

USER INSTRUCTIONS

HYPEX[®] LITE

KNEE ORTHOSIS

WITH 4-POINT-PRINCIPLE AND EXTENSION- / FLEXIONLIMITATION



albrecht[®]
FUNKTIONELLE REHABILITATION

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1. Introduction

1.1. Foreword

Functional braces relief and stabilize joints and ligaments after trauma and surgery. They support joints and ligaments in the healing process while maintaining the natural range of motion.

Whilst protecting fragile joints and ligaments during rehabilitation, our functional braces are also designed to allow a guided, step by step return to full physiological mobility.

1.2. Customer information

For your own safety, please read this customer information sheet carefully before using the brace. Proper use and operation of the brace will only be possible if you have carefully read and understood all instructions, notes and procedures. Should you have any doubts with regard to the user instructions, or should any of the instructions, operations or safety notes be unclear, please contact your local dealer or the manufacturer albrecht GmbH directly before using the brace. This holds particularly true for the safety notes.

1.3. Mode of operation

The Hypex® Lite Knee Brace stabilises and relieves the knee during conservative and post-operative rehabilitation. Straps and shells may be adjusted individually for high wearing comfort.

The continuously variable extension limit between + 45° and -15° allows for individual terminal extension.

1.4. Application

The brace has been designed exclusively for the orthotic treatment of the knee joint and for contact with intact skin.

1.5. Scope of delivery

Please check the completeness of the brace at delivery.

- Brace with padding and straps
- User instructions

1.6. Declaration of conformity

The albrecht GmbH company, as the manufacturer solely responsible, declares that the Hypex® Lite conforms to the Regulation (EU) 2017/745 concerning medical devices.

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1.7. Features

- Anatomically formed hinge rods and shells
- Individually adjustable straps
- Limits can be adjusted without tools
- Easy handling and high wearing comfort

Hypex[®] Lite L/L, M/L, L/M, S/S and Junior:

- Continuously adjustable extension between -15° and 45° to allow for physiological hyperextension of the knee
- Flexion can be adjusted in 15° intervals up to 90° (max flexion 130°)
- Continuous immobilisation of the brace between -15° and 45°

Hypex[®] Lite XS/XS, XXS, Bambini and Malinki:

- Extension limit can be adjusted in 10° intervals from -10° until 100° , to allow for physiological hyperextension
- Flexion limit can be adjusted in 10° intervals from -10° until 130°
- Immobilisation of the brace can be adjusted in 10° intervals between -10° and 100°

1.8. Indications

The physician will decide on the type of treatment to apply based on his diagnosis.

Generally, the use is indicated in:

- Collateral ligament injuries
- ACL and PCL ruptures
- Meniscus injury
- Femur condyle fracture
- Patella fracture
- Tibial plateau fracture
- Condition after meniscus reconstruction
- Condition after microfracturation, Pridie drilling
- Condition after abrasion chondroplasty
- Condition after cartilage transplantation
- Condition after osteotomies (procedures)
- Patella luxation
- Moderate instability of the knee
- Multiligamentous instability
- Genu recurvatum

For all aberrant indications the physician has to be asked.

1.9. Contra indications

- Massive circulatory disorder
- Massive varikosis

1.10. Safety notes

- The maximum effectiveness of the brace will only be achieved if it is used correctly.
- The brace is only to be used in an intact, complete, mechanically faultless condition with complete and undamaged padding and straps. Prior to each use, the user should check that these conditions are met.
- Failure to close one or more of the straps, or their removal, or any excessive loosening of the straps during usage will diminish the therapeutic effect of the brace and may cause injuries.
- The brace must not be worn on open wounds.
- The skin should be free of oils, greases, gels or other residues in order to avoid skin reactions or reactions on the material structure.
- The brace should be tight, but not too tight - so as not to adversely affect circulation. Thus excessive compression should be avoided.
- A combination with other products is currently not foreseen and must thus be agreed with the manufacturer in writing.
- The brace is not a single-use product, but has been designed for use by one person only.
- The product is not supplied in a sterile condition.
- When adjusting the hinge rods to the shape of the extremity by using an orthopaedic bending iron, you must not bend the rods in the area of the hinge housing or the hinge cover as this could lead to damage or break of the hinge.

- In case of allergic reactions, immediately contact your physician.

