

USER INSTRUCTIONS

CDS® ANKLE BRACE NEURO

DYNAMIC SPRING-LOADED ANKLE ORTHOSIS



albrecht®
FUNKTIONELLE REHABILITATION

CDS® Ankle Brace Neuro

User Instructions

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User Instructions

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® Ankle Brace Neuro functions according to the CDS®-principle and has been designed to treat an extension deficit of the ankle. The brace applies a dynamic low load prolonged stretch to stimulate growth in the contracted tissue. **The adjustable redression range protects the tissue from painful overstretching.**

1.4. Application

The brace has been designed exclusively for the orthotic treatment of the ankle 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 and vacuum foot rest
- albrecht GmbH hexagon key
- User Instructions
- Vacuum pump

1.6. Declaration of conformity

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

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1.7. Features

- Therapy in dorsalextension
- **Small hinge with proven features:**
 - Individual adjustment of the spring tension
 - Spring tension can be switched on and off without tools and without varying the set spring tension
 - Infinitely variable adjustment of the redression range in dorsalextension
- **All-over and secure fixation by vacuum grip**
 - Individually adjustable inlay
 - Adjustable pronation and supination
 - Adjustable rotation
 - Including vacuum pump
- **Optimized paddingsystem**
 - Easy attachment thanks to flexible pads
 - Optionally attachable hinge covers

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:

- Joint contractures:
 - After strokes
 - After spinal cord injuries
 - Paralysis (discrete palsy of peripheral origin)
 - After cranio-cerebral trauma (CCT)

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.

- 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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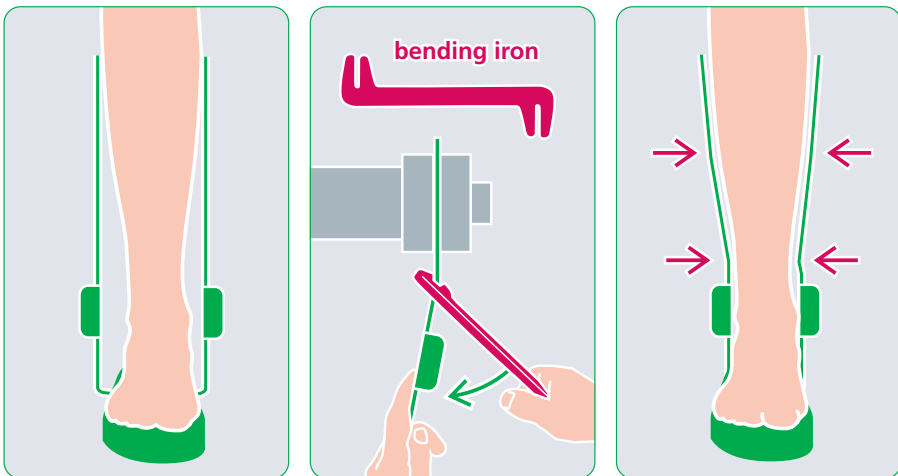
2. Adjustment by the orthopaedic technician

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.



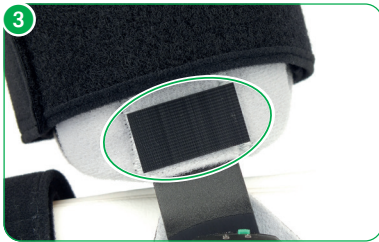
When adjusting the hinge rods to the shape of the extremity by using an orthopaedic bending iron, you must not bend the rods in the area of the hinge housing or the hinge cover as this could lead to damage or break of the hinge.

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2.1.2. Optional installation of the brace covers

