USER INSTRUCTIONS

CDS® SUP-PROSAN

DYNAMIC SPRING-LOADED PRO-/SUPINATION ORTHOSIS

albrecht©
FUNKTIONELLE REHABILITATION

CDS® SUP-PROSAN

User Instructions

Contents

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® Sup-Prosan functions according to the CDS®-principle and has been designed to treat a Pro-/Supination deficit. 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.**

1.4. Application

The brace has been designed exclusively for the orthotic treatment.

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 the manufacturer solely responsible, declares that the CDS® Sup-Prosan conforms to the Regulation (EU) 2017/745 concerning medical devices.

1.7. Features

- Therapy in pro-/supination
- Individually adjustable spring tension
- Spring tension can be switched on and off without tools and without varying the set spring tension
- Infinitely adjustable setting of the redression range
- With carrying strap
- Individually adjustable shell and strap system
- Easy handling and high comfort in wear
- Adjustable palm plate
- Conversion is possible from supination on the right to pronation on the left and from supination on the left to pronation on the right.

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 burns
  - After strokes
  - Paralysis
  - After cranio-cerebral trauma (CCT)
  - After radius fractures
  - After ulna fractures
  - Radius head dislocation
  - After scaphoid fractures
- Treatment after biceps tendon rupture
- To prevent new contractures after arthrolysis

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 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.

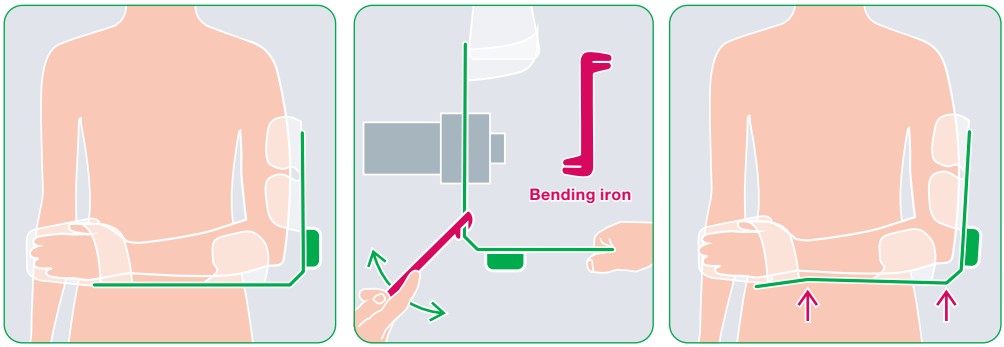
2. Adjustment by the orthopaedic technician

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"

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.

