

USER INSTRUCTIONS

CDS[®] KNEE BRACE AMPUTATION

DYNAMIC SPRING-LOADED KNEE ORTHOSIS



CDS® Knee Amputation

User Instructions

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1. Introduction

1.1. Foreword

Dynamic spring-loaded orthoses can be used to treat joint contractures caused by both neurological and orthopaedic conditions. The shortening of the tissue surrounding the joint decreases the range of motion affecting the patient's everyday life. Therefore, our CDS® concept aims to increase the range of motion without pain by applying a constant, appropriate low load prolonged stretch (LLPS).

1.2. Customer information

For your own safety please read through these User Instructions carefully and accurately before using the brace. The instructions, notes and procedures must be read and understood thoroughly in order to benefit from the correct operation and use of the device. If anything in the User Instructions is not clear, or any instructions, operating procedures or safety information is not fully understandable, please contact the appropriate specialist retailer or albrecht GmbH directly, before you use the brace. This particularly applies to the safety instructions.

1.3. Mode of operation

The CDS® Knee Brace Amputation is based on the CDS®-principle and can be used for the treatment of extension deficits in the knee joint. The dynamic stretch stimulates the healthy growth of the shortened tissue. **The adjustable redression range protects the tissue from painful overstretching and allows for individual extension until -15°.**

1.4. Application

The brace has been designed exclusively for the orthotic treatment of the knee joint.

1.5. Scope of delivery

Please check the completeness of the brace at delivery.

- Brace with padding and straps
- albrecht GmbH hexagon key
- User Instructions
- Strap padding

1.6. Declaration of conformity

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

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1.7. Features

- Therapy in extension
- Infinitely variable adjustment of the redression range between -15° bis $+30^{\circ}$
- Flexion stop possible from 0° to 60° by inserting the stop wedge
- Individual adjustment of the spring tension
- Spring tension can be switched on and off without tools and without varying the set spring tension
- High flexibility thanks to adjustable shell elements
- Large calf element for even pressure application

1.8. Indications

The physician will prescribe the type of treatment to apply based on his or her diagnostic findings.

Generally, the use is indicated in:

- Extension deficit of the knee after lower leg amputation

For all other indications a physician must be consulted.

1.9. Contraindications

- Bony obstruction, osteoporosis thrombophlebitis

The brace is intended exclusively for contact with intact skin.

1.10. Safety Instructions

The optimal effect of the brace is only achieved when used correctly.

- The brace must only be used in the intact, complete and mechanically undamaged condition and with complete and intact cushioning and walers. This must be verified by the user before each usage.
- Opening or removing one or more belts, as well as excessive loosening of the waler when using the brace leads to a reduction of the therapeutic effect of the brace and may lead to injury.
- The brace must not be worn over open wounds.
- The skin should be free of oils, grease, gels or other debris, to prevent reactions with the skin or the structure of the material.
- The orthosis should fit firmly but not too tight, so as not to restrict the blood circulation and adversely affect nerve and lymph vessels. Excessive compression is therefore to be avoided.
- Combination with other products is currently not provided for or is to be agreed with the manufacturer in writing.
- The brace is not intended for single use, but is intended for multiple use by a single person.
- The product as delivered is not sterile.
- Contact your physician immediately in the event of an allergic reaction.
- Please note that cushioned sections can heat up under direct sunlight. Protect the orthosis from direct sunlight if necessary.

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- Currently there is no test for flammability. Exercise caution when using the orthosis in the direct vicinity of open flames such as lighters and cigarettes.
- The mechanical functions must only be adjusted using the supplied tools in order to avoid injuries and damage of the hinge.
- 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.

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.

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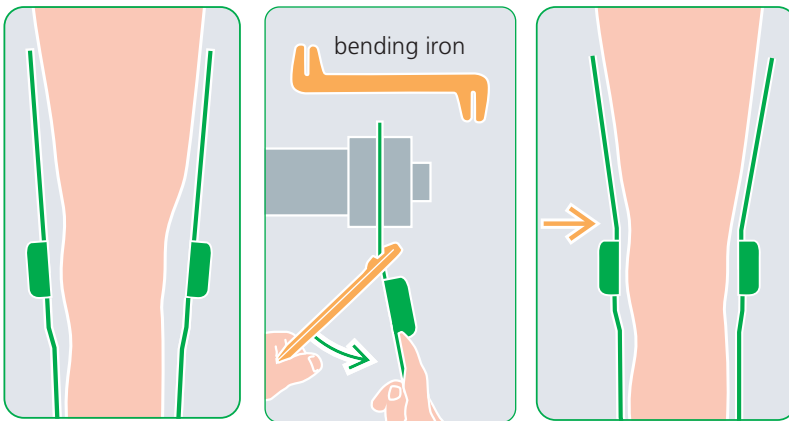
2. Adjustment by the orthopaedic technician

2.1. Fitting to the patient

- Our CDS[®] braces are constructed to be adjustable.
- The position of the shell components can be changed and they can be shaped.
- The hinge rods can be adapted to the shape of the extremity by using an orthopaedic bending iron.
- The strap lengths can be adjusted to different girths and shortened if necessary.