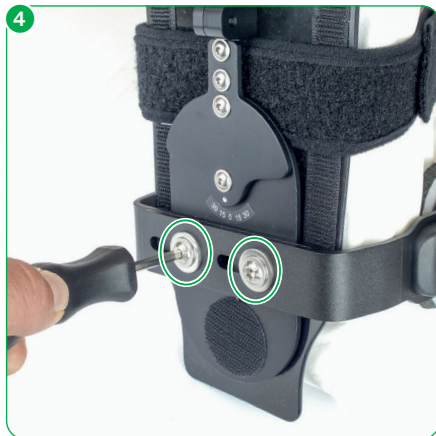
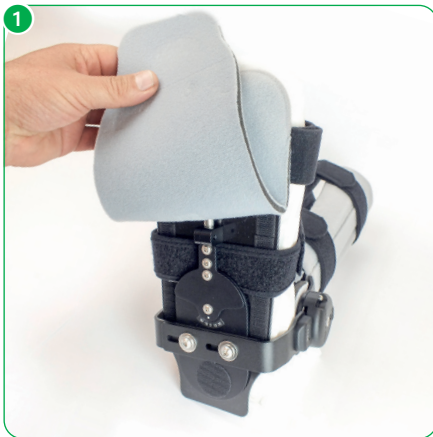
- 1 Stick the big adhesive coin onto the hinge rod underneath the fine adjustment.
- 2 Stick the three small adhesive coins onto the hinge.
- 3 Hook-and-loop fasten the gripper to the calf pad.
- 4 Pull the cut out pad over the hinge and hook-and-loop fasten it to the hinge rod.
- 5 Position the second pad on the hinge and hook-and-loop fasten it to the gripper.



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2.1.3. Adjusting the distance between the hinge rods

- 1 You can change the distance of the hinge rods from the lateral edge of the sole.
- 2 To do so, loosen the screws in the sole plate.
- 3 Move the hinge rods singly.
- 4 When the optimal position of both rods has been found, fix the footbar again.



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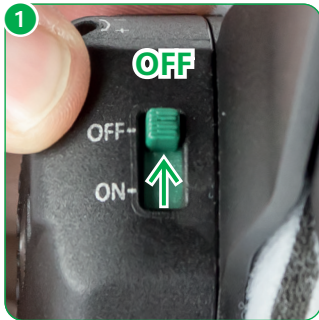
2.2. Adjusting the brace

2.2.1. Setting the limitation

Before setting the limitation, you must deactivate the spring tension.

- 1 Turn the switch to "off".
- 2 Bring the brace into plantar extension.
- 3 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 maximum plantar extension. This prevents the stop screw from making contact with the mobile hinge rod when it is tightened, which could damage the CDS® housing.



The limitation should be adjusted to treatment progress with increasing motility.

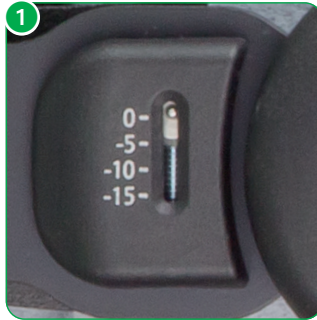
User Instructions

2.2.2. Fine adjustment

Fine adjustment gives you the option of infinitely variable limitation (stop).

Ensure that the spring tension is deactivated.

- 1 Set the flexion stop according to the scale (0-15). The setting reduces the already set limitation.



CDS® Ankle Brace Neuro

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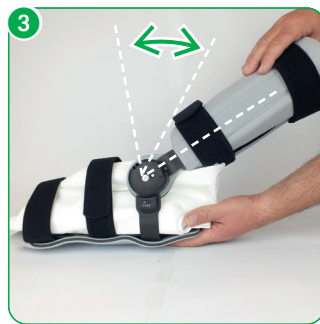
2.2.3. Changing the working range of the CDS® Ankle Brace in extreme dorsiflexion

In neurological patients it may be necessary to bring the working range of the CDS® Ankle Brace Neuro further into dorsiflexion than the factory setting.

This adjustment is made possible by rotating the hinge capsule relative to the lower leg hinge rod. To do this, there are two screws on the inside of the hinge capsule. By removing these screws, you can adjust the hinge capsule to the required working range in 15° steps.

- 1 Remove the pad.
- 2 Remove the screws with the supplied tool.
- 3 Set the required angle.
- 4 Insert the screws again and tighten them.
- 5 Insert the pad.

The setting must be the same for both hinges.



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2.3. Attaching of the brace by the orthopaedic technician

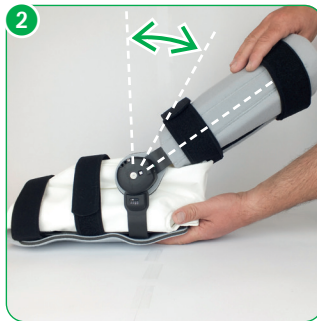
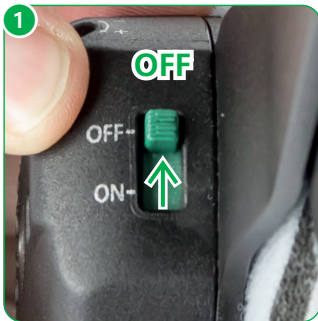
2.3.1. Deactivate the spring tension

Before attaching the brace you must deactivate the spring tension.

