

Sehr geehrte Kunden, sehr geehrter Kunde,

vielen Dank, dass Sie sich für ein Bauerfeind-Produkt entschieden haben.

Jeden Tag erhalten wir eine Verbesserung der medizinischen Wirksamkeit unserer Produkte, denn Ihre Gesundheit liegt uns am Herzen. Bitte lesen Sie die **Gebrauchsanweisung** sorgfältig. Bei Fragen wenden Sie sich an Ihren Arzt oder Ihr Fachgeschäft.

- ### Zweckbestimmung
- Die SofTec Coxa ist ein Medizinprodukt zur Stabilisierung und Führung des Hüftgelenks.
- Luxationsprophylaxe
 - Totendropoperatives Eingriff
 - Totendropoperatives Revisionsingriff
 - Hüftprothesektion (Girdlestone-Weilastion)
 - Hüftspacer bei zweizeitiger Weilverteileroperation
 - Coaxarthrose (mittelschwer bis schwerer Grad)
 - Instabilitäten

Anwendungsrisiken

⚠ Vorsicht:

• Nebenwirkungen, die den gesamten Organismus betreffen, sind bis jetzt nicht bekannt. Das sachgemähe Anwenden/Anlegen wird vorausgesetzt. Alle von außen an den Körper angelegten therapeutischen Hilfsmittel – Bandagen und Orthesen – können, wenn sie verwendet, zu lokalen Druckerkrankungen führen oder in seltenen Fällen auch Blutgefäße oder Nerven einengen. Bei Versorgungen, direkt postoperativ ist darauf zu achten, dass keine unnötigen Druckstellen im OP-Narbenbereich auftreten.
Die Gürtelansche SofTec Coxa sind ein verschleißtaugliches Produkt, das vom Arzt vorordnet und unter ärztlicher Anleitung getragen werden muss. Sie darf nur gemäß der Angaben dieser Gebrauchsanweisung und den aufgeführten Anwendungsgebieten getragen werden. Die Gürtelansche SofTec Coxa sind ein verschleißtaugliches Produkt, das vom Arzt vorerfolgen. Bei Nichtbeachtung kann die Leistung des Produktes beeinträchtigt werden, so dass eine Produktion/ausgeschlössen wird.
Sollten Sie außergewöhnliche Veränderungen an sich selbst feststellen (z.B. Zunahme der Beschwerden), suchen Sie bitte umgehend Ihren Arzt auf.
• Eine Kombination mit anderen Produkten muss vorher mit dem behandelnden Arzt abgesprochen werden.
• Bitte lassen Sie das Produkt nicht mit fett- und säurehaltigen Mitteln, Salben und Lotionen in Berührung kommen.
• Hinsichtlich bestehender Rückgabemöglichkeiten zur ordnungsgemäßen Verwertung der Verpackung beachten Sie bitte die Hinweise der jeweiligen Verkaufsstelle, in der Sie dieses Produkt erhalten haben.

⚠ Enthält Naturkautschuklatex (Elastodien) dies kann bei Überempfindlichkeit zu Hautreaktionen führen. Legen Sie die Orthes ab, wenn Sie allergische Reaktionen bemerken.

Kontraindikationen

Überempfindlichkeiten von Krankheitswert sind bis jetzt nicht bekannt. Bei nachfolgenden Krankheitsbildern ist das Anlegen und Tragen eines solchen Hilfsmittels nur nach Rücksprache mit Ihrem Arzt angeeignet.

1. Hauterkrankungen / -verletzungen im versorgten Körperabschnitt, insbesondere bei entzündlichen Erscheinungen; ebenso bei aufgeworfenen Narben mit Anschwellung, Rötung und Juckreiz
2. Empfindungsstörungen
3. Verstärkte Einschränkung der Leistungsfähigkeit von Herz und Lunge (Gefahr der Blutdrucksteigerung bei anlegemim Hüftmittel und verstärkter körperlicher Leistung)

Anwendungshinweise

An- und Ablegen der SofTec Coxa:
• Legen Sie die SofTec Coxa um Ihr Becken. Positionieren Sie die Ortheseformschlaufe auf Ihren Beckenkämmen. Achten Sie darauf, dass die Gelenkschse richtig und mittig zum Oberschenkel verläuft **1**

