USER INSTRUCTIONS

CDS® MANUSAN

DYNAMIC FINGER ORTHOSIS

albrecht©
FUNKTIONELLE REHABILITATION

CDS® Manusan

User Instructions

Contents

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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® Manusan functions according to the CDS®-principle and has been designed to treat an flexion deficit of the fingers and wrist.

Active use trains the appendicular finger muscles.

Passive use stimulates growth of contracted tissue due to continuous dynamic tension.

1.4. Application

The brace must only be used for the orthotic care of the hand.

1.5. Scope of delivery

Please check the completeness of the brace at delivery

- Brace with pads and straps
- albrecht GmbH hexagonal screwdriver
- User Instructions
- Strap pad set
- Optional chain left

1.6. Declaration of conformity

The albrecht GmbH company, as the manufacturer solely responsible, declares that the CDS® Manusan 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
- Adjustment of the redression range in 15° steps
- Optimized shell- and strapsystem
- High wearing comfort thanks to air-permeable, light aluminium shell elements
- High flexibility thanks to adjustable shell elements
- Adjustable hand plate
- No tool necessary for adjusting spring force
- Individual toolless adaptation of chains to finger length

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
  - After spinal cord injuries
  - Paralysis (discrete palsy of peripheral origin)
  - After cranio-cerebral trauma (CCT)
- To prevent new contractures after arthrolysis
- Lacerations
- Tendon sutures
- Dupuytren´s contracture

For all other indications a physician must be consulted.

1.9. Contra indications

- Bony obstruction, osteoporosis thrombophlebitis

The finger brace is intended exclusively for contact with intact skin.

1.10. Safety Instruction

The optimal effect of the finger brace is only achieved when used correctly.

- The finger 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 finger brace leads to a reduction of the therapeutic effect of the finger brace and may lead to injury.
- The finger 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 finger 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 brace
- 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.

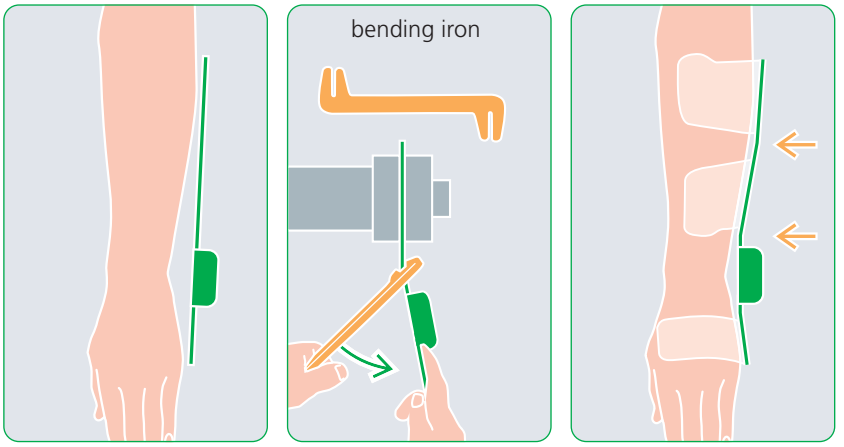
2. Adjustment by the orthopaedic technician

2.1. Fitting to the patient

- Our CDS® Manusan is 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 rod can be adjusted to the shape of the patient’s forearm 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 rod to the shape of the extremity.