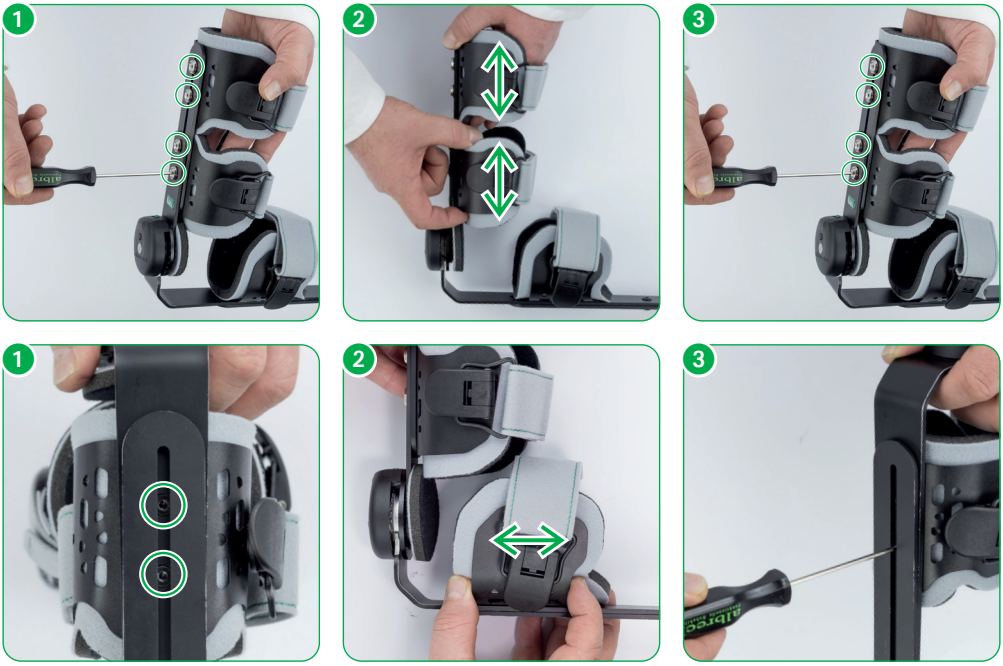


When adjusting the hinge rods to the shape of the extremity by using an orthopaedic bending iron, you must not bend the rods in the area of the hinge housing or the hinge cover as this could lead to damage or break of the hinge.

2.1.2. Setting the shell components

The shell components are movable.

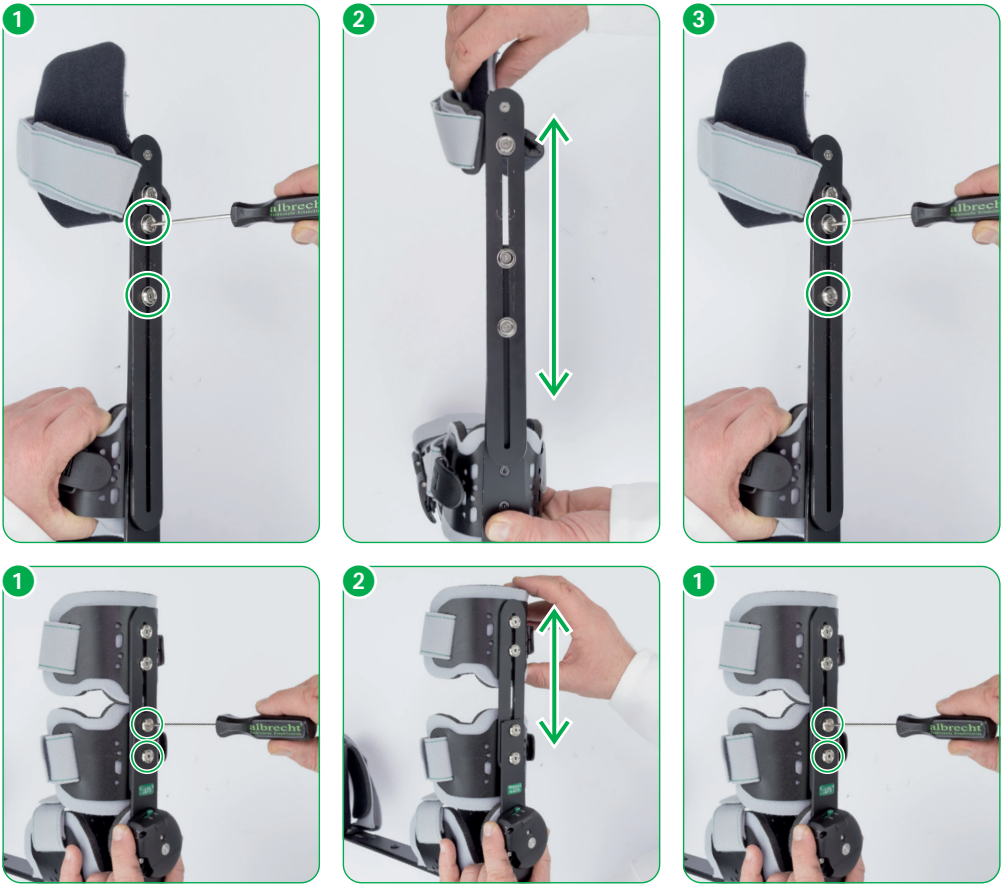
1. Loosen the screws on the shell components with the supplied tool.
2. Move the shell components into the desired position.
3. Tighten the screws again.



