CDS® KNEE BRACE FLEXION

KNEE ORTHOSIS

DYNAMIC SPRING-LOADED KNEE ORTHOSIS





User Instructions

Contents

1. Introduction	
1.1. Foreword	
1.2. Customer information	
1.3. Mode of operation	
1.4. Application	
1.5. Scope of delivery	
1.6. Declaration of conformity	
1.7. Features	
1.8. Indications	
1.9. Contraindications	6
1.10. Safety Instructions	6
1.11. Warranty	
2. Adjustment by the orthopaedic technician	
2.1. Fitting to the patient	
2.1.1. Adjusting the brace to the leg shape by an orthopaedic "bending iron"	using
2.1.2. Setting the shell components – size L/L	, L/M, L/S, M/S9
2.1.3. Setting the textile shell components – s	ize S/S, XS/XS, XXS 10
2.2. Setting the hinge	1
2.2.1. Adjusting the position of the redression for CDS® Knee Braces Flexion – size L/L, L/M	
2.2.2. Adjusting the position of the redression for CDS® Knee Braces Flexion S/S, XS/XS, XX	
2.2.3. Setting the limitation for CDS® Knee Braces Flexion L/L, L/M, M/L, M/S	13



for CDS® Knee Braces Flexion L/L, L/M, M/L, M/S	14
2.2.5. Inserting the stop wedge for CDS® Knee Braces Flexion L/L, L/M, M/L, M/S	15
2.3. Attaching of the brace by the orthopaedic technician	
2.3.1. Deactivate the spring tension	16
2.3.2. Attach the brace to the leg	17
2.3.3. Adjust strap lengths as necessary	19
2.3.4. Final adjustment	22
2.3.5. Activate the spring tension	23
2.3.6. Setting the spring tension to the intensity needed by the patient	24
2.3.7. Changing the spring tension	26
3. Handling by the patient	27
3.1. Removing the brace	27
3.2. Putting on the brace	30
4. Cleaning, maintenance and disinfection	32
4.1. Pads and straps	32
4.2. Rods (Hinges)	32
5. Technical data	33
6. Size chart and article numbers	33
7. Transfer of the brace	34
8. Disposal	34

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® Knee Brace Flexion | CDS® Knee Brace Flexion Junior functions according to the CDS®-principle and has been designed to treat a flexion deficit of the knee. 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.

1.4. Application

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

1.5. Scope of delivery

The CDS® Knee Brace Flexion | CDS® Knee Brace Flexion Junior 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® Knee Brace Flexion | CDS® Knee Brace Flexion Junior conforms to the Regulation (EU) 2017/745 concerning medical devices.



1.7. Features

- Therapy in flexion
- CDS hinge with established features:
 - Individual adjustment of the spring tension
 - Spring tension can be switched on and off without tools and without varying the set spring tension.
 - Infinitely variable adjustment of the redression range in flexion (Size L/L, L/M, L/S, M/S)
 - adjustment of the redression range in 10° steps (Size S/S, XS/XS, XXS)
 - High wearing comfort thanks to air-permeable, light textile shell elements
 - High flexibility thanks to adjustable shell elements
 - The sizes S/S, XS/XS, XXS are available in black, green, blue, pink and orange

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 due to:
 - vegetative state
 - cerebral palsy
 - genetic syndromes
 - epilepsy
 - spina bifida
 - near-drowning
 - burns
 - stroke
 - spinal injury
 - paralysis
 - craniocerebral injury
- capsular ligament injury
- surgery
- before and after knee replacement
- arthrosis and chromic polyarthritis
- to prevent recurring contractures following arthrolysis
- conservative, post-surgical for all indications that contraindicate active flexion of the knee

For all other indications a physician must be consulted.

User Instructions

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

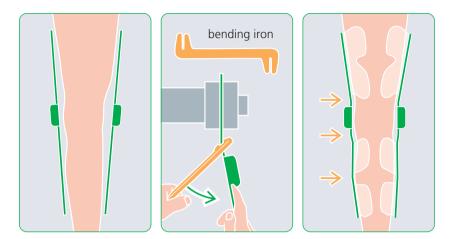
2.1. Fitting to the patient

- 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 leg shape by using an orthopaedic "bending iron"

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.