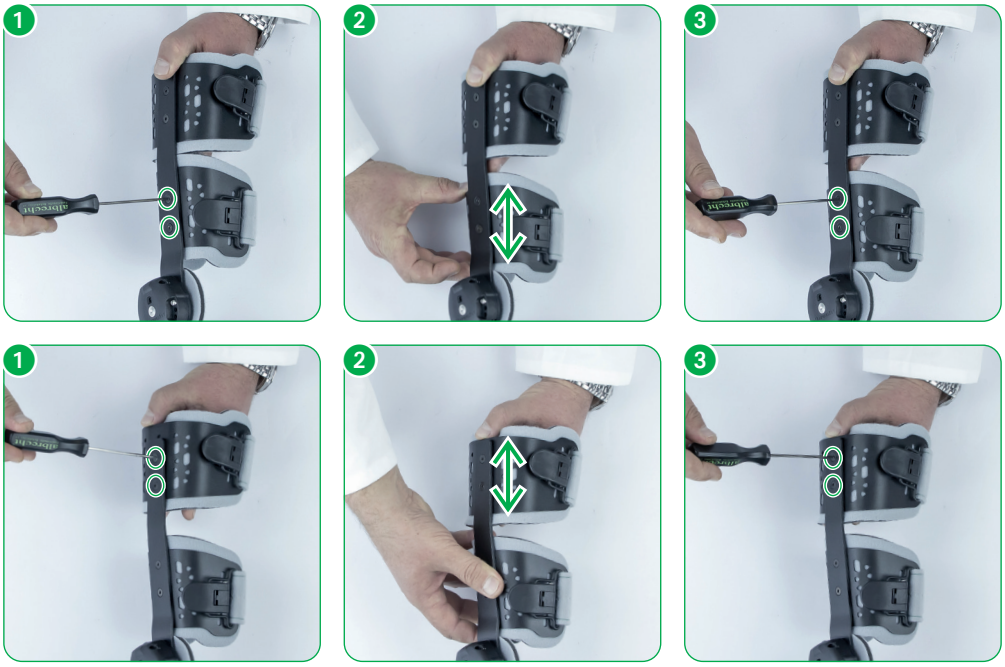


When adjusting the hinge rod to the shape of the extremity by using an orthopaedic bending iron, you must not bend the rod in the area of the hinge housing or the hinge cover as this could lead to damage or break of the hinge.

2.1.2. Adjusting the shell components

The shell components are moveable.

1. Loosen the screws on the shell components with the supplied tool without unscrewing them completely.
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 position of the redression and limitation range

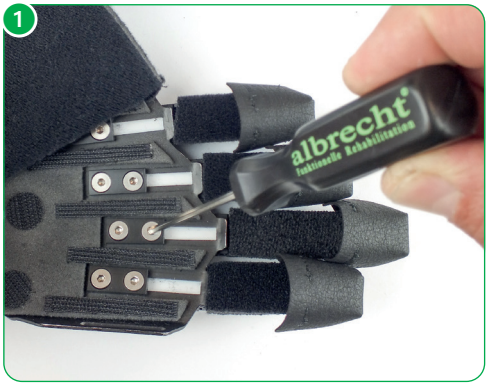
The CDS® Manusan is constructed on the basis of a 360° hinge. In a 360° hinge, the position of the spring housing is adjustable in relation to the forearm hinge rod. The position of the redression and limitation range can be thereby altered and adjusted to the patient. The position of the stops depends on the position of the redression and limitation range.

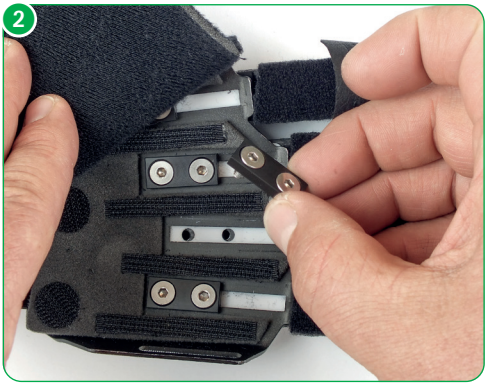
1. Remove the pad.
2. Remove the two screws.
3. You can adjust the position of the redression range in 15° steps. Use a goniometer to determine the desired position and adjust the hinge accordingly.
4. Insert the screws again and tighten them.
5. Insert the pad again.