• Zur Grundpositionierung führen Sie Ihre Finger in die dafür vorgesehenen "Fingerringe" auf beiden Verschlussstellen und verschieben unter einlegemaligen Zug den Orthesenrager (Bandage). Die rechte Verschlusshälfte wird dabei in die Veranschaulichte geklettet **2**. Nehmen Sie zuerst die Finger aus der linken und dann aus der rechten Tasche.
• Die rechte Positionierung der SofTec Coxa und die medizinisch-therapeutische Wirkung werden durch Zugurtigkeit sichergestellt.
• Zur Fixierung der SofTec Coxa nehmen Sie die Zuggurte, die im Rückenbereich umgelegt werden, in beide Hände und ziehen diese gleichmäßig nach vorne **3**. Achten Sie dabei darauf, dass die Gurte im unteren Anteil der Beckenschalen verlaufen und kletten Sie beide Gürtelenden auf den unteren Bereich des vorderen Verschlusses **4**. Die Gürtelansche können im Bedarfsfall auch übereinander geklettet werden.
• Zur leichteren Handhabung der SofTec Coxa kletten Sie die geöffneten Zuggurte immer gleichmäßig wieder auf selbigen fest. Das richtige Anlegen muss mit Ihnen gemäß der Gebrauchsanweisung und den aufgeführten Anwendungsgebieten getragen werden. Die Gürtelansche der Grundpositionierung sind verschleißtauglich, damit die SofTec Coxa nicht verrutschen kann. Zu locker geführte Gurte führen zum Verlust der medizinischen Wirkung.

Beinfassung:
• Positionieren Sie die unten geführte Beinfassung mittig am Oberschenkel und legen Sie die Beinbandage von hinten auf den Oberschenkel. Führen Sie Ihre Finger in die dafür vorgesehenen Fingertaschen auf beiden Verschlusshälften **5**.
• Schließen Sie den Verschluss, indem Sie die von innen kommende Verschlussseite auf die von außen kommende Formschlaufe aufklettet.
• Verschieben Sie nun die beiden vorderen Zuggurte der Beinfassung **6**.
• Die Hinten Unten-Länge-Zuggurte müssen beim An- und Ablegen der SofTec Coxa entfernt werden. Die Hinten Zuggurte werden bereits durch Fachpersonal an Ihren Oberschenkelumfang angepasst. Falls Sie diese in ihrer Position verstellen müssen, achten Sie bitte darauf, dass die Beinfassung mittig zum Oberschenkel verläuft. Lösen Sie zur Neuverstellung der Beinfassung die Hinten und vorderen Zuggurte.
• Positionieren Sie die Beinfassung mittig zum Oberschenkel und ziehen Sie gleichmäßig an dem unteren vorderen und unteren hinteren Zuggurt. Wiederholen Sie diese Vorgehensweise bei den oberen Zuggurt.
• Bei der Versorgung von beiden Hüftgelenken legen Sie die zweite Beinfassung zur ersten an.

Ablegen der SofTec Coxa:
• Öffnen Sie zuerst die vorderen Zuggurte der Beinbandage und kletten Sie diese locker auf der Oberschurte und öffnen Sie dann die Verschluss der Beinbandage. Danach öffnen Sie die Zuggurte der Beckenschalen und kletten diese locker auf die Zuggurte. Nun kann der Verschluss der Beckenschalen geöffnet werden. Halten Sie dabei die SofTec Coxa auf dem Rücken der sich auf dem Oberschenkel befindet, fest.
• Zur leichteren Handhabung der SofTec Coxa kletten Sie die geöffneten Zuggurte immer gleichmäßig wieder locker auf selbigen fest.

Das richtige Anlegen und Ablegen muss mit Ihnen geübt werden.

Reinigungshinweise
Hinweis: Setzen Sie die Orthes nie direkter Hitze aus z.B. Heizung, Sonnenstrahlung, usw.
• Das Gestrickteil der SofTec Coxa kann mit einem Feinwaschmittel bei 30°C durch Handwäsche gereinigt werden.
• Die Beinfassung kann einfach mit einem Schwamm und einer pH-neutralen Seife oder einem Haarshampoo (gerneigt) werden.
• Für die dafür notwendige Demontage und spätere Montage wenden Sie sich bitte an Ihr Fachpersonal.
Wir haben das Produkt im Rahmen unserer integrierten Qualitätsmanagementprozesse geprüft. Sollten Sie trotzdem eine Beanstandung haben, setzen Sie sich bitte mit Ihrem Sanitätsfachhandel oder in R Verbindung.

