USER INSTRUCTIONS

## COMBINATION BRACE CDS<sup>®</sup> KNEE / ANKLE

DYNAMIC SPRING-LOADED KNEE / ANKLE ORTHOSIS





## Combination Brace CDS<sup>®</sup> Knee / Ankle

### **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<sup>®</sup> 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 Combination Brace CDS® Knee / Ankle functions according to the CDS®-principle and has been designed to treat an extension deficit of the knee and a dorsalflexion 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 and allows for individual extension until -15°.

#### 1.4. Application

The brace has been designed exclusively for the orthotic treatment of the knee hinge / ankle hinge.

#### 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 set

#### **1.6. Declaration of conformity**

The albrecht GmbH company as manufacturer with sole responsibility declares the conformity of the Combination Brace CDS® Knee / Ankle with European Council Directive 93/42/EEC for medical devices.



## 1.7. Features

- Fast disconnection and reconnection of the elements by Coniungi
- Variable length between pivotal points
- Therapy in extension (knee brace)
- Therapy in dorsalextension (ankle brace)
- Individual adjustment of the spring tension
- Spring tension can be switched on and off without tools and without varying the set spring tension
- Optimized shell- and strapsystem
- High wearing comfort thanks to airpermeable, light aluminium shell elements
- Infinitely variable adjustment of the redression range between -15° and +30°

#### **1.8. Indications**

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

In general, the device is used to treat combined impairments on the knee and ankle:

- Joint contractures:
  - After surgery
  - After conservative treatment of capsular ligament injuries
  - Before and after joint replacement
  - In arthrosis and chronic polyarthritis
  - After burns
  - After strokes
  - After spinal cord injuries
  - Paralysis (discrete palsy of peripheral origin)
  - After cranio-cerebral trauma (CCT)
- To prevent new contractures after arthrolysis
- Rupture of a muscle fibre of quadriceps femoris
- Patella tendon rupture
- Extension deficit from weakness of quadriceps
- Conservative and postoperative indications, where active extension of the knee is contraindicated.

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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#### **User Instructions**

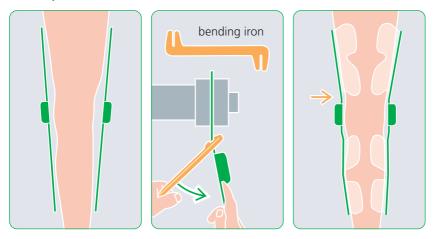
## () 2. Adjustment by the orthopaedic technician

### 2.1. Fitting to the patient

- Our CDS<sup>®</sup> 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"

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.



### 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 completly.
- **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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#### **User Instructions**

#### 2.1.3. Length adjustment between knee and ankle

The Combination Brace CDS<sup>®</sup> Knee / Ankle can be adjusted in lenght to ensure the pivotal points of the brace are optimally aligned with the hinges.

- 1 Loosen the screws of the forearm support without fully removing them.
- 2 Move the support to the distance you need.
- **3** Tighten the two clamping screws again.







If necessary, you can change the mounting position of the support.

- 1 Remove both lower arm support screws.
- 2 Position the screws in a different position in the hole grid and tighten them.



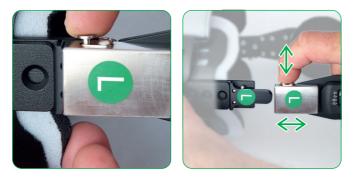


Please be aware, all steps must be executed identically on both sides.



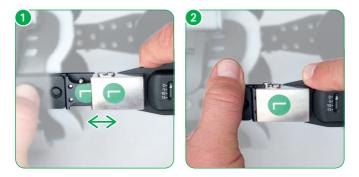
## 2.1.4. Disconnect Coniungi

Push the twistlock and pull the elements apart.



### 2.1.5. Reconnect Coniungi

- 1 Ensure that the green marking points are correctly aligned.
- **2** The rods can be adjusted to ensure the correct distance between the pivotal points.