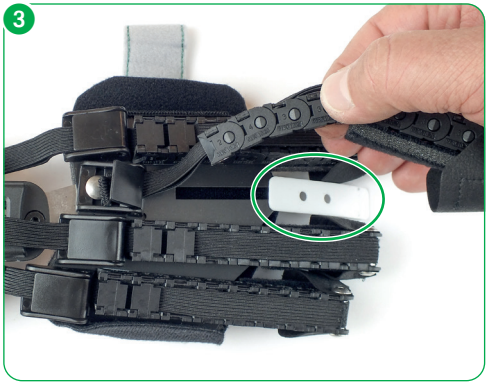
That way, you can adjust the range of motion of the brace to the patient even if there are extreme motion deficits.

2.1.4. Removing individual finger components

1. Open the palm strap and fold aside the pad for the back of the hand.
2. Unscrew both screws from the finger component you want to remove and remove the slide block.
3. Open the toggle clamp and pull out the rubber cord with the finger component. Remove the white Teflon strip.

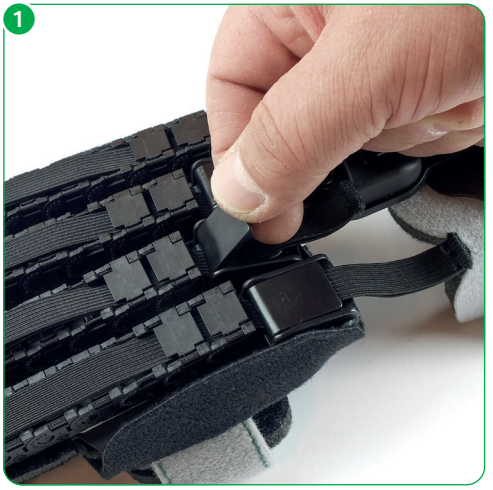






2.1.5. Tightening or loosening the rubber cord

1. Open the toggle clamp.
2. Stretch the rubber cord to the tension you need and then close the toggle clamp.



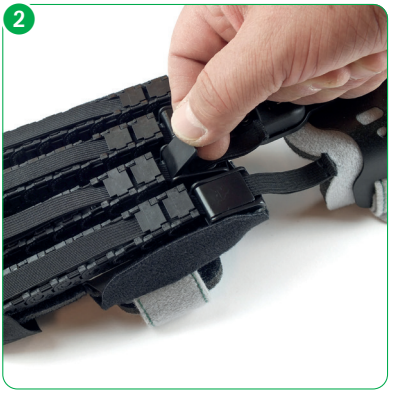
2.1.6. Height adjustment of the hand plate

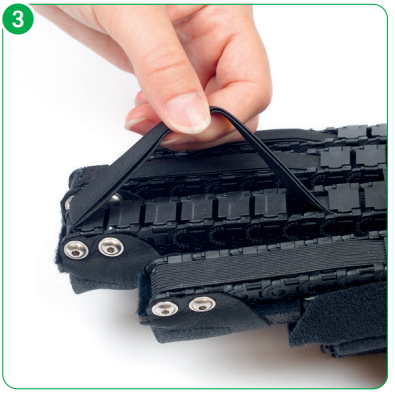
1. Remove the pad.
2. Loosen the two clamping screws of the height adjustment with the tool supplied.
3. Adjust the hand plate to the height required by the patient.
4. Tighten the two clamping screws again.
5. Put the pad back on again.

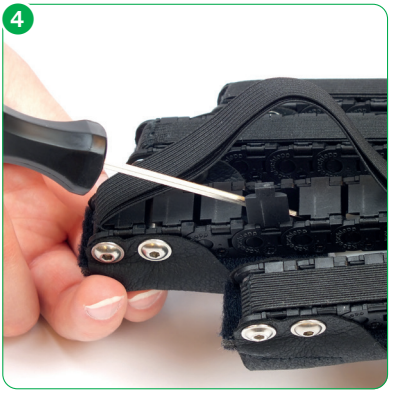
2.1.7. Adjusting the finger length

Caution: In order to change the finger length of the orthosis, you must first loosen the rubber cord.