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

To ensure that the brace fits perfectly, the hinge rods can be adjusted to the shape of the patient’s leg with the aid of a bending iron.



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.

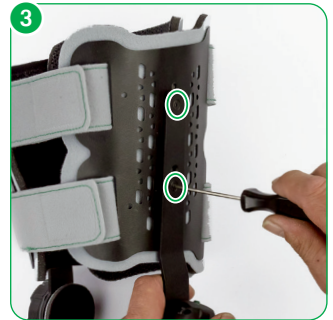
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2.1.2. Setting the shell components

The shell components are moveable.

- 1 Loosen the screws on the shell components with the supplied tool without unscrewing them completely.
- 2 Move the shell components into the desired position.
- 3 Tighten the screws again.



The shell components can be adjusted to the shape of the extremity.

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2.2. Setting the limitation

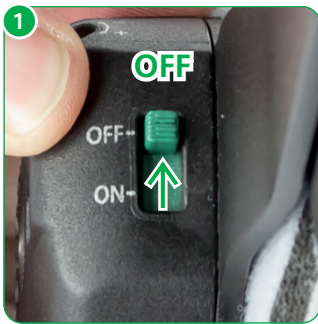
The limitation restricts the range of motion.

All steps must be executed identically with both hinges.

Extension and the redression range are limited by the stop screw. In a second step, the set value can be reduced up to a maximum of 15°, enabling infinitely variable adjustment of the redression range.

- 1 Before setting the limitation, you must deactivate the spring tension. Turn the switches on both hinges to "off".
- 2 Bring the brace into flexion.
- 3 On the side of the CDS[®] housing are three holes that are marked with the degrees 0, 15 and 30. In the hole marked with 0 is the stop screw. Then turn the stop screw with the supplied tool from the CDS[®] housing.

Before screwing it into one of the three holes, bring the brace into flexion, so that the holes are freely accessible. Position the stop screw in the desired position and tighten the screw.



The limitation can be adjusted to the treatment progress with increasing mobility of the patient.

Please be aware that the brace must only be used with the stop screw positioned and tightened in one of the holes, otherwise the hinge will be damaged.

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2.2.1. Fine adjustment

Fine adjustment gives you the option of infinitely variable extension limitation.

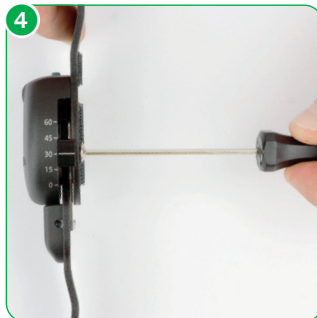
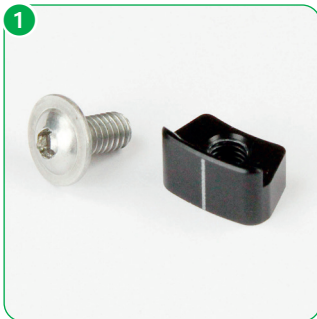
- 1 Set the fine adjustment to a value between 0 and -15. The setting reduces the limitation already set by the stop screw.
- 2 All steps must be executed identically with both hinges



User Instructions

2.2.2. Inserting the stop wedge

- 1 Flexion can be limited with the stop wedge. All steps must be executed identically with both hinges.
- 2 Before adjusting the flexion limitation you must activate the spring tension. Turn the switches on both hinges to "on". Bring the brace into flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.
- 3 On the side opposite of the three holes are five positions marked with the degrees 0, 15, 30, 45 and 60. Insert the stop wedge in the desired position.
- 4 Fix the stop wedge with the supplied screw.



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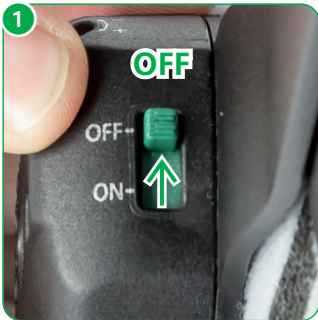
User Instructions

2.3. Attaching of the brace by the orthopaedic technician

2.3.1. Deactivate the spring tension

Before attaching the brace you must deactivate the spring tension.