Einsatzort

Entsprechend den Indikationen (Hüfte). Siehe Zweckbestimmung.

Wartungshinweise

Bei richtiger Handhabung und Pflege ist das Produkt praktisch wartungsfrei.

Technische Daten / Parameter, Zubehör

Die SofTec Coxa ist eine Orthese für das Hüftgelenk. Sie besteht aus einer dreiteiligen Beinfassung, einem Gelenk, einer Becken- und Beinfassung.

Hinweis zum Wiedereinsatz

Das Produkt ist allein für Ihre Versorgung vorgesehen.

Gewährleistung
Es gelten die gesetzlichen Bestimmungen des Landes, in dem das Produkt erworben wurde. Soweit relevant, gelten länder spezifische Gewährleistungsregeln zwischen Händler und Konsument. Bitte lesen Sie die Gebrauchsanweisung. Diese basieren auf unseren langjährigen Erfahrungen und stellen die Funktionen unserer medizinisch wirksamen Produkte für lange Zeit sicher. Denn nur optimal funktionierende Hilfsmittel unterstützen Sie. Außerdem kann die Nichtbeachtung der Hinweise die Gewährleistung einschränken.

Meldepflicht
Aufgrund regionaler gesetzlicher Vorschriften sind Sie verpflichtet, jeden schwerwiegenden Schaden an dem Produkt zu melden. Bitte wenden Sie sich an den Hersteller, aus dem auch dem BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) unverzüglich zu melden. Unsere Kontaktdaten finden Sie auf der Rückseite dieser Broschüre.

Entsorgung
Sie können das Produkt entsprechend den nationalen gesetzlichen Vorschriften entsorgen.

Stand der Information: 2019-08

1 Orthes = orthotisches Hilfsmittel zur Stabilisierung, Entlastung, Ruhstellung, Führung oder Korrektur von Gliedmaßen oder Rumpf.
2 Fachpersonal in diesem Sinne ist jede Person, die sich nach für sie geltenden staatlichen Regelungen zur Anpassung und Einweisung in den Gebrauch von Orthesen befugt ist.
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- ### Indications
- Prevention of dislocation
 - Total replacement surgery
 - Total replacement revision surgery
 - Femoral head resection (Girdlestone arthroplasty)
 - Hip spacer for two-stage revision procedures
 - Osteoarthritis of the hip (moderate to severe)
 - Instabilities

Risks of using this product

⚠ Caution

• Side effects are not known to date. Proper use / application is assumed. All therapeutic aids applied externally on the body – supports and orthoses – can cause local pressure (irritations) if applied too tightly or in rare cases also constrict blood vessels or nerves. When fitted immediately after surgery, it is important to ensure that there are no unnecessary pressure points in the region of the surgical wound.
• Car devices are prescription medical devices. It is to be applied under medical supervision. SofTec Coxa must only be applied in compliance with these Instructions for Use and the indications listed.
• The SofTec Coxa is not to be opened or modified by a specific user.
• Manipulation of the joint must only be performed by appropriately trained specialist personnel. Failure to observe this may impair the performance of the product such that product liability is excluded.
• Improper modification of the product, including retrospective changes to the knitted fabric component must not be undertaken. Failure to observe this may impair the efficacy of the product such that product liability is no longer provided.
• If you experience unusual changes (e.g., your symptoms get worse), consult your physician immediately.
• Combination with other products must be agreed to in advance by the attending physician.
• Please do not allow the product to come into contact with fatty or acidic substances, ointments and lotions.
• Do not use the product in conjunction with household waste without problems.
• For package recycling see local regulations.

⚠ Contains natural rubber latex (Elastodien) which can cause skin irritation in persons with an allergy. Take off the support if you notice any allergic reaction.

Contraindications
Pathological hypersensitivities are not known to date. Given the following symptoms, the application and use of such an aid is only indicated following consultation with your physician.

1. Skin diseases / injuries in the region of the body under treatment, especially those with inflammatory phenomena, as well as open scars with swelling, reddening and overheating

2. Sensory deficits

3. Increased impairment of performance of the heart and lungs (risk of raised blood pressure with the application of aids and increased physical activity).