1. Loosen the finger pad (hook-and-loop closure).
2. Open the toggle clamp to release the tension on the rubber cord.
3. Push the rubber cord to the side.
4. Insert the included tool between two chain links and lever it gently backward until the cover pops off. Repeat this process so that two adjacent covers are open.







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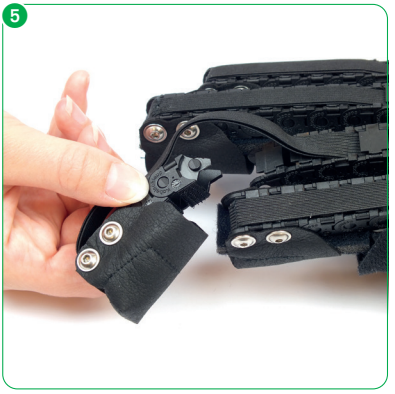
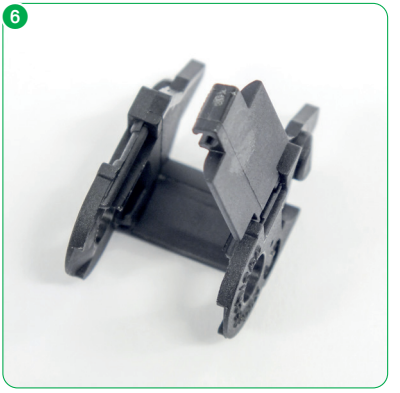
5. Press the chain links together where the covers are open and turn them sideways. The chain is split. Now you can remove or add chain links.
6. When adding chain links, make sure that the open covers face upward. Each chain link changes the finger length by 13 mm. Stretch the rubber cord to the desired tension and then close the toggle clamp.
7. Caution: After adjusting the finger length, trim the finger pads so they are flush with the pad for the back of the hand.



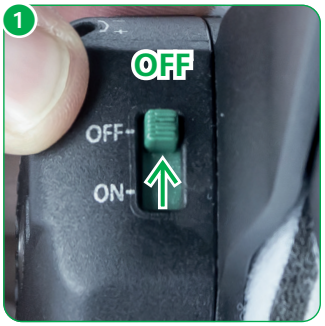


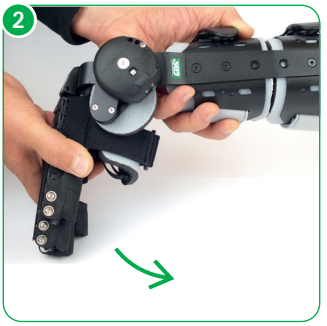
2.1.8. Setting the limitation

The limitation restricts the range of motion. Extension and the redression range are limited by the stop screw. Before setting the extension limitation, you must deactivate the spring tension.

1. Turn the green switch to „off".
2. Bring the brace into flexion.

   There are three holes on the side of the CDS® housing. The number of degrees depends on the position of the straightening and limitation range and can be determined with a goniometer. The stop screw is located in one of the holes.
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 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 tightened in one of the holes, otherwise the hinge will be damaged.

2.1.9. Inserting the stop wedge

Flexion can be limited with the stop wedge.

Before adjusting the flexion limitation you must activate the spring tension.

Turn the green switch to “on”. Bring the brace into flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.

There are five positions on the side opposite the three holes. The number of degrees depends on the position of the redression and limitation range and can be determined with a goniometer.

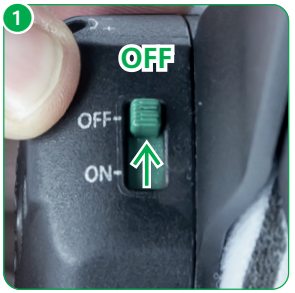
Insert the stop wedge in the desired position and fix it with the supplied screw.

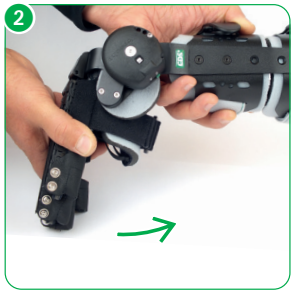
2.2. Application of the brace by the orthopaedic technician

2.2.1. 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 as far into flexion as the patient is allowed to move. Now, the activation mechanism of the hinge is set to this position and the patient can reactivate the spring tension in this position.