User Instructions



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 – size L/L, L/M, L/S, M/S

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. Setting the textile shell components – size S/S, XS/XS, XXS

The textile shells can be moved along the rod by 2,5 cm.

- 1 Loosen the screws on the shell components with the supplied tool without unscrewing them completely.
- 2 Remove the textile shells.
- 3 Punch another hole vertically below the existing screw hole using a punch plier (max 2,5 cm).
- 4 Slide the shell over the rod and attach it in the new screw hole.









Please note that, because of its construction, the lower leg shell in the size S/S, XS/XS, XXS consists of one textile shell component.



2.2. Setting the hinge

2.2.1. Adjusting the position of the redression and limitation range for CDS® Knee Braces Flexion – size L/L, L/M, L/S, M/S

The CDS® Knee Braces Flexion L/L, L/M, L/S, M/S are constructed on the basis of the 360° hinge. In the 360° 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 Remove the two screws.
- 3 You can adjust the position of the redression range in 15° steps. Use a gonimometer to determine the desired position and adjust the hinge accordingly.
- 4 Insert the screws again and thighten them.
- 5 Insert the pad again.

All steps must be executed identically with both hinges.













User Instructions

2.2.2. Adjusting the position of the redression and limitation range for CDS® Knee Braces Flexion S/S, XS/XS, XXS

The CDS® Knee Braces Flexion Junior S/S, XS/XS, XXS 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 thigh rod. The position of the redression and limtation 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 thigh rod completly from the gearing.
- 3 You can adjust the position of the redression range in 10° steps. Use a gonimometer to determine the desired position and adjust the hinge accordingly. By altering the redression range the extension and flexion stops can be adjusted in 10° steps.
 - All steps must be executed identically with both hinges.
- Place the the thigh rod on the gearing and thighten the central screw.
- **5** Insert the pad again.













2.2.3. Setting the limitation for CDS® Knee Braces Flexion L/L, L/M, M/L, M/S

The limitation restricts the range of motion.

All steps must be executed identically with both hinges.

Flexion 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 extension.
- 3 There are three holes on the side of the CDS® 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® housing.

Before screwing it into one of the three holes, bring the brace into extension, 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 beaware that the brace must only be used with the stop screw postioned and tightend in one of the holes, otherwise the hinge will be damaged.

User Instructions

2.2.4. Fine adjustment for CDS® Knee Braces Flexion L/L, L/M, M/L, M/S

Fine adjustment gives you the option of infinitely variable flexion limitation.

- 1 Set the fine adjustment to a value between 0 and -15. The setting reduces the limitation already set by the stop screw.
- 2 All steps must be executed identically with both hinges.







2.2.5. Inserting the stop wedge for CDS® Knee Braces Flexion L/L, L/M, M/L, M/S

- Flexion can be limited with the stop wedge. All steps must be executed identically with both hinges.
- 2 Before adjusting the extension limitation you must activate the spring tension. Turn the switches on both hinges to "on".
- 3 Bring the brace into extension 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 on the position of the redression and limitation range can be determined with a goniometer. Insert the stop wedge in the desired position.
- **5** 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 extension 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 postion.
- 3 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.

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







Size S/S, XS/XS, XXS





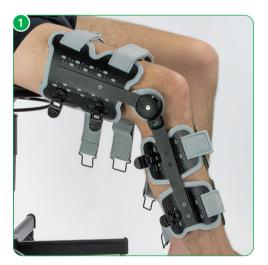




2.3.2. Attach the brace to the leg

- 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

It is possible to adjust the thigh rods to the shape of the patient's leg by using an orthopaedic bending iron.





User Instructions

Size S/S, XS/XS, XXS





Ensure that the hinges are as parallel to one another as possible to ensure proper function of the brace.



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 upper calf strap.
- 2 Then fasten the upper shin strap.
- 3 Fasten the upper posterior thigh strap next to the knee.