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

2.1.3. Adjusting the length of the brace

1. Loosen the clamping screws.
2. Set to the desired length.
3. Tighten the screws again.

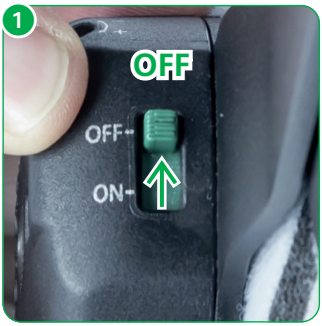


2.2. Setting the limitation

2.2.1. Setting the limitation when using as a supination brace

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

1. To do this, set the switch to “off”.
2. Bring the brace into pronation.
3. Then turn the stop screw with the supplied tool out of the CDS® housing.



Before screwing into one of the three holes, bring the brace into maximum pronation. This prevents the stop screw from striking the movable hinge rod, which could damage the CDS® housing.

The limitation should be adjusted to the progress of treatment as the patient’s mobility increases.

2.2.2. Setting the limitation when using as a pronation brace

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

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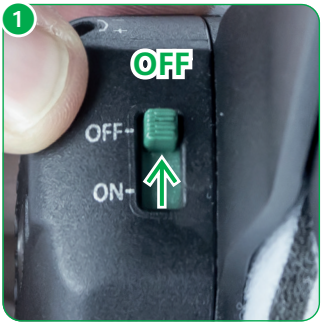


Before screwing into one of the three holes, bring the brace into maximum supination. This prevents the stop screw from striking the movable hinge rod, which could damage the CDS® housing.

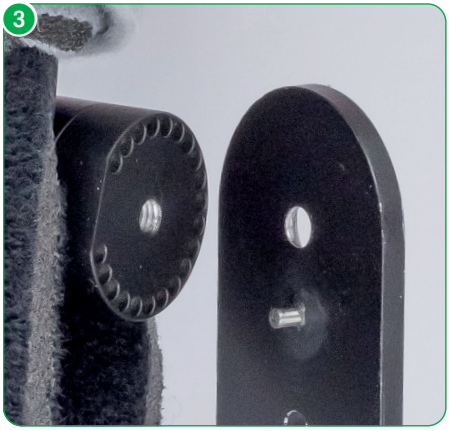
The limitation should be adjusted to the progress of treatment as the patient's mobility increases.

2.2.3. Adjusting the palm plate

1. Loosen the screw in the forearm rod with the supplied tool.
2. Turn the palm plate into the desired position and ensure that the locking pin of the forearm rod locks into the hole pattern.
3. Then tighten the screws again.

2.2.4. Optional conversion from right to left or from left to right

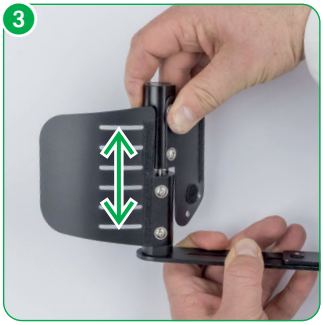
1. Example of left side.
2. Loosen the screw in the forearm rod with the supplied tool.
3. Rotate the hand piece through 180°.



4. Then tighten the screws again.
5. Change the upper arm shells so that the fasteners are laterally.
6. Example of converted right brace.

2.2.5. Adjusting the finger plate

1. Loosen the pad beneath the palm of the hand.
2. Remove the pad.
3. Push the finger plate towards the thumb.
4. While pressing on the finger plate, set the desired position. Ensure that the locking pin locks into the hole pattern.
5. Insert the pad again.



Please note that there are slits beneath the pad that can be used for finger fixation.

2.2.6. Inserting the stop wedge

Insert the stop wedge in the desired position and fix it with the supplied screw.

The spring tension must be activated before inserting the stop wedge.