1.14.2. Open the strap clips

To facilitate attaching of the brace on the patients, adjust the length of all brace straps to their maximum length without unthreading them. First loosen the finger strap. Then loosen the forearm straps by opening the clips.

2.2.3. Attaching the brace to the arm

1. Lay the rail adjacent to the patient's forearm and position the fingers in the finger baskets so that they are flush.

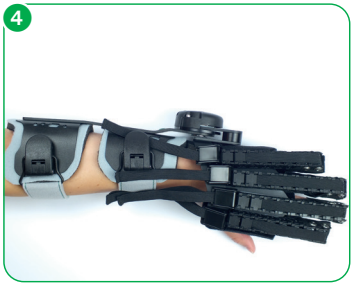
Ensure that the pivot of the brace hinge matches the physiological pivot of the wrist.

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

2.2.4. Adjust strap lengths as necessary

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

1. First fasten the forearm strap next to the joint.
2. Fasten the forearm strap further from the joint.
3. Fasten the palm strap.
4. Brace application complete.



2.2.5. 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.

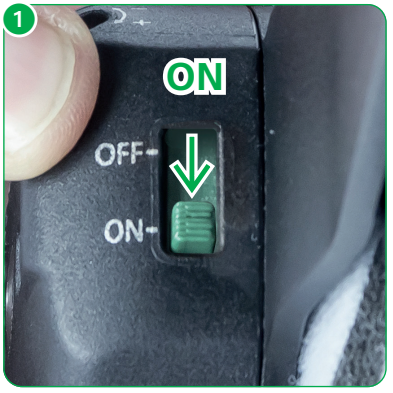
The shell elements are anatomically contoured. You can also shape the shell elements with the hand to the forearm contour directly on the patient.

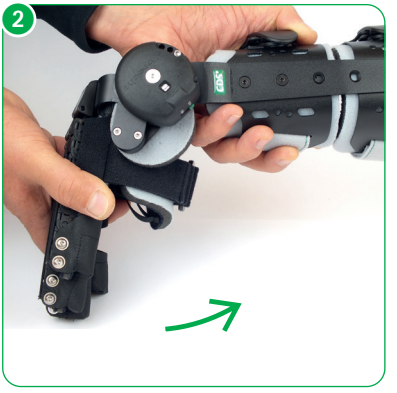
If necessary, the additional strap padding supplied with the product can be attached under the straps.

2.2.6. Activate the spring tension

1. To activate the spring tension, turn the green 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.

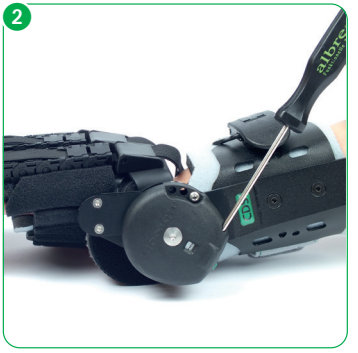
The intensity of the spring tension is not altered by activation or deactivation of the spring tension.