1.11. Warranty

In addition to the legal warranty, we provide a 6-month durability guarantee for the orthosis. If properly used, this guarantees that the orthosis will function without fault. This excludes the padding and straps, which are usually liable to a certain amount of wear and tear. This kind of wear and tear does not represent a product defect. This manufacturer's warranty is subject to the condition that the orthosis is used as a medical rehabilitation device and for no other purpose than that described in the instructions for use. Changes to the orthosis or the removal / damage to the quality management seal will invalidate the warranty.

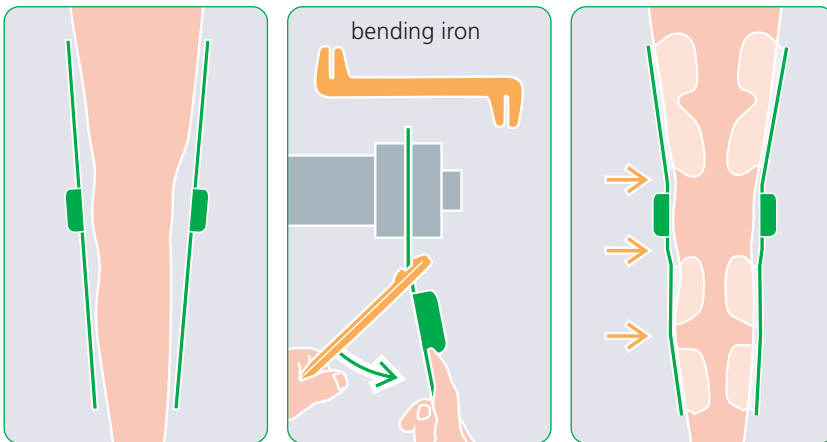
User Instructions

2. Adjustment by the orthopaedic technician

2.1. Fitting to the patient

2.1.1. Adjusting the brace to the leg shape by using an orthopaedic “bending iron”

The brace is anatomically contoured. However, if a different shape is required, the hinge rods can be adjusted to the shape of the patient’s leg with the aid of an orthopaedic bending iron. Loosen the screws on the shell components and either move or remove them. Then adjust the hinge rods to the shape of the extremity.



When adjusting the hinge rods to the shape of the extremity by using an orthopaedic bending iron, you must not bend the rods in the area of the hinge housing or the hinge cover as this could lead to damage or break of the hinge.

Please note:

- The setting for both hinges must be the same.
- Both stop pins of each hinge must be in the pin holes.
- The hinge covers must always be closed after any adjustment.

Hypex® Lite

User Instructions

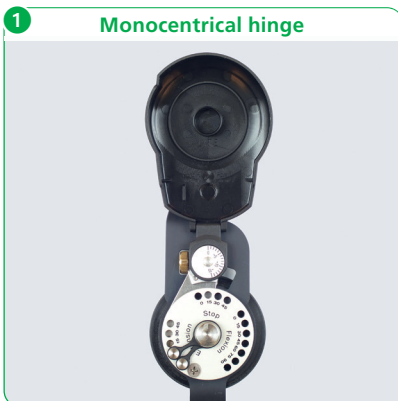
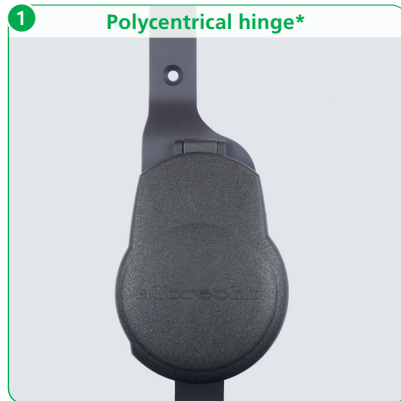
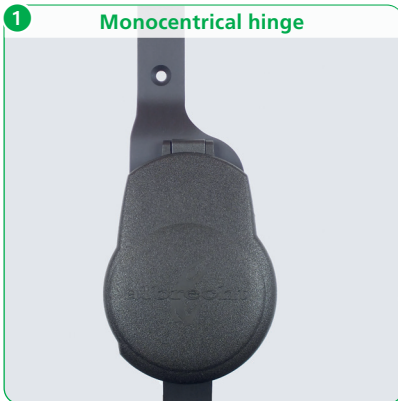
2.2. Setting the hinge for Hypex® Lite L/L, L/M, M/L, S/S and Junior

Extension and flexion can be limited in 15° steps by appropriate positioning of the stop pins.

In order to set the Extension/ Flexion limitation and the immobilisation the following steps must be executed.

