CDS® ELBOW BRACE EXTENSION

ELBOW ORTHOSIS

DYNAMIC SPRING-LOADED ELBOW ORTHOSIS





User Instructions

Contents

. Introduction	4
1.1. Foreword	4
1.2. Customer information	4
1.3. Mode of operation	4
1.4. Application	4
1.5. Scope of delivery	4
1.6. Declaration of conformity	4
1.7. Features	5
1.8. Indications	5
1.9. Contraindications	5
1.10. Safety Instructions	6
1.11. Warranty	7
2. Adjustment by the orthopaedic technician	8
2.1. Fitting to the patient	8
2.1.1. Adjusting the brace to the arm shape by using an orthopaedic "bending iron"	8
2.1.2. Setting the shell components	9
2.1.3. Assembling and adjusting the adjustable handle for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior	10
2.2. Setting of the hinge	.11
2.2.1. Adjusting the position of the redression and limitation range for CDS® Elbow Braces Extension XS/XS and Bambini	. 11
2.2.2. Setting the limitation for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior	12
2.2.3. Fine adjustment for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior	13
2.2.4. Inserting the stop wedge for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior	14



2.3. Application of the brace by the orthopaedic technician	15
2.3.1. Deactivate the spring tension	15
2.3.2. Attaching the brace to the elbow	16
2.3.3. Adjust strap lengths as necessary	17
2.3.4. Final adjustment	17
2.3.5. Activate the spring tension	18
2.3.6. Setting the spring tension to the intensity needed by the patient	19
2.3.7. Changing the spring tension	20
3. Handling by the patient	21
3.1. Removing the brace	21
3.2. Putting on the brace	22
4. Cleaning, maintenance and disinfection	23
4.1. Care	23
5. Technical data	24
6. Size chart and article numbers	24
7. Transfer of the brace	25
8. Disposal	25

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® Elbow Brace Extension functions according to the CDS®-principle and has been designed to treat an extension deficit 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 extension until -15.

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 Extension 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
- Strap padding set

1.6. Declaration of conformity

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



1.7. Features

- Therapy in extension
- 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
- High flexibility thanks to adjustable shell elements

CDS® Elbow Brace Extension L/L, M/M, S/S and Junior:

 Infinitely variable adjustment of the redression range between -15° and +30°

CDS® Elbow Brace Extension XS/XS and Bambini:

 Adjustment of the redression range in 10° steps

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
 - Before and after joint replacement
 - In arthrosis and chronic polyarthritis
 - After hurns
 - After strokes
 - 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. Contraindications

 Bony obstruction, osteoporosis thrombophlebitis

The brace is intended exclusively for contact with intact skin.

User Instructions

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 extermity 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.

User Instructions

2. Adjustment by the orthopaedic technician

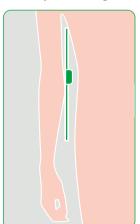
2.1. Fitting to the patient

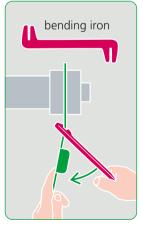
- Our CDS® braces are constructed to be adjustable.
- The position of the shell components can be changed and they can be shaped.
- The hinge rods can be adapted to the shape of the extremity by using an orthopaedic bending iron.
- The strap lengths can be adjusted to different girths and shortened if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

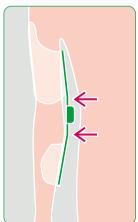
2.1.1. Adjusting the brace to the arm shape by using an orthopaedic "bending iron"

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 arm 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 extermity 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.

User Instructions

2.1.3. Assembling and adjusting the adjustable handle for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior

- 1 You can separate the forearm shell from the hinge rod by loosening the two fixing screws.
- 2 Now place the handle's assembly rod between the hinge rod and forearm shell
- **3** After aligning the components, insert the longer fixing screws supplied with the handle into the threaded holes in the hinge rod.
 - To adjust the length of the handle to the length of the arm, loosen the screws by one turn each. Adjust the handle and tighten the screws again.
- 4 By loosening the knurled screw, you can adjust the angle of the handle infinitely from 70° pronation to 70° supination. Fix it in the desired position and tighten the knurled screw again.