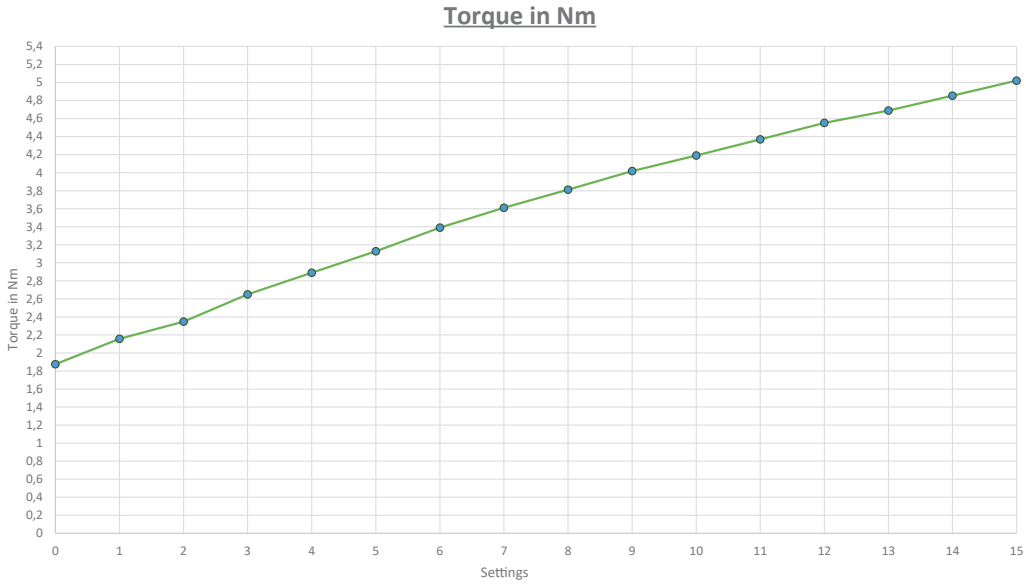


2.2.7. Setting the spring tension to the intensity needed by the patient

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



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



2.2.8. 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 joint. 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.

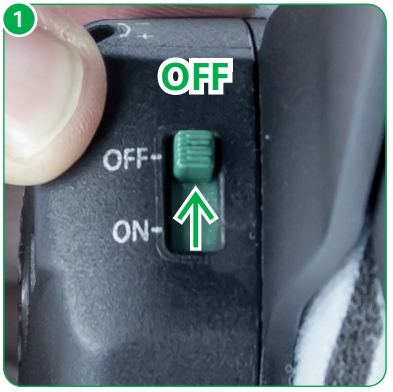
3. Handling by the patient

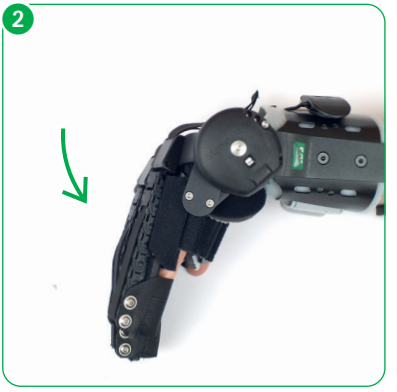
3.1. Removing the brace

Deactivate the spring tension

Before removing the brace you must deactivate the spring tension.

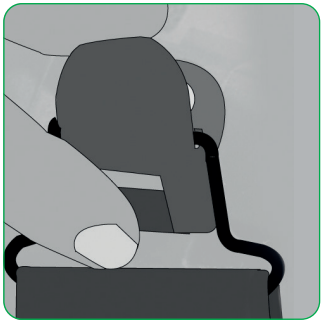
1. To do so, turn the green switch to „off".
2. Bring the brace into flexion.





Open the straps

To remove the brace, open the clips and straps in the stated order.



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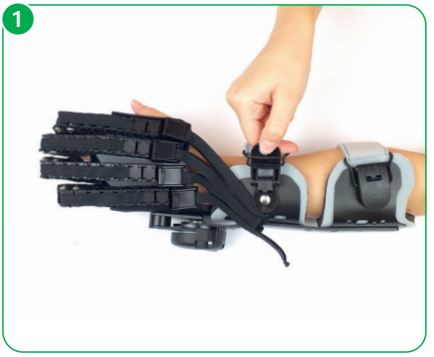
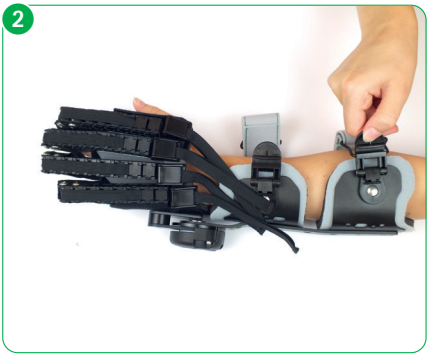
1. Loosen the forearm strap next to the joint.
2. Loosen the forearm strap further from the joint.
3. Open the palm strap.