2.2.1. Opening of the hinge cover

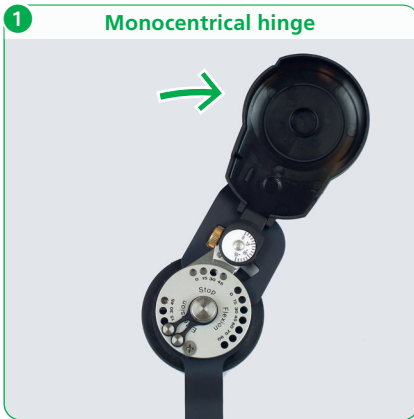
- 1 Open the hinge cover.



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2.2.2. Setting the extension limitation

1 In order to set the extension limitation, bring the brace into flexion.



2 Place the stop pin into the desired position.



* not at S/S and Junior

Hypex® Lite

User Instructions

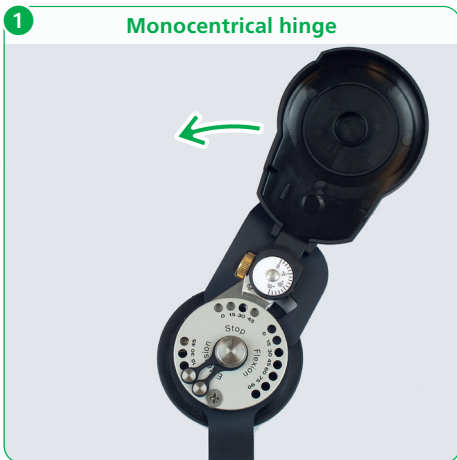
2.2.3. Setting the fine adjustment

- 1 Additionally, the extension limitation can be adjusted infinitely using the fine adjustment from 45° via 0° to -15°.



2.2.4. Setting the flexion limitation

- 1 In order to set the flexion limitation, bring the brace into extension.



User Instructions

- Place the stop pin into the desired position.



2.2.5. Immobilisation

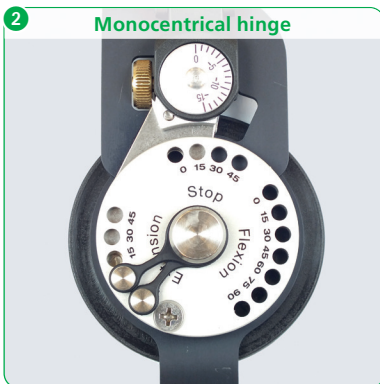
- Immobilisation can be set in 15° steps by appropriate positioning of a stop pin in the stop area. Additionally, the set immobilisation can be infinitely adjusted from 45° via 0° to -15° using the fine adjustment.



* not at S/S and Junior

2.2.6. Unlimited flexion

- 1 For unlimited flexion put one stop pin into the position ∞.
- 2 Make sure that both stop pins are placed in the pinholes and that there is always at least one stop pin positioned in the pinholes of the extension stops.



The hinge cover must always be closed after any adjustment in order to secure the stop pins.

* not at S/S and Junior

User Instructions

2.3. Setting the hinge for Hypex[®] Lite XS/XS, XXS, Bambini and Malinki

Extension and flexion can be limited in 10° steps by appropriate positioning of the stop pins.

In order to set the Extension/ Flexion limitation and the immobilisation the following steps must be executed.

2.3.1. Remove the hinge cover

- 1 Rotate the hinge cover 90°.
- 2 Remove the cover from the hinge.

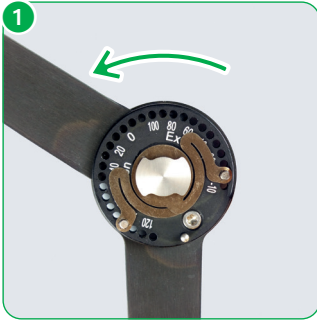


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User Instructions

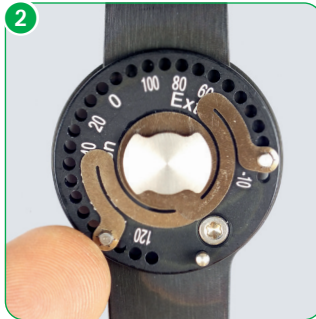
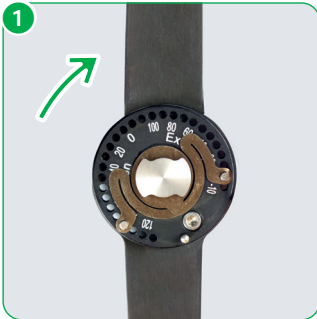
2.3.2. Setting the extension limitation

- 1 In order to set the extension limitation, bring the brace into flexion.
- 2 Place the stop into the desired position.