2.2.7. Changing the position of the supports

The CDS® Sup-Prosan is constructed on the basis of a 360° hinge. With the 360° hinge, the spring housing and forearm rod can be pivoted against one another.

1. Remove the pad.
2. Remove the two screws.
3. Adjust the hinge in 15° steps.
4. Replace the screws and tighten them.
5. Insert the pad again.

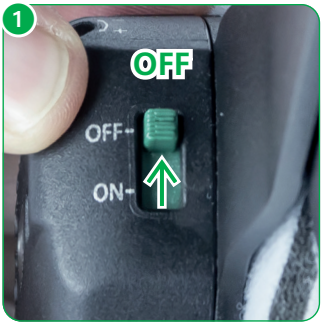
In addition, you can thereby adjust the range of motion to the patient.

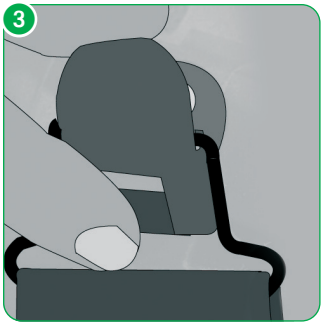
2.3. Application of the brace by the orthopaedic technician when using as supination orthosis

2.3.1. Deactivate the spring tension

Before attaching the brace you must deactivate the spring tension.

1. Turn the green switch to "off".
2. Bring the brace into pronation.
3. 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.





2.4. Application of the brace by the orthopaedic technician when using as pronation orthosis

2.4.1. Deactivate the spring tension

Before attaching the brace you must deactivate the spring tension.

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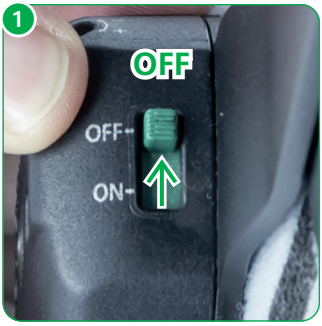
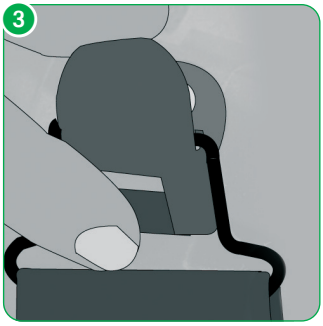