2.2. Setting of the hinge

2.2.1. Adjusting the position of the redression and limitation range for CDS® Elbow Braces Extension XS/XS and Bambini

The CDS® Elbow Braces Extension XS/XS and Bambini are constructed on the basis of the 360° Nano hinge. In the 360° Nano hinge, the position of the spring housing is adjustable on relation to the upper arm rod. The position of the redression and limitation range can be thereby altered and adjusted to the patient. The position of the stops depends on the position of the redression and limitation range.

- 1 Remove the pad.
- 2 Loosen the central screw with the supplied tool until you can remove the upper arm rod completly from the gearing.
- 3 You can adjust the position of the redression range in 10° steps. By adjusting the position of the redression
- range, you can set flexion and extension limitation. Use a gonimometer to determine the desired position and adjust the hinge accordingly.
- 4 Place the the upper arm rod on the gearing and thighten the central screw.
- **5** Insert the pad again.











User Instructions

2.2.2. Setting the limitation for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior

The limitation restricts the range of motion.

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 switch 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. Positon 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.



2.2.3. Fine adjustment for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior

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.





User Instructions

2.2.4. Inserting the stop wedge for CDS® Elbow Braces Extension L/L, M/M, S/S and Junior

- 1 Flexion can be limited with the stop wedge.
- 2 Before adjusting the flexion limitation you must activate the spring tension. Turn the switch 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.
- ① 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.
- 5 Fix it with the supplied screw.













2.3. Application 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 switch 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 patients, adjust the length of all brace straps to their maximum length without unthreading them. First open the wide elastic upper arm strap. Now open the remaining straps by opening the clips.

For XS/XS and Bambini, you must open and close the straps in order to attach and remove the brace





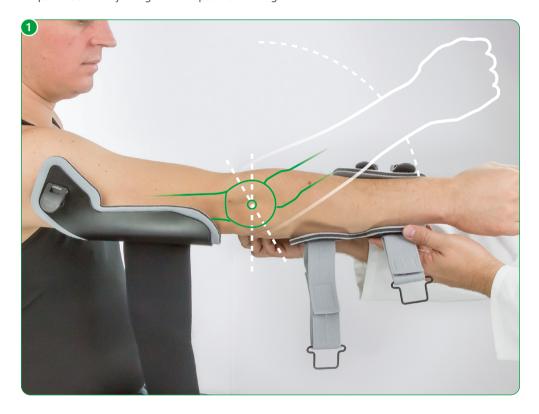


User Instructions

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





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.

- 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, elastic upper arm strap.









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 arm contour directly on the patient.

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

User Instructions

2.3.5. Activate the spring tension

- 1 To activate the spring tension, turn the switch 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.







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 -.

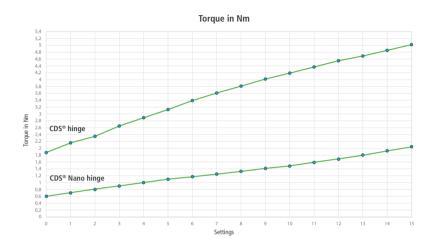




The intensity of the spring tension is not altered by activation or deactivation of the spring tension.

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

User Instructions



The CDS® hinge is used for the sizes L/L, M/M, S/S and Junior.

The CDS® Nano hinge is used for the XS/XS and Bambini.

2.3.7. Changing the spring tension

The spring tension can be adjusted according to the to 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.



3. Handling by the patient

3.1. Removing the brace

Before removing the brace you must deactivate the spring tension.