- 1 Turn the switches on both hinges to “off”.
- 2 Bring the brace as far into flexion as the patient is allowed to move. Now, the activation mechanism of the hinge is set to this the position and the patient can reactivate the spring tension in this position.
- 3 To facilitate attaching of the brace on the patient, adjust the length of all brace straps to their maximum length without unthreading them. Now loosen the posterior straps on the thigh and lower leg by opening the clips.



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2.3.2. Attach the brace to the leg

The patient bends the leg to an angle of about 30° to 45°. Now attach the brace to the patient's leg from in front.

Ensure that the pivots of the brace hinges match the physiological pivots of the knee.



It is possible to adjust the thigh rods to the shape of the patient's leg by using an orthopaedic bending iron.

Ensure that the hinges are as parallel to one another as possible to ensure wear-free function of the brace.

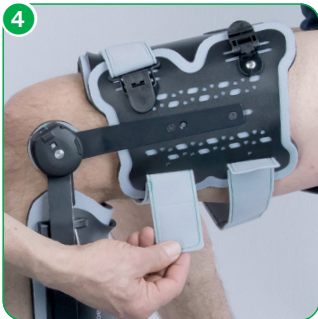
The calf element was designed without holes on purpose, in order to prevent oedemas.

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2.3.3. Attaching the additional shell to the thigh and fastening of the straps

- 1 Position the additional shell at the thigh.
- 2 Please make sure that the additional thigh shell is positioned within the lateral thigh shell.
- 3 Place the anterior distal thigh strap over the additional shell and fasten the buckles. Adjust the length of the straps to align the shells parallel to the thigh.
- 4 Then adjust the length of the posterior distal thigh strap and make sure the shells are still aligned parallel with the thigh.
- 5 Then adjust the length of the posterior proximal thigh strap and make sure the shells are still aligned parallel with the thigh.
- 6 Fasten the anterior proximal thigh strap above the hook and loop point of the additional thigh shell. Readjust the strap if necessary.



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Attach the calf shell to the patient's calf and correct the position if necessary.



2.3.4. Final adjustment

After fastening the individual straps, check that the straps are the correct length and that the brace is in the correct position, and correct if necessary.

Ensure that the straps are not too tight so as not to interfere with the circulation.

The shell elements are anatomically contoured. You can also shape the shell elements with the hand to the leg contour directly on the patient.

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2.3.5. Activate the spring tension

- 1 To activate the spring tension, turn the switches on both hinges to "on".
- 2 Bring the brace into flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.



The intensity of the spring tension is not altered by activation or deactivation of the spring tension.

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2.3.6. Setting the spring tension to the intensity needed by the patient

- 1 The spring tension setting is displayed on the CDS® housing by a scale from 0 to 15. The ranges above 15 and below 0 are marked in red.

To prevent damage to the CDS® hinge, the red range in the CDS® hinge window must be avoided.

- 2 Insert the tool as far as it will go into the side hole on the hinge. By turning clockwise or towards + the spring tension is increased and it is decreased by turning anticlockwise or towards -.



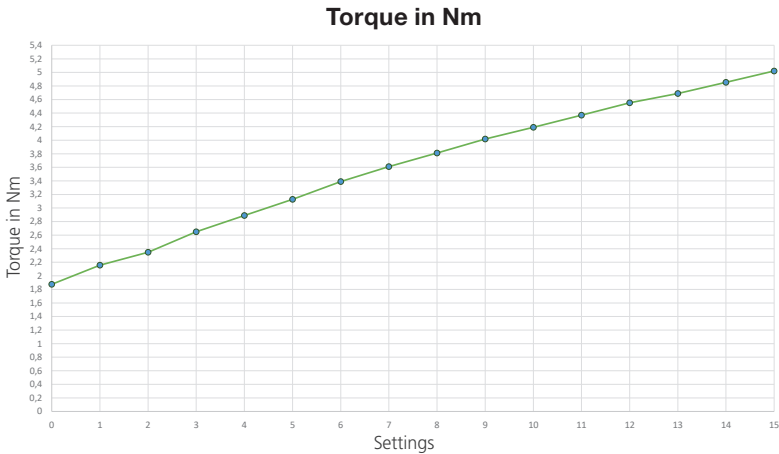
The intensity of the spring tension must be equal in both hinges.

The intensity of the spring tension is not altered by activation or deactivation of the spring tension.

The spring tension may be adjusted only in consultation with the treating physician.

