

USER INSTRUCTIONS

CDS® ELLBOW BRACE DUO

DYNAMIC SPRING-LOADED ELBOW ORTHOSIS



CDS® Elbow Brace Duo

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® Elbow Brace Duo functions according to the CDS®-principle and has been designed for the simultaneous treatment of extension and flexion deficits of the elbow. The brace applies a dynamic low load prolonged stretch to stimulate growth in the contracted tissue. The adjustable redression range protects the tissue from overstretching and allows for individual terminal extension until -10° .

1.4. Application

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

1.5. Scope of delivery

The CDS® Elbow Brace Duo is delivered to you ready to use in the size requested, with User Instructions and labeling on the product.

Please check the completeness of the brace at delivery.

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

1.6. Declaration of conformity

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

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1.7. Features

- Therapy in extension and flexion
- Spring tension can be adjusted individually and tool-free
- Stops can be set in flexion and extension
- Extension stop adjustable to up to -10°
- Immobilization function between -10° and $+150^{\circ}$
- Shell and strap system can be adjusted individually
- Switchover point can be set between $+46^{\circ}$ and $+92^{\circ}$
- Ease of handling and highly comfortable to wear

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 surgery
 - After conservative treatment of capsular ligament injuries
 - In arthrosis and chronic polyarthritis
 - After burns
 - After strokes
 - After spinal cord injuries
 - After cranio-cerebral trauma (CCT)
- To prevent new contractures after arthrolysis
- Treatment after biceps tendon rupture

For all other indications a physician must be consulted.

1.9. Contra-indications

- Bony obstruction, osteoporosis
thrombophlebitis

The brace is intended exclusively for contact with intact skin.

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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

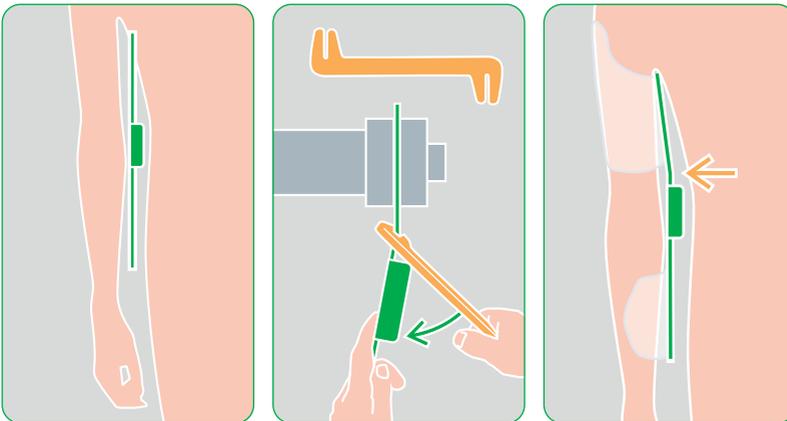
2. Adjustment by the orthopaedic technician

2.1. Fitting to the patient

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

2.1.1. Adjusting the brace to the arm 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 arm 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 Detach the pad.
- 2 Loosen the screws on the shell components with the supplied tool without unscrewing them completely.
- 3 Move the shell components into the desired position.
- 4 Tighten the screws again.
- 5 Attach the pad again.



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

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2.2. Setting the limitation

2.2.1. Setting the flexion stop

Bring the brace into extension. Turn the outer ring of the casing from "STOP" through flexion as far as the stop. You can now set the flexion stop to the desired number of degrees.