- ❶ Turn the green switch to "off".
- ❷ Bring the brace into plantar extension.

❸ Open the strap fasteners

To make it easier to apply the brace to the patient, adjust the length of the lower leg straps to their maximum length without unthreading them. Open the instep and toe strap.

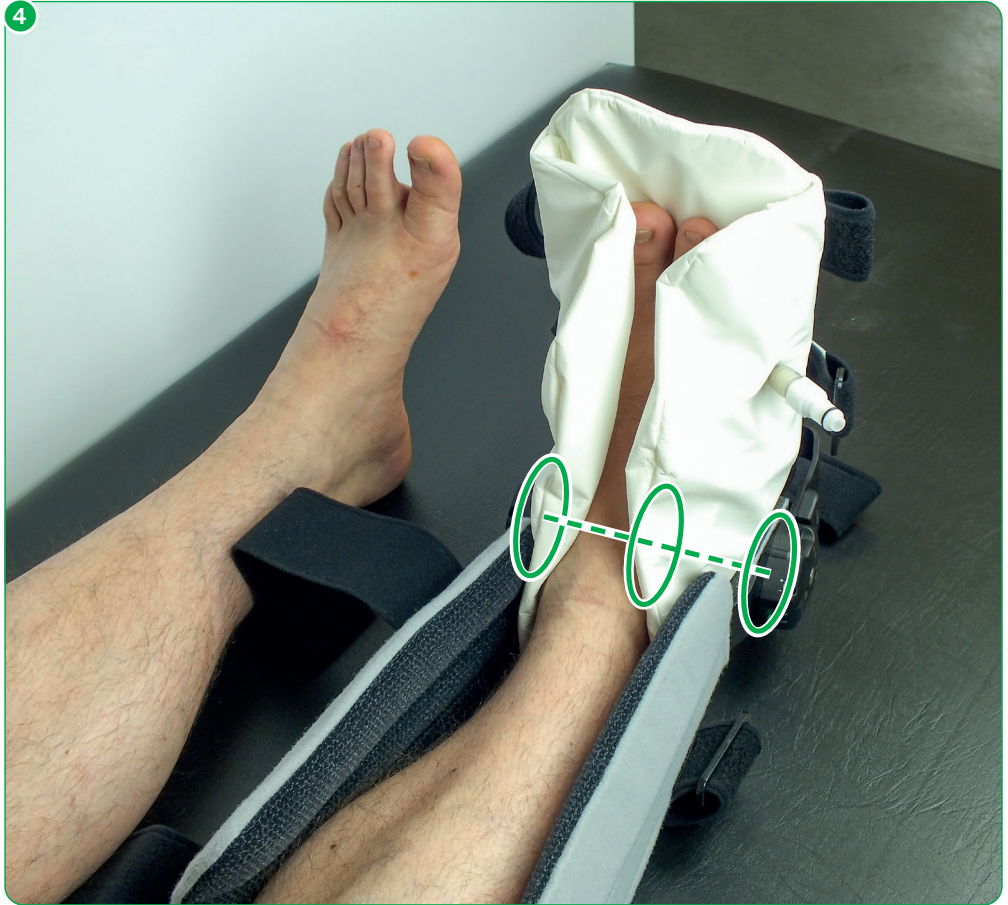


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4 Attaching the brace

Ensure that the pivot of the brace hinges matches the physiological pivot of the ankle. It is possible to adjust the thigh rods to the shape of the patient's leg by using a bending iron. Ensure that the hinges are as parallel to one another as possible to ensure wear-free function of the brace.

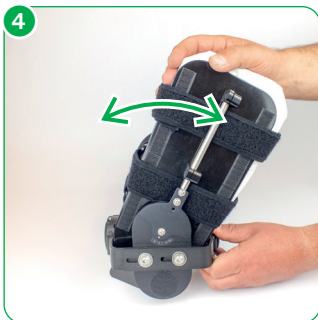
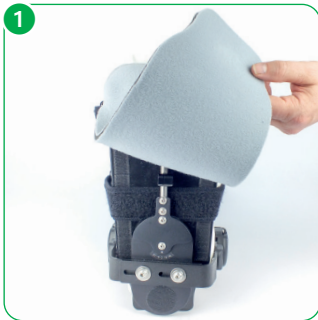


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2.3.2. Setting rotation on the foot part

The foot piece is preset to 0°. However, it is possible for you to set the angle of rotation to 15° or 30°.