2.3.3. Setting the flexion limitation

- 1 In order to set the flexion limitation, bring the brace into extension.
- 2 Place the stop into the desired position.



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2.3.4. Immobilisation

In order to immobilize the brace, first set the the extension limitation.

Move the hinge rod against the extension limitation and position the flexion stop adjacent to the hinge rod.

2.3.5. Reattach the hinge cover

- 1 Make sure that both stops are placed in the holes.
- 2 Reattach the cover and rotate it 90° until the locking position. The hinge cover must always be closed after any adjustment in order to secure the stops.



2.4. Attaching of the brace by the orthopaedic technician

2.4.1. Attaching the brace

1 Preparation:

Adjust the length of the anterior brace straps. The straps do not have to be pulled out of their lugs. Release the posterior straps by opening the buckles.

2 Attaching:

Bend your knee to an angle of approx. 30° to 45° and align the orthosis corresponding to picture 1 on your knee. Make sure to align the pivotal points of the orthosis hinges with the pivotal point of the knee.

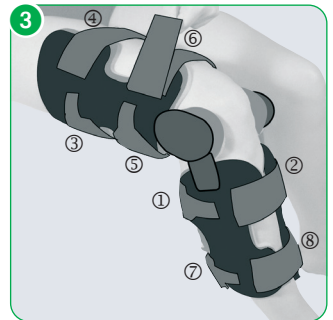
Position: Mid patella, posterior third of the joint. By adjusting the anterior straps, this step is made easier when attaching the brace for the first time.

tighten the anterior straps. The following sequence is recommended:

1. Upper calf strap
2. Upper tibia strap
3. Upper posterior thigh strap
4. Upper anterior thigh strap
5. Posterior thigh strap near hinge
6. Anterior thigh strap near hinge
7. Lower posterior calf strap
8. Lower anterior calf strap

3 Fixation:

When fastening the posterior straps, slightly



To achieve optimal fit the two calf straps near the hinge must be fastened tightly. Their purpose is to ensure no migration by being positioned on the belly of the gastrocnemius (calf).

After fastening the single straps, check the correct position of the brace and if necessary, re-adjust it. Please take care, that the straps are not fastened too tightly, so that blood circulation is not affected.

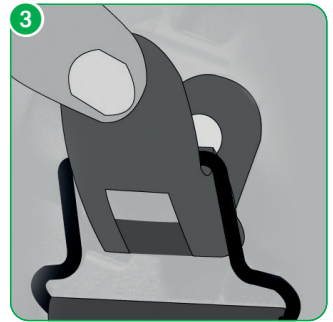
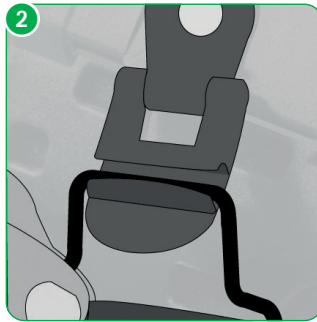
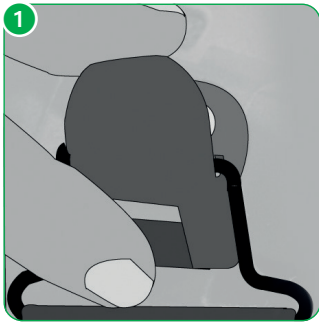
User Instructions

2.4.2. Using the clips

- 1 Open the clip.
- 2 Hook in the D-Ring.
- 3 Close the clip.

The length of the straps remains unchanged.

The sizes **XS/XS**, **XXS**, **Bambini** and **Malinki** are opened and closed using the straps.





Hand wash at 30°C



Do not bleach



Do not iron



Do not dry-clean



Do not tumble dry

3. Cleaning, maintenance and disinfection

The orthosis is designed to be maintenance-free. To ensure proper operation over the period of treatment the orthosis should be cleaned regularly (at least every 3 months) or as required, according to the following instructions.