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User Instructions



2.3.7. Changing the spring tension

- 1 The spring tension can be adjusted according to the treatment progress.
- 2 Insert the tool as far as it will go into the side hole on the hinge. By turning clockwise or towards + the spring tension is increased and it is decreased by turning anticlockwise or towards -.

The intensity of the spring tension must be equal in both hinges.



The spring tension may be adjusted only in consultation with the treating physician.

User Instructions

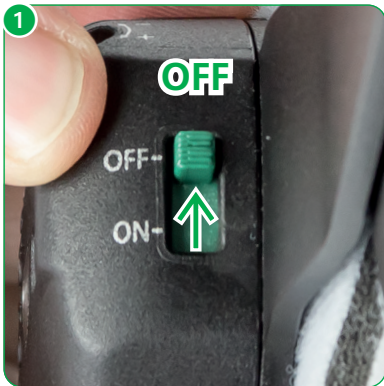
3. Handling by the patient

3.1. Removing the brace

3.1.1. Deactivate the spring tension

Before removing the brace you must deactivate the spring tension.

- 1 To do so, turn the switches on both hinges to "off".
- 2 Bring the brace into flexion.

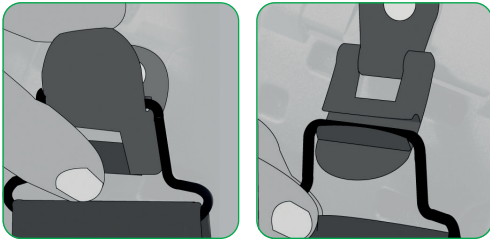


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3.1.2. Open the buckles of the straps (on upper and lower shells)

Due to the user-friendly buckle system it is not necessary to open the hook and loop fasteners when fitting and removing the brace. To fit the brace, simply undo the buckles and open the anterior straps of the brace.



- 1 Undo the distal anterior thigh strap by opening the buckle without unthreading them.
- 2 Undo the proximal anterior thigh strap by opening the buckle. Do not allow the strap to slip out.
- 3 Remove the additional thigh shell.
- 4 Remove the brace downwards. Detach the brace.

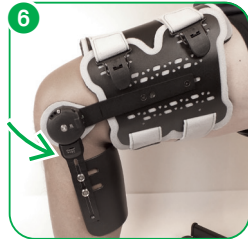


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3.2. Putting on the brace

Close the clips in the stated order.

- 1 Place the brace on your leg from behind.
- 2 Position the additional shell at the thigh.
- 3-4 Close the clips in the stated order.
- 5 To activate the spring tension, turn the green switch to "on".
- 6 Bring the brace into flexion.



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Hand wash at 30°C



Do not bleach



Do not iron



Do not dry-clean



Do not tumble dry

4. 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.

4.1. Pads and straps

- All fabrics can be washed by hand at 30°C using water and a mild detergent and/or disinfectant.
- Not machine washable.
- In the case of more severe soiling, a replacement set of textile parts is available.

4.2. Rods (hinges)

- Clean all parts of the brace with a wet cloth soaked with water and a mild detergent and/or disinfectant.
- 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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5. Technical data

Name	Material
Weight	1256g (Medium)
Padding material	PU foam with PA hook and loop velour
Strap material	PA strap with PA hook and loop velour
Brace material	Aluminium, Calf element ABS

6. Size chart and article numbers

Size	Length of thigh shell medial	Length of lower leg shell	Circumference of thigh	Circumference of stomp	Art.-No. left	Art.-No. right
L/L	23 - 25,5 cm	17 - 25 cm	36 - 66 cm	40 - 48 cm	903LL-L	903LL-R
LM/M	23 - 25,5 cm	17 - 25 cm	33 - 43 cm	33 - 40 cm	903LMM-L	903LMM-R
SS	17,5 - 20 cm	17 - 25 cm	30 - 40 cm	27 - 33 cm	903SS-L	903SS-R

7. Transfer of the brace

The brace is not intended for single use, but rather is intended for multiple use by a single person. We do not recommend transfer to other users. Should this be desired however, please ensure to pass on the care and cleaning instructions and have the brace checked by an authorized specialist dealer for safe and proper operation.

8. Disposal

The brace contains recyclable materials without toxic or other harmful substances or other environmentally hazardous substances. Provided it is not contaminated with infectious germs, the brace can be deposited in the normal waste disposal. To be sure, consult your specialist orthopaedics dealer.

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.

PATENTS: EP 0 841 044 / US 5,954,677 / EP 3352713

FURTHER PATENTS PENDING

VERSION: EN 01.2023



Medical device



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