Please deactivate the spring force if you want to take individual parts away from the orthosis or add parts to it (see 2.3.1.).



#### **User Instructions**

### 2.1.6. Adjusting the distance between the hinge rods

You can change the distance of the hinge rods from the lateral edge of the sole.

- 1 To do so, loosen the screws in the sole plate.
- 2 Move the hinge rods singly.
- 3 When the optimal position of both rods has been found, tighten the screws again.



The foot piece of the paediatric brace is constructed in a manner to enable adjustment by the orthopaedic technican. The footbed has to be prepared individually by the orthopaedic technican in order to guarantee an optimal fit.

### 2.2. Adjust the hinge

# 2.2.1. Adjusting the position of the redression and limitation range

The Combination Brace CDS<sup>®</sup> Knee / Ankle is constructed on the basis of a 360° hinge. In a 360° hinge, the spring housing and the lower leg rod can be pivoted against each other. The position of the redression and limitation range can be thereby altered and adjusted to the patient.

In neurological patients it may be necessary to bring the redression range of the Combination Brace CDS<sup>®</sup> Knee / Ankle further into plantar flexion than the factory setting. The position of the stops depends on the position of the redression and limitation range.



- 1 Remove the pad.
- 2 Remove the two screws.
- 3 You can adjust the position of the redression range in 15° steps. Use a goniometer to determine the desired position and adjust the hinge accordingly.
- **4** Insert the screws again and tighten them.
- **5** Insert the pad again.

The setting must be the same for both hinges.





#### **User Instructions**

## 2.2.2. Setting the limitation for the ankle hinge

The limitation restricts the range of motion. All steps must be executed identically with both hinges.

Dorsal 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.

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

- 1 Turn the green switches on both hinges to "off".
- **2** Bring the brace into plantar flexion.
- 3 There are three holes on the side of the CDS<sup>®</sup> housing. The number of degrees depends on the position of the redression and limitation range and can be determined with a goniometer. The stop screw is located in one of the holes.

Then turn the stop screw with the supplied tool from the CDS<sup>®</sup> housing.



Before screwing it into one of the three holes, bring the brace into plantar 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.



## 2.2.3. Setting the limitation for the knee hinge

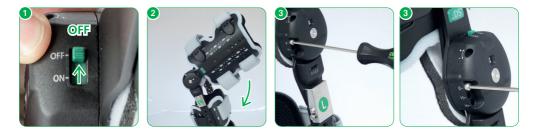
The limitation restricts the range of motion.

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 infinitly variable adjustment of the redression range.

- Before setting the limitation, you must deactivate the spring tension. Turn the switches on both hinges to "off".
- **2** Bring the brace into flexion.
- On the side of the CDS<sup>®</sup> 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<sup>®</sup> 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 tightend in one of the holes, otherwise the hinge will be damaged.



#### **User Instructions**

### 2.2.4. Fine adjustment for the knee hinge / ankle hinge

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.

All steps must be executed identically with both hinges.





### 2.2.5. Inserting the stop wedge for the knee hinge

- 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".
- **3** Bring the brace into flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.
- 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 and fix the stop wedge with the supplied screw.







#### **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 / plantar 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.

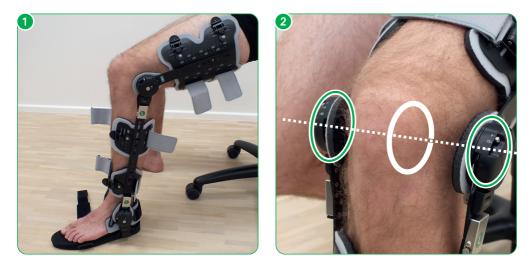
To facilitate attaching of the brace on the patient, adjust the length of all brace straps to their maximum length without unthreading them. Now loosen the posterior straps on the thigh and lower leg by opening the clips.