3.1. Care

- The product as delivered is not sterile and is not suitable for sterilization.
- Do not use harsh or abrasive cleaners.
- All fabrics can be washed by hand at 30 °C using water and a mild detergent and/or disinfectant.
- Not machine washable.
- The Hypex® Lite can be dried in the open air.
- In the case of more severe soiling, a replacement set of textile parts is available.
- Wipe down surfaces with a cloth soaked with disinfectant.
- Wet completely, and do not wipe off.
- Spray inaccessible surfaces.
- When spraying ensure complete wetting.
- A mild alcohol-based disinfectant is recommended.

Ask your physician or pharmacist when selecting a disinfectant, and follow the instructions given by the disinfectant manufacturer. The Robert Koch list of approved disinfectants can be found at www.rki.de.

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4. Technical data

Name	Material
Padding material	PU foam with PA hook and loop velour
Strap material	PA strap with PA hook and loop velour
Brace material	aluminium
Weight	876g

5. Size chart and article numbers

Name	Length of thigh shell medial	Length of lower leg shell	Circumference of thigh	Circumference of lower leg	Art.-No. left	Art.-No. right
Hypex® Lite L/L	24 cm	26,5 cm	36 - 66 cm	27 - 47 cm	804LL-L	804LL-R
Hypex® Lite L/M	19 - 23 cm	25 - 28 cm	33 - 44 cm	24 - 35 cm	804LM-L	804LM-R
Hypex® Lite M/L	18 - 21 cm	20 - 23 cm	36 - 63 cm	27 - 45 cm	804ML-L	804ML-R
Hypex® Lite M/S	17 - 20 cm	21 - 25 cm	36 - 63 cm	22 - 32 cm	804MS-L	804MS-R
Hypex® Lite S/S	18 cm	20 cm	30 - 40 cm	22 - 32 cm	804SS-L	804SS-R
Hypex® Lite XS/XS	15 cm	18 cm	25 - 35 cm	20 - 30 cm	804XSXS-L	804XSXS-R
Hypex® Lite XXS	12 cm	15 cm	20 - 30 cm	15 - 25 cm	804XXS-L	804XXS-R
Junior Grün	18 cm	20 cm	30 - 40 cm	22 - 32 cm	804SS-GL	804SS-GR
Junior Blau	18 cm	20 cm	30 - 40 cm	22 - 32 cm	804SS-BL	804SS-BR
Junior Orange	18 cm	20 cm	30 - 40 cm	22 - 32 cm	804SS-OL	804SS-OR
Junior Pink	18 cm	20 cm	30 - 40 cm	22 - 32 cm	804SS-PL	804SS-PR
Bambini Grün	15 cm	18 cm	25 - 35 cm	20 - 30 cm	804XSXS-GL	804XSXS-GR
Bambini Blau	15 cm	18 cm	25 - 35 cm	20 - 30 cm	804XSXS-BL	804XSXS-BR
Bambini Orange	15 cm	18 cm	25 - 35 cm	20 - 30 cm	804XSXS-OL	804XSXS-OR
Bambini Pink	15 cm	18 cm	25 - 35 cm	20 - 30 cm	804XSXS-PL	804XSXS-PR
Malinki Grün	12 cm	15 cm	20 - 30 cm	15 - 25 cm	804XXS-GL	804XXS-GR
Malinki Blau	12 cm	15 cm	20 - 30 cm	15 - 25 cm	804XXS-BL	804XXS-BR
Malinki Orange	12 cm	15 cm	20 - 30 cm	15 - 25 cm	804XXS-OL	804XXS-OR
Malinki Pink	12 cm	15 cm	20 - 30 cm	15 - 25 cm	804XXS-PL	804XXS-PR

The girths of the braces correspond to the shell sizes.

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6. Transfer

The brace is not a single-use product, but has been designed for use by one person only. We advise against passing it on to others. Should you nonetheless wish to do so, please note the cleaning and care instructions and have the brace checked for safe and reliable operation by an authorized dealer.

7. Disposal

The brace contains recyclable materials and is free from toxic or otherwise polluting agents or substances. Provided that it is not contaminated with infectious germs, it can be disposed of by normal means. In order to be certain, please consult your orthopaedics store.

Duty to report

Due to regional legal regulations, you are required to immediately report any serious incident involving the use of this medical device to the manufacturer and the responsible authorities. Please find our contact details on the back of this brochure.

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PATENTS: DE 199 33 197 / EP 0 956 837 / US 6,375,632

FURTHER PATENTS PENDING

VERSION: EN 12.2022



Medical device



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