Size S/S, XS/XS, XXS







User Instructions

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







Size S/S, XS/XS, XXS









- **7** Fasten the lower calf strap.
- 8 Fasten the lower shin strap.

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





Size S/S, XS/XS, XXS





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.

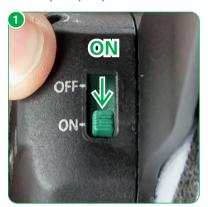
The shell elements are anatomically contoured. You can also shape the shell elements with the hand to the leg contour directly on the patient.



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 extension until you feel a slight resistance that you have to overcome in order to activate the spring tension.

Size L/L, L/M, L/S, M/S





Size S/S, XS/XS, XXS





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

User Instructions

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

- 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 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.

Size L/L, L/M, L/S, M/S









Size S/S, XS/XS, XXS







Drehmoment in Nm bei Beugung 90° 5,4 5,2 5 4,8 4,6 4,4 4,2 3,8 3,6 3,4 3,2 Drehmoment in Nm 2,8 2,6 2,4 2,2 CDS[®] Gelenk 1,8 1,6 CDS® Nano Gelenk 0,8 0,6 0,4 0,2 Einstellungsstufen

CDS® hinge (size L/L, L/M, L/S, M/S)
CDS® Nano hinge (size S/S, XS/XS, XXS)

User Instructions

2.3.7. Changing the spring tension

- 1 The spring tension can be adjusted according to the to treatment progress.
- 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 must be equal in both hinges.







Size S/S, XS/XS, XXS







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 switches on both hinges to "off".
- 2 Bring the brace into extension.





Size S/S, XS/XS, XXS





User Instructions

- 3 6 To remove the brace, only open the clips and do not unthread the straps. For S/S, XS/XS, XXS, you must open and close the straps in order to attach and remove the brace.
- 7 Take off the brace.

















Size S/S, XS/XS, XXS











User Instructions

3.2. Putting on the brace

- 1 Place the brace on your leg from above.
- 2 For S/S, XS/XS, XXS, you must open and close the straps in order to attach and remove the brace.
- 3 First fasten the upper calf strap.
- 4 Fasten the upper posterior thigh strap next.
- 5 Fasten the posterior thigh strap next to the knee.
- 6 Fasten the lower calf strap.
- To activate the spring tension, turn the switches on both hinges to "on".
- 3 Bring the brace into extension until you feel a slight resistance that you have to overcome in order to activate the spring tension.



















Size S/S, XS/XS, XXS



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

User Instructions



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. 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)

- Plastic and aluminium may be wiped with a wet cloth using a mild detergent 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	1080g
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

CDS® Hinge / Aluminium shells Name	Length of thigh shell	Length of lower leg shell		Circumference of lower leg	ArtNo. left	ArtNo. right
Knee Flexion L/L	23 - 25,5 cm	26,5 - 29 cm	36 - 66 cm	32 - 47 cm	904LL-L	904LL-R
Knee Flexion L/M	23 - 25,5 cm	26,5 - 29 cm	33 - 43 cm	24 - 35 cm	904LM-L	904LM-R
Knee Flexion M/L	18,5 - 21 cm	20,5 - 23,5 cm	36 - 66 cm	32 - 47 cm	904ML-L	904ML-R
Knee Flexion M/S	17,5 - 20 cm	20,5 - 22,5 cm	30 - 40 cm	22 - 32 cm	904MS-L	904MS-R
CDS® Nano Hinge / Textile Shell Name	Length of thigh shell	Length of lower leg shell		Circumference of lower leg	ArtNo. left	ArtNo. right
Knee Flexion Junior / S/S	18 cm	20 cm	30 - 40 cm	22 - 32 cm	904SS-L	904SS-R
Knee Flexion Bambini / XS/XS	15 cm	18 cm	25 - 35 cm	20 - 30 cm	904XSXS-L	904XSXS-R
Knee Flexion Malinki / XXS	12 cm	15 cm	20 - 30 cm	15 - 25 cm	904XXS-L	904XXS-R

User Instructions

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.

VERSION: EN 08.2022



Medical device



Manufacturer



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