Application and removal of the SofTec Coxa:
• Place SofTec Coxa around your pelvis. Position the orthosis snugly on your iliac crests. Take care that the side bar runs laterally, centered on the thigh **1**.
• For basic positioning, insert your fingers into the finger pockets on both parts of the side bar and pull them evenly towards the front **2**. Take care here that the straps run along the lower part of the pelvic shells and across both ends of the straps with Velcro® tape to the lower part of the front fastener **3**. The ends of the straps can also be attached to one another with Velcro® tape, as required.
• For easier handling of the SofTec Coxa, always refasten the opened tension straps loosely right away with the Velcro® tape. We need to help you practice putting on the orthosis correctly. There must be basic tension of the straps on the pelvic shells so that the SofTec Coxa cannot slip. Straps that are too loose lead to a loss of medical efficacy.

Leg harness:
• Position the outside leg harness centered on the thigh and place the leg support around the thigh from the back. Insert your fingers into the finger pockets on both halves of the fastener provided for this purpose **4**.

• Pull the Velcro® tape from the side of the fastener coming from the inside with the fastener coming from the outside **5**.

• Now fasten the two front straps on the leg harness **6**.

• To fix the SofTec Coxa, take the tension straps, which are passed around the back, in both hands and pull them evenly towards the front **7**. Take care here that the straps run along the lower part of the pelvic shells and across both ends of the straps with Velcro® tape to the lower part of the front fastener **8**. The ends of the straps can also be attached to one another with Velcro® tape, as required.

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Leg harness:
• Position the outside leg harness centered on the thigh and place the leg support around the thigh from the back. Insert your fingers into the finger pockets on both halves of the fastener provided for this purpose **4**.

• Pull the Velcro® tape from the side of the fastener coming from the inside with the fastener coming from the outside **5**.

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Removing the SofTec Coxa:
• Open the front tension straps of the leg support first and attach these loosely to the tension straps with the Velcro® tape and then open the closure belt in the leg support. Then open the straps on the pelvic harness and attach them loosely to the straps with Velcro® tape. Now the closure belt on the pelvic harness can be opened. Keep the SofTec Coxa tight on the side on which the joint / leg shell is located.

• For easier handling of the SofTec Coxa, always refasten the opened straps loosely with the Velcro® tape.

Correct application has to be practiced with you.

Care instructions
• Do not expose the orthosis to direct heat (e.g., heaters, sunlight, etc.)!
• The SofTec Coxa knitted fabric may be cleaned by hand washing at 30 °C with mild detergent.
• The pelvic harness can be cleaned easily with a sponge and pH-neutral soap or shampoo.
• Please consult your orthotist about the necessary disassembly and subsequent assembly in this case.

We have tested the product as part of our integrated quality management system. Should you still have a complaint, please contact our technical advisor on-site or our customer service department.

Part of the body this product is used for
In accordance with the indications (Hip). See Purpose.

Maintenance instructions
With correct handling and care, the product is practically maintenance-free.

Technical specifications / parameters, accessories
The SofTec Coxa is an orthosis for the hip joint. It consists of a three-part pelvic frame – a hinge, a pelvic frame and a thigh harness.

Notes on reuse
The SofTec Coxa is intended for your treatment only.

Warranty
The legal provisions of the country in which the product was purchased apply. Country-specific warranty regulations that govern the relationship between the retailer and the buyer also apply where relevant. If you believe that a claim may be made under the warranty, please first contact the retailer from which you purchased the product directly.

Please do not make any changes to the product yourself! This particularly applies to individual adjustments made by specialists. Please follow our instructions for use and care. These are based on our experience gained over many years and ensure the functionality of our medically effective products for a long time. Only aids that function optimally can help you. Failure to follow the instructions may also restrict the warranty.

Duty to report
Due to regional legal regulations, you are obliged to immediately report any serious incident involving the use of this medical product to both the manufacturer and the responsible authority. Our contact details can be found on the back of this brochure.

Disposal
You can dispose of the product in accordance with national legal requirements.

Information status: 2019-08

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2 Specialist is any person who is authorized, according to their state's regulations, to fit and provide instructions on the use of supports and orthoses.
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