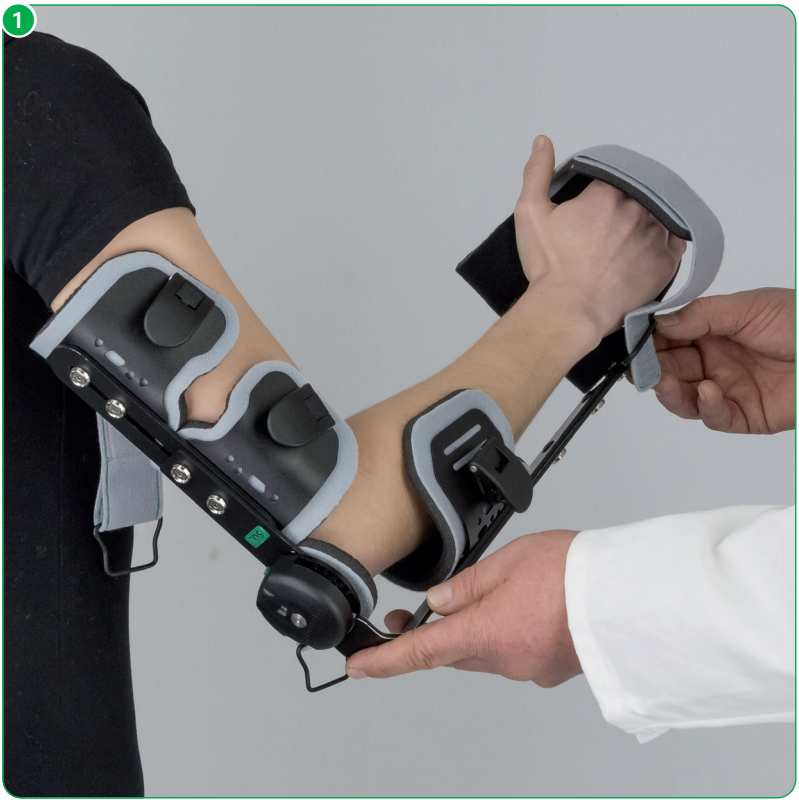


2.4.2. Attaching the brace to the elbow

Place the brace on the patient's arm from below.

1. Ensure that the pivot of the brace hinge matches the physiological pivot.

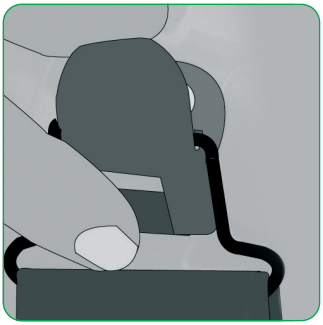
   It is possible for you to adjust the arm rods to the shape of the patient's arm by using a bending iron.



2.4.3. Adjust strap lengths as necessary

Adjust the strap to the desired length and shorten it 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 hand dorsum strap.

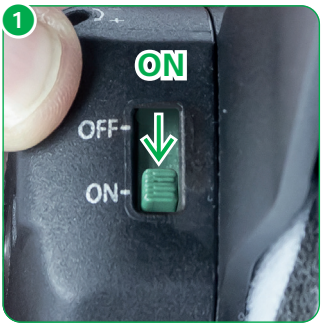

2.4.4. Final adjustment

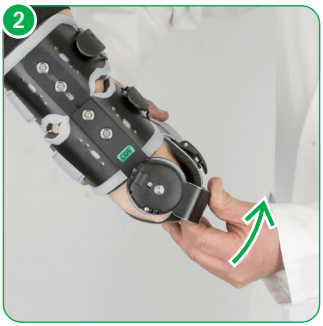
After fastening the individual straps, check that the straps are the correct length and that the brace is in correct position, and correct if necessary. Ensure that the straps are not too tight so as not to interfere with the circulation. If necessary, the strap padding supplied to the product can be attached under the straps.

