling and care of the product.
- ► Instruct the patient to see a physician immediately if any exceptional changes are noted (e.g. worsening of the complaint).

5.1 Selecting the Size

1) Select the brace size according to the ankle height.
2) Check whether the foot size matches the brace sole. If the brace is too small, select the next larger brace size.
3) Verify that the lateral contact is at least 3 cm below the fibular head. If the lateral contact extends closer than 3 cm to the fibular head, select the next smaller brace size.

5.2 Adaptation

⚠ CAUTION

Incorrect alignment, assembly or adjustment

Injury and damage to product components

- ► Observe the alignment, assembly and adjustment instructions.
- ► Work on the product may only be carried out by qualified personnel.

NOTICE

Improper molding or application

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

- ► The product may only be molded by qualified personnel.
- ► Do not make any improper changes to the product.
- ► Always apply the product according to the information in the instructions.

Adjusting the distance from the brace joint to the ankle

1) Mark the foot contour on the foot component. The pivot point of the brace joint has to line up with the pivot point of the ankle joint (see fig. 2).
2) Trim the sole to fit the inner contour of the shoe (see fig. 3). Take the foot contour into account in doing so.
3) Round the edges of the foot component. Use a silicone cone for this purpose.

4) **Optional: Bend the foot stirrup:** Bend the foot stirrup with a bending iron.

Optional: Gluing on the insole

1) Roughen the top of the foot component.
2) Apply adhesive to the roughened foot component and glue on the insole. Note that the distance between the brace ankle joint and the ankle joint is reduced.

Adjusting the correction strength

1) Insert the brace into the shoe (see fig. 4).
2) The manufacturer recommends using the heel raiser on the contralateral side to compensate for the sole thickness of up to 6mm. The heel raiser is included in the scope of delivery.
3) Put the brace on together with the shoe.
4) Loosen the 2 Allen head screws (see fig. 5).
5) Twist the bars until the desired correction strength is reached. In doing so, push the bars into the brace ankle joint up to the mark and tighten the 2 Allen head screws (torque: 6 Nm).

Optional: Optimizing straps

► Remove the hook and loop closure of the strap and shorten the strap.

Conducting the dynamic trial fitting

► Conduct the dynamic trial fitting. In the process, observe the position of the ankle joint and reduce the setting of the lower leg component in case of a non-physiological heel strike (excessive supination of the foot).

5.3 Application

⚠ CAUTION

Using the brace without padding

Risk of local pressure points, superficial injuries or skin irritation due to skin contact with rigid or sharp brace components

► Only use the brace with undamaged padding.

⚠ CAUTION

Brace is put on too tightly

Risk of local pressure points and restriction of adjacent blood vessels or nerves

► Check that the brace is correctly positioned and fitted.

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.

1) Unfasten the hook-and-loop closure of the strap.
2) Insert the brace into the shoe.
3) Put the brace on together with the shoe.
4) Fasten the hook-and-loop closure of the strap.

5.4 Removal

1) Unfasten the hook-and-loop closure of the strap.
2) Remove the shoe together with the brace.
3) **If necessary:** Remove the brace from the shoe and re-insert the inner sole of the shoe.

5.5 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 brace regularly:

1) Remove the strap and the padding.
2) Wash the strap and the padding in 30 °C warm water using a standard mild detergent. Do not use fabric softener. Rinse thoroughly.
3) Allow to air dry. Do not expose to direct heat (e.g. sunshine, stove or radiator).

6 Disposal

Dispose of the product in accordance with national regulations.

7 Legal Information

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

7.1 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 disregard of this document, particularly due to improper use or unauthorized modification of the product.

7.2 CE Conformity

This product meets the requirements of the European Directive 93/42/EEC for medical devices. This product has been classified as a class I device according to the classification criteria outlined in Annex IX of the directive. The manufacturer therefore drew up the declaration of conformity on its own responsibility in accordance with Annex VII of the directive.

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1 Avant-propos

INFORMATION

Date de la dernière mise à jour : 2016-06-22

- ► Veuillez lire attentivement l'intégralité de ce document avant d'utiliser le produit.
- ► Respectez les consignes de sécurité afin d'éviter toute blessure et endommagement du produit.
- ► Apprenez à l'utilisateur à bien utiliser son produit et informez-le des consignes de sécurité.
- ► Conservez ce document.

Les présentes instructions d'utilisation vous apportent des informations importantes pour adapter et poser l'orthèse pour gonarthrose Agilium Freestep 50K4-1.

2 Description du produit

2.1 Composants (voir ill. 1)

Pos. :	Désignation	Pos. :	Désignation
1	Tiges	2	Étrier de pied
3	Partie du pied	4	Articulation de cheville orthétique
5	Vis à six pans creux	6	Sangle

Composants non représentés dans l'illustration	
Talonnette	Clé Allen