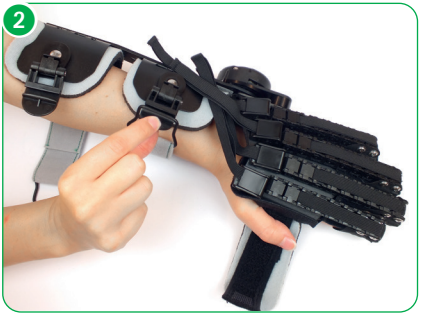
Remove the brace sideways

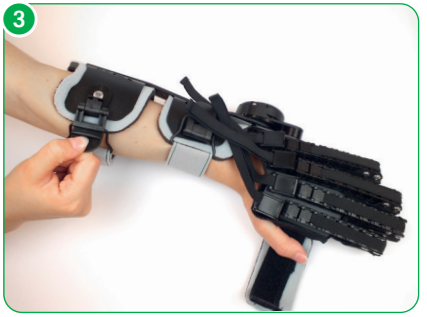
Take off the brace.

3.2. Putting on the brace

Close the clips in the stated order:

1. Place the brace on your arm from the side.
2. First fasten the forearm strap next to the joint.
3. Fasten the forearm strap further from the joint.
4. Fasten the palm strap.





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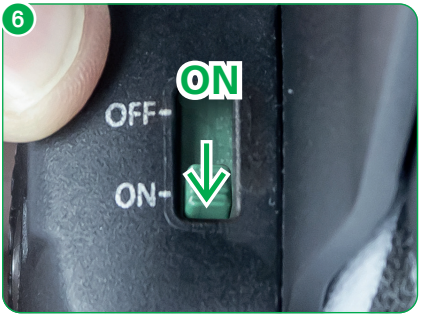
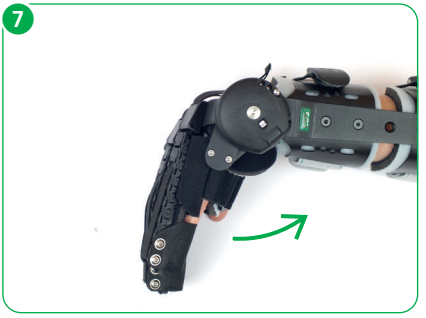
5 Brace application complete.

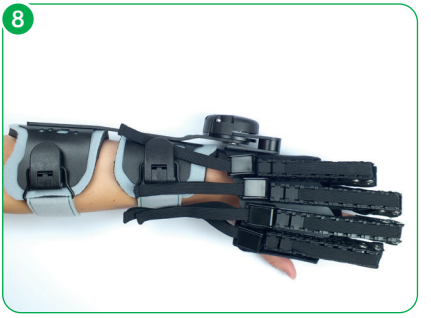
6 To activate the spring tension, turn the green switch to „on".

7 Bring the brace into flexion until you feel a slight resistance that you have to overcome in order to activate the spring tension.

8 Brace application complete.







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 dry clean

Not suitable for dryer

4. Cleaning, maintenance and desinfection

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

Name	Material
Weight	788g
Pad material	PU foam with PA hook-and-loop fabric
Strap material	PA strap with PA hook-and-loop fabric
Brace material	Aluminium
Finger cage material	Vapor permeable microfiber PU/PA

6. Sizes and part numbers overview

Bezeichnung	Umfang	Breite Handplatte	Art.-Nr. links	Art.-Nr. rechts
Manusan Kombi CDS® LL	22 - 30 cm	10 cm	960LL-L	960LL-R
Manusan Kombi CDS® MM	18 - 24 cm	9 cm	960MM-L	960MM-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 hinge 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 hinge 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 3352713
FURTHER PATENTS PENDING

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MD
Medical device

Manufacturer

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