2.4.5. Activate the spring tension (supination orthosis)

1. To activate the spring tension, turn the green switch to "on".
2. Bring the brace into pronation.

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

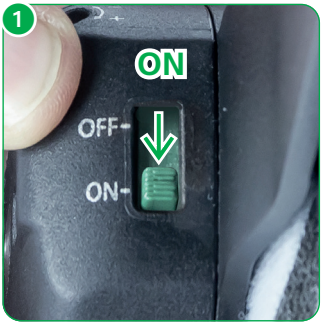


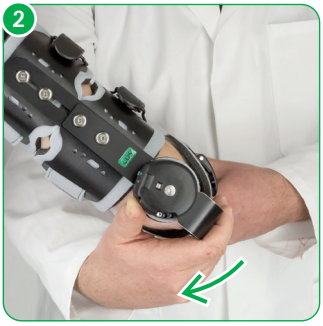


2.4.6. Activate the spring tension (pronation orthosis)

1. To activate the spring tension, turn the green switch to "on".
2. Bring the brace into supination.

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

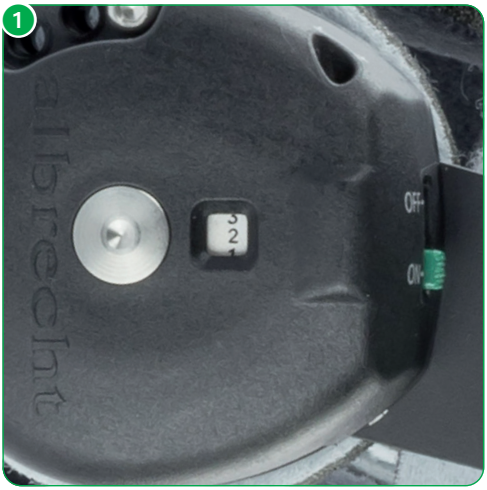




2.4.7. Setting the spring tension to the intensity needed by the patient

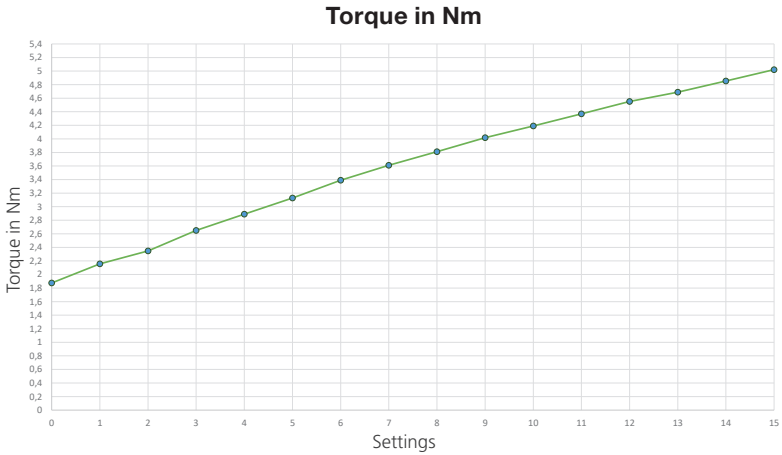
The spring tension can be adjusted continuously.

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.



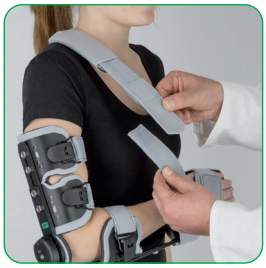
2.4.8. Changing the spring tension

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.

2.4.9. Adjusting carrying strap



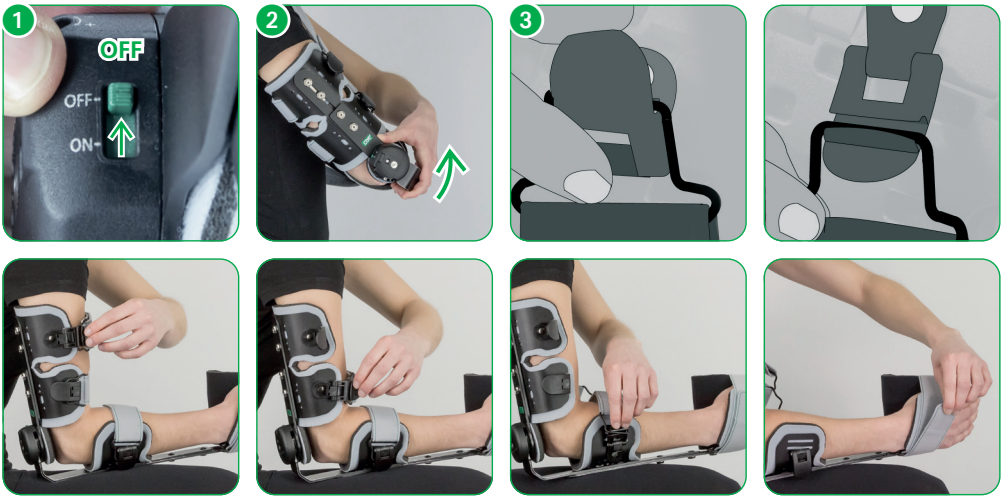
The carrying strap can be shortened individually.

3. Handling by the patient

3.1. Removing the brace (supination)

Before removing the brace you must deactivate the spring tension.

1. To do so, turn the green switch to "off".
2. Bring the brace into pronation.
3. To remove the brace, only open the clips and do not unthread the straps. Take off the brace.