- ❶ Remove the pad beneath the sole.
- ❷ Loosen the fixing screw with the supplied tool.
- ❸ Unscrew the adjusting screw.
- ❹ Position the foot piece at the number of degrees required by the patient.
- ❺ Insert the adjusting screw again and tighten it.
- ❻ Tighten the fixing screw.

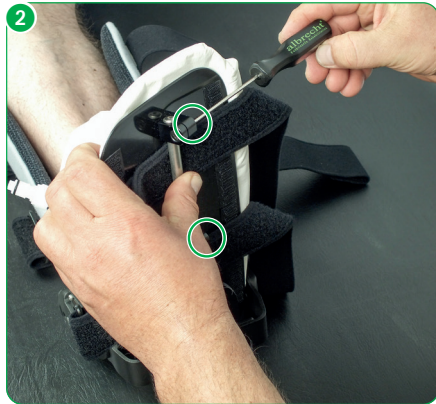
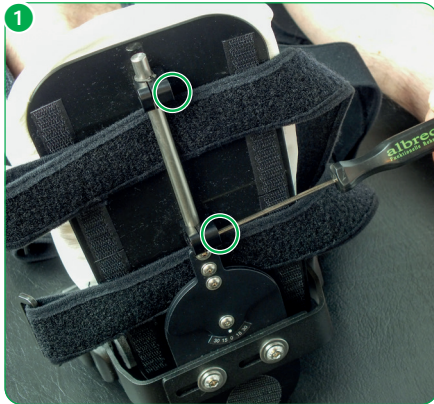


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2.3.3. Setting pronation or supination on the foot part

- 1 Loosen the screws of the two terminal blocks with the supplied tool.
- 2 Turn the sole part into the desired pronation or supination and tighten the two screws again.
- 3 Insert the pad again.



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2.3.4. Adjusting the vacuum foot rest

Adjust the straps to the desired length and shorten them as needed.

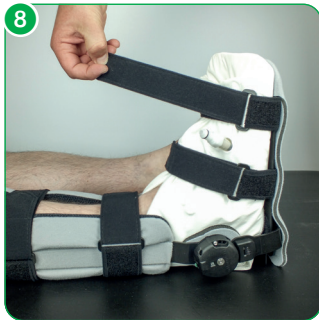
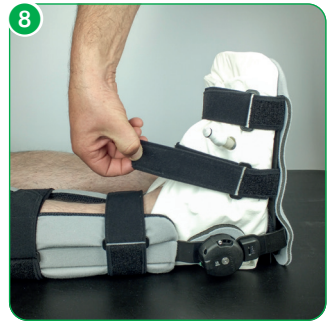
- ❶ Open the two foot straps.
- ❷ Place the brace on the patient's leg.
- ❸ Close the two lower leg straps.
- ❹ Close the two foot straps.
- ❺ Attach the valve of the vacuum pump to the vacuum pad valve connector without pressing the grey release button. Please note: the two valves must lock audibly.



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- 6 Aspirate all the air from the vacuum pad with the vacuum pump. Please note: the air is fully aspirated when you feel obvious resistance when pumping.
- 7 Detach the valve of the vacuum pump from the vacuum pad valve connector of the by pressing the grey release button.
- 8 Open the foot straps again to retighten them and close them again.
- 9 Brace in place.



User Instructions

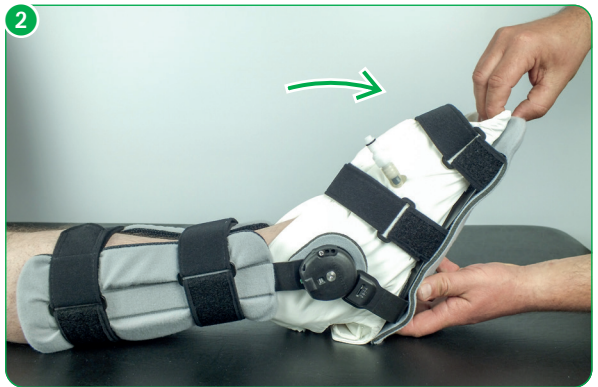
2.3.5. Final adjustment

After fastening the individual straps, check that the straps are the correct length and that the brace is in correct position, and correct if necessary. Ensure that the straps are not too tight so as not to interfere with the circulation.