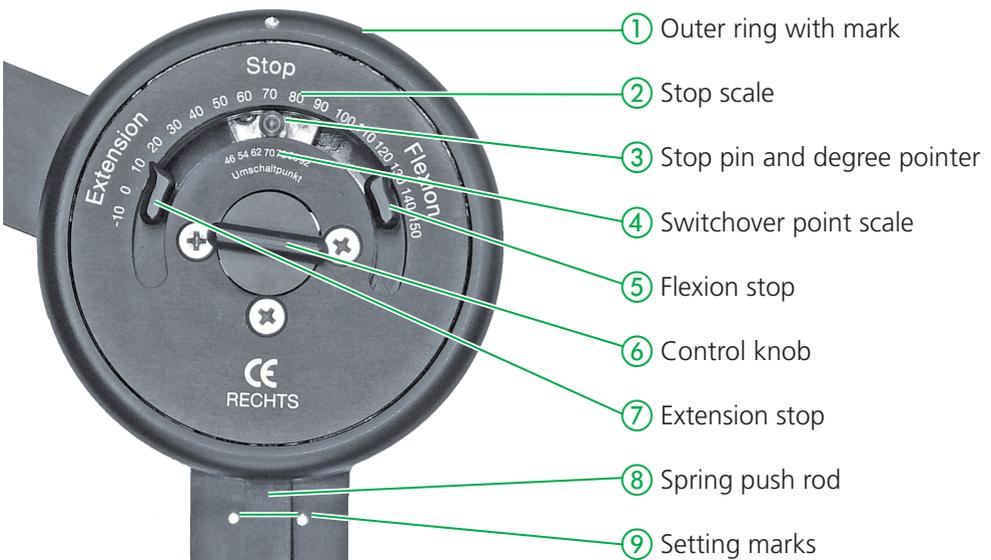
Then turn the outer ring back until the marker hole clicks into place at STOP.

2.2.2. Setting the extension stop

Bring the brace into flexion. Turn the outer ring of the casing from "STOP" through "extension" as far as the stop. You can now set the extension stop to the desired number of degrees.

Then turn the outer ring back until the marker hole clicks into place at STOP.

The extension and flexion stops should be adjusted to the progress of treatment as the patient's mobility increases.



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2.2.3. Setting the switchover point between flexion and extension

By moving the brace from flexion to extension and vice versa, the thrust of the spring changes at one point. This point is called the switchover point. You can set the switchover point in seven steps between 46° and 92°.

To set this point, you should tense the spring slightly. To adjust the switchover point, align the spring push rod exactly between the two setting marks on the joint rod. Swivel the brace accordingly.

The knob can now be pushed in. Turn the knob clockwise in this position until the stop. The stop pointer shows the number of degrees for the switchover point on the inner scale.

After you have set the desired number of degrees, turn the knob anticlockwise until it springs back.

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2.3. Assembling and adjusting the adjustable handle

- 1 Remove the pad.
- 2 Loosen the fixing screws and unscrew them.
- 3 Now place the handle's assembly rod between the hinge rod and forearm shell. After aligning the components, insert the longer fixing screws provided into the threaded holes in the hinge rod.
You can adjust the angle of the handle infinitely from 70° pronation to 70° supination by loosening the knurled screw and fix it in the desired position.
- 4 Insert the fixing screws again and tighten them.
- 5 Insert the pads again.



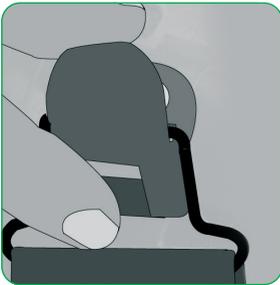
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2.4. Application of the brace by the orthopaedic technician

2.4.1. Attaching the brace to the arm

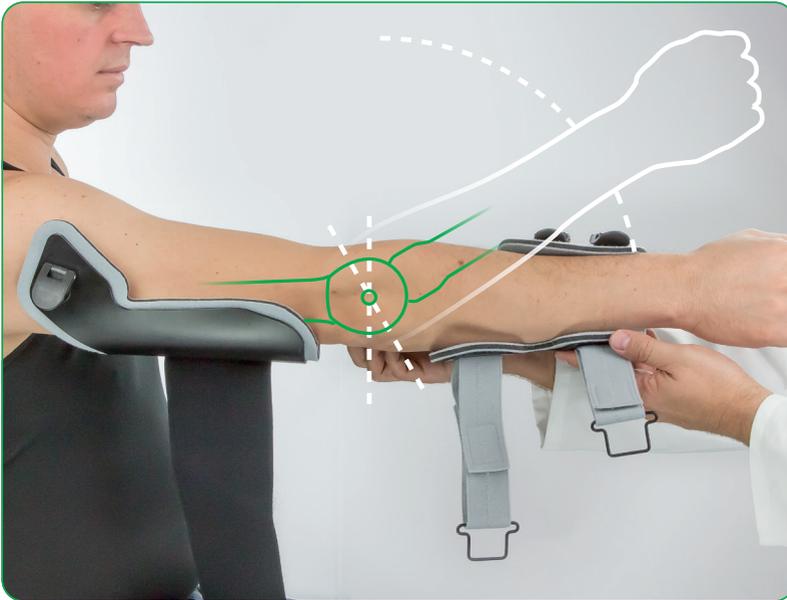
Now open the straps by opening the clips. To facilitate attaching of the brace on the patients, adjust the length of all brace straps to their maximum length without unthreading them.