### 2.3.2. Attach the brace to the leg

- 1 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.
- 2 Ensure that the pivots of the brace hinges match the physiological pivots of the knee / ankle.



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 proper function of the brace.



#### **User Instructions**

#### 2.3.3. Adjust strap lengths as necessary

Adjust the straps to the desired length and shorten them if necessary on the strap end containing the doublesided hook end.

- First fasten the heel strap. This prevents the foot from slipping dorsally. Adjust the length of the strap so that it sits snugly on the heel.
- 2 First fasten the upper calf strap.
- **3** Then fasten the upper shin strap.
- Fasten the upper posterior thigh strap next to the knee.

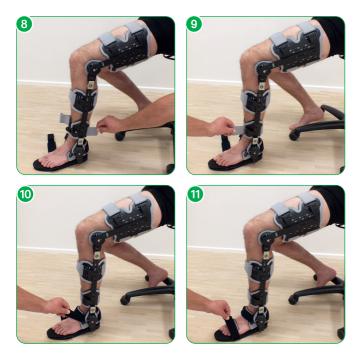


- **5** Fasten the anterior thigh strap further from the knee.
- 6 Fasten the posterior thigh strap next to the knee.
- **7** Fasten the anterior thigh strap next to the knee.





- 8 Fasten the lower calf strap.
- 9 Fasten the lower shin strap.
- 1 Fasten the instep strap.
- 1 Fasten the toe strap.



If necesssary, the additional strap padding supplied with the product can be attached under the straps.



#### **User Instructions**

### 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.

### 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 / plantar flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.

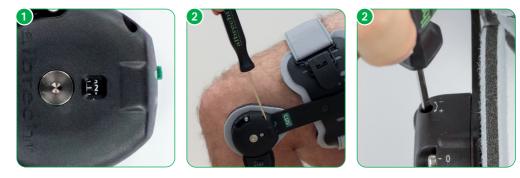


The intensity of the spring tension is not altered by activation or deactivation of the spring tension.



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

- The spring tension setting is displayed on the CDS<sup>®</sup> 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<sup>®</sup> hinge, the red range in the CDS<sup>®</sup> hinge window must be avoided.
- 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 -.



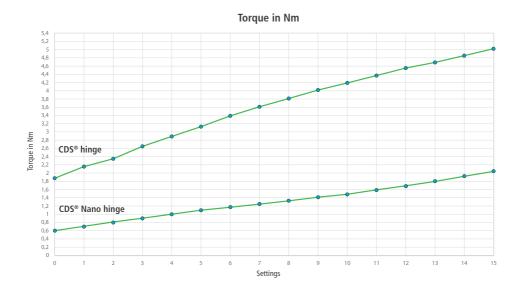
The intensity of the spring tension must be equal in both hinges.

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.



#### **User Instructions**





## 2.3.7. Changing the spring tension

- **1** 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 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**



### 3.1. Removing the brace

#### 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 / plantar flexion.





- 1 To remove the brace, only open the clips and do not unthread the straps.
- **2** Loosen the toe strap.
- **3** Loosen the instep strap.
- **4** Take off the brace.











#### **User Instructions**



#### Hand wash at 30°C





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.



## 🖉 5. Technical data / material

Name	Material
Weight	2275 g
Padding material	PU foam with PA hook and loop velour
Strap material	PA strap with PA hook and loop velour
Brace material	aluminium

## $\langle \! angle$ 6. Size chart and article numbers

Name	ArtNo. left	ArtNo. right
Combination Brace CDS® Knee / Ankle	980C-L	980C-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.



## Combination Brace CDS<sup>®</sup> Knee / Ankle

**User Instructions** 





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#### albrecht GmbH

CHIEMSEESTRASSE 81 D-83233 BERNAU AM CHIEMSEE / GERMANY PHONE +49 (0)8051 96129-0 FAX +49 (0)8051 96129-30

INFO@ALBRECHTGMBH.COM WWW.ALBRECHTGMBH.COM





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www.tuv.com ID 0000046096