2.3.6. Activate the spring tension

- ❶ To activate the spring tension, turn the green switch to "on".
- ❷ Bring the brace into plantar extension.

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



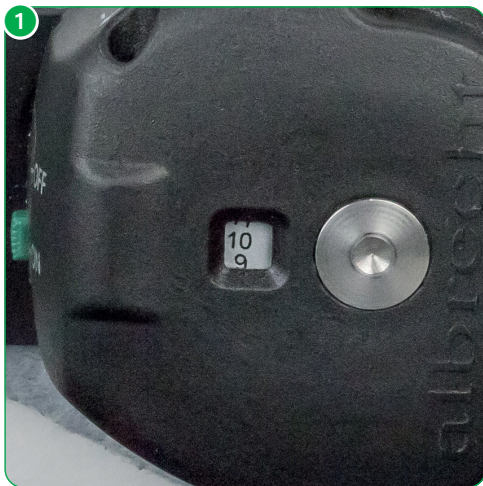
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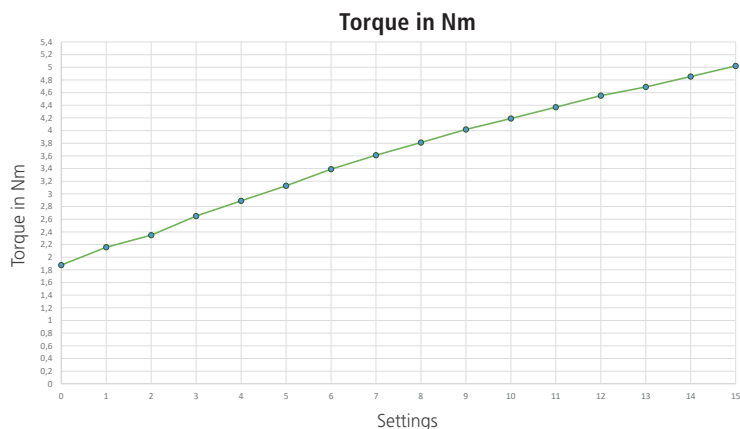
2.3.7. Setting the spring tension to the intensity needed by the patient

- 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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2.3.8. Changing the spring tension

The spring tension can be adjusted according to the treatment progress. 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 spring tension may be adjusted only in consultation with the treating physician.

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



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2.3.9. Removing the brace

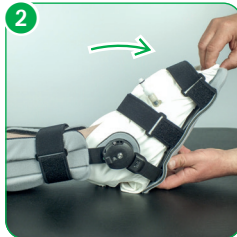
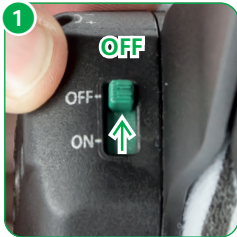
1 Deactivate the spring tension

Before removing the brace you must deactivate the spring tension. To do so, turn the green switch to "off".

2 Bring the brace into plantar extension.

3 To remove the brace, only open the clips and straps.

4 To release the vacuum, press the small ring on the vacuum pad valve connector for a few seconds. The vacuum pad refills with air and is now ready for use again.



User Instructions



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 CDS[®] Ankle Brace Neuro 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
Weight	1250
Padding material	PU foam with PA hook and loop velourm partially silicone coated
Strap material	PA strap with PA hook and loop velour
Brace Material	aluminium
Vacuum pad	PU foil
Coating Vacuum Pad	Cotton terry with PU coating

5. Size chart and article numbers

Name	Length of thigh shell	Circumference of the calf	EU-Shoe Sizes	Sole Length	Art.-No. right
Ankle Brace Neuro L/L	36 - 38,5 cm	32 - 47 cm	44 - 47	32 cm	922LL
Ankle Brace Neuro L/M	36 - 38,5 cm	32 - 47 cm	37 - 43	28,5 cm	922LM

6. 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.

7. 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.

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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: EP 0 841 044 / US 5,954,67 / EP 3352713

FURTHER PATENTS PENDING

VERSION: EN 01.2023



Medical device



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