- 1 To do so, turn the switch to "off".
- 2 Bring the brace into flexion.
- 3 To remove the brace, first open the wide, elastic upper arm strap.
- 4 Then open the remaining straps by opening the clips and do not unthread the straps. Take off the brace.

For XS/XS and Bambini, you must open and close the straps in order to attach and remove the brace.















User Instructions

3.2. Putting on the brace

- 1 Place the brace on your arm from below.
- 2 For XS/XS and Bambini, you must open and close the straps in order to attach and remove the brace

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.
- **6** To activate the spring tension, turn the switch to "on".
- **7** Bring the brace into flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.

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

























Hand wash at 30°C



Do not bleach



Do not iron





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 Extension 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.

User Instructions

5. Technical data

Bezeichnung	Material		
Gewicht	650g ohne Handgriff / 800g mit Handgriff		
Polstermaterial	PU-Schaum mit PA-Klettvelours		
Gurtmaterial	PA-Gurt mit PA-Klettvelours		
Handgriff	Latexfreies Schaummaterial		
Schienenmaterial	Aluminium		

6. Size chart and article numbers

Name	Length of upper arm shell	Length of forearm shell	Circumfe- rence upper arm shell	Circumfe- rence forearm shell	ArtNo. left	ArtNo. right
Elbow Extension L/L	17 - 21 cm	20 - 24 cm	28 - 39 cm	22 - 30 cm	906LL-L	906LL-R
Elbow Extension L/L with handle	17 - 21 cm	20 - 24 cm	28 - 39 cm	22 - 30 cm	9061LL-L	9061LL-R
Elbow Extension M/M	17 - 20,5 cm	19,5 - 22 cm	20 - 30 cm	18 - 24 cm	906MM-L	906MM-R
Elbow Extension M/M with handle	17 - 20,5 cm	19,5 - 22 cm	20 - 30 cm	18 - 24 cm	9061MM-L	9061MM-R
Elbow Extension S/S	17 - 20 cm	17,5 - 20,5 cm	15 - 21 cm	14 - 19 cm	906SS-L	906SS-R
Elbow Extension XS/XS	17 - 20 cm	17,5 - 20,5 cm	15 - 21 cm	14 - 19 cm	906XS-GL	906XS-GR
Elbow Extension Junior Green	17 - 20 cm	17,5 - 20,5 cm	15 - 21 cm	14 - 19 cm	906SS-GL	906SS-GR
Elbow Extension Junior Blue	17 - 20 cm	17,5 - 20,5 cm	15 - 21 cm	14 - 19 cm	906SS-BL	906SS-BR
Elbow Extension Junior Orange	17 - 20 cm	17,5 - 20,5 cm	15 - 21 cm	14 - 19 cm	906SS-OL	906SS-OR
Elbow Extension Junior Pink	17 - 20 cm	17,5 - 20,5 cm	15 - 21 cm	14 - 19 cm	906SS-PL	906SS-PR
Elbow Extension Bambini Green	14 - 17 cm	14 - 17,5 cm	12 - 17 cm	12 - 14 cm	906XSXS-GI	906XSXS-GF
Elbow Extension Bambini Blue	14 - 17 cm	14 - 17,5 cm	12 - 17 cm	12 - 14 cm	906XSXS-BL	906XSXS-BR
Elbow Extension Bambini Orange	14 - 17 cm	14 - 17,5 cm	12 - 17 cm	12 - 14 cm	906XSXS-OI	906XSXS-OR
Elbow Extension Bambini Pink	14 - 17 cm	14 - 17,5 cm	12 - 17 cm	12 - 14 cm	906XSXS-PL	906XSXS-PR



Name	ArtNo. left	ArtNo. right
adjustable handle*	993A-HL	993A-HR
* Only for L/L and M/M		

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.

User Instructions



PATENTS: EP 0 841 044 / US 5,954,677 / EP 3 352 713
FURTHER PATENTS PENDING

VERSION: EN 08.2022



Medical device



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