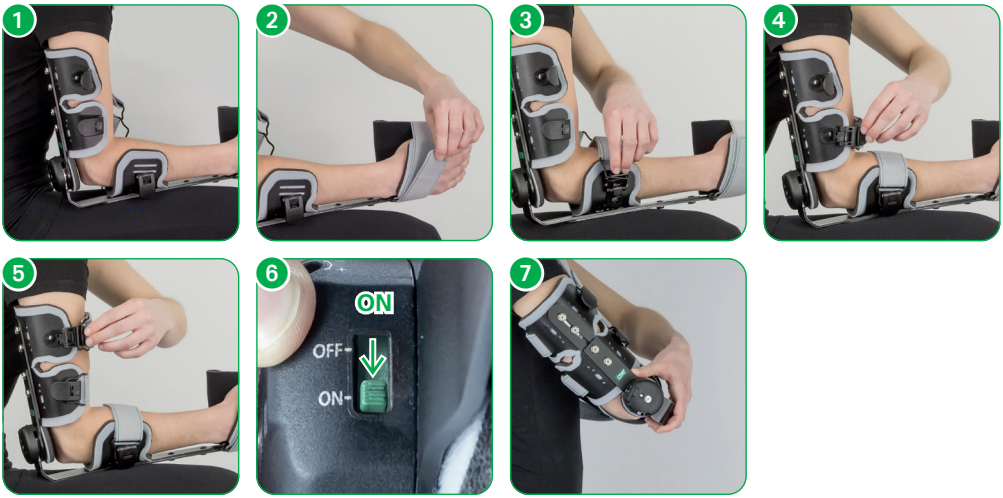
3.2. Removing the brace (pronation)

Before removing the brace you must deactivate the spring tension.

1. To do so, turn the green switch to "off".
2. Bring the brace into supination.
3. To remove the brace, only open the clips and do not unthread the straps. Take off the brace.

3.3. Putting on the brace

1. Place the brace on your arm from below.
2. - 5. Close the clips in the stated order.
6. To activate the spring tension, turn the green switch to “on”.
7. Bring the brace into pronation respectively supination.



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 fabric can be hand washed at 30° C using water and a mild detergent and/or disinfectant.
- Do not machine wash.
- A replacement set of fabric parts is available if the device becomes extremely dirty.

4.2. Supports (hinges)

- Wipe plastic and aluminium parts down with water and a mild detergent and/or disinfectant using a moist cloth.
- 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

Name	Material
Weight	750g
Padding material	PU foam with PA hook and loop velour
Strap material	PA strap with PA hook and loop velour
Brace material	aluminium

6. Size chart and article numbers

Name	Length* of upper arm shell	Length** of forearm shell	Circum-ference upper arm shell	Circumfe-rence forearm shell	Width palm plate	Art.-No. left	Art.-No. right
L/L Supination	20 - 24 cm	21 - 36 cm	28 - 38 cm	27 - 36 cm	10 cm	908LL-L	908LL-R
M/M Supination	20 - 24 cm	21 - 36 cm	22 - 30 cm	20 - 30 cm	8 cm	908MM-L	908MM-R
S/S Supination	20 - 24 cm	21 - 36 cm	18 - 24 cm	16 - 26 cm	6 cm	908SS-L	908SS-R
L/L Pronation	20 - 24 cm	21 - 36 cm	28 - 38 cm	27 - 36 cm	10 cm	909LL-L	909LL-R
M/M Pronation	20 - 24 cm	21 - 36 cm	22 - 30 cm	20 - 30 cm	8 cm	909MM-L	909MM-R
S/S Pronation	20 - 24 cm	21 - 36 cm	18 - 24 cm	16 - 26 cm	6 cm	909SS-L	90SS-R

* When only one upper arm shell is used the measurements 12 - 14 cm for all orthosis
** Length lower arm from pivitual point elbow to wrist

- Further sizes are available on request

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 / DE 10 2015 012 320
EP 3 352 713

FURTHER PATENTS PENDING

VERSION: EN 01.2023

MD

Medical device

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