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2.4.2. Attaching the brace to the elbow

Place the brace on the patient's arm from below. Ensure that the pivot of the brace hinge matches the physiological pivot of the elbow. Adjust strap lengths as necessary.



It is possible for you to adjust the arm rods to the shape of the patient's arm by using a bending iron.

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2.4.3. Adjust strap lengths as necessary

Adjust the straps to the desired lengths and shorten them if necessary.

- 1 First fasten the narrow upper arm strap to secure it.
- 2 Fasten the forearm strap next to the joint.
- 3 Fasten the forearm strap further from the joint.
- 4 Fasten the wide upper arm strap.



2.4.4. 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.

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

You can set the spring tension by the hinged crank on the forearm of the brace. After flipping up the crank, you can increase the spring tension by turning it clockwise. Then close the crank again.

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



2.4.6. Changing the spring tension

The spring tension can be adjusted to treatment progress. After flipping up the crank, you can increase the spring tension by turning it clockwise and reduce it by turning it anticlockwise.

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

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3. Handling by the patient

3.1. Removing the brace

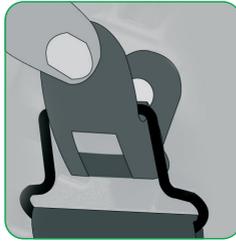
- 1 To remove the brace, first open the wide, elastic upper arm strap.
- 2 Then open the remaining straps by opening the clips and do not unthread the straps.
Take off the brace.



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3.2. Putting on the brace

- 1 Place the brace on your arm from below.
- 2 First fasten the narrow upper arm strap to secure it.
- 3 Fasten the forearm strap next to the joint.
- 4 Fasten the forearm strap further from the joint.
- 5 Fasten the wide, elastic upper arm strap.



We wish you a successful course of treatment and are available for further questions.

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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. 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® Elbow Brace Duo 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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5. Technical data

Name	Material
Weight	857g / 1058g / 1081g
Padding material	PU foam with PA hook and loop velour
Strap material	PA strap with PA hook and loop velour
Handle	latex-free foam material
Brace material	aluminium

6. Size chart and article numbers

Name	Length of upper arm shell	Length of forearm shell	Circumference upper arm shell	Circumference forearm shell	Art.-No. left	Art.-No. right
Ellbogen DUO L/L	18 - 22 cm	23 cm	28 - 39 cm	22 - 30 cm	905LL-L	905LL-R
Ellbogen DUO L/L with handle	18 - 22 cm	23 cm	28 - 39 cm	22 - 30 cm	9051LL-L	9051LL-R
Ellbogen DUO M/M	18 - 21,5 cm	23 cm	20 - 30 cm	18 - 24 cm	905MM-L	905MM-R
Ellbogen DUO M/M with handle	18 - 21,5 cm	23 cm	20 - 30 cm	18 - 24 cm	9051MM-L	9051MM-R

Name	Art.-No. left	Art.-No. right
Adjustable handle	993A-HL	993A-HR
Adjustable hand rest L	994L-HL	994L-HR
Adjustable hand rest M	994M-HL	994M-HR
Adjustable hand rest S	994S-HL	994S-HR
Strap L	580-200-S	

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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.

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FURTHER PATENTS PENDING

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Medical device



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