



## ENGLISH

### SYMBOLS



Medical Device

### INTENDED USE

The device is intended to support the ankle

### Indications for use

Situations requiring inversion/eversion restriction. These may include:

- Mild to severe ankle sprains
- Chronic ankle instability
- Post-cast and post-walker support
- Ankle injury rehabilitation and/or post-surgical use

No known contraindications.

### Warnings and Cautions:

- Always wear an absorbent sock under the device.
- Inspect the skin under the device's contact area before and after each use.

### GENERAL SAFETY INSTRUCTIONS

Read these instructions carefully before use. Keep them for future reference. Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

The patient should stop using the device and contact a healthcare professional:

- If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions.
- If any pain, skin irritation, or unusual reaction occurs with the use of the device. The device is for single patient – multiple use.

### USAGE

#### Device Application

This device is designed to be worn over an athletic sock. For safe use and optimal support wear the device inside a laced athletic shoe.

- Undo the contact closure straps.
- Spread the side stirrups and step into the device. Center the sides along the lower leg and ankle (Fig. 1).
- Hold the stirrups up against the leg while wrapping the lower contact closure strap snugly around the device (Fig. 2). Secure contact closure.
- If required, adjust the heel width by peeling back the bottom layer and reapply by engaging the hook and loop where the brace is snug (Fig. 3). Position the bottom of the stirrups to be at or slightly above the bottom of the foot.
- Wrap the contact closure top strap snugly around device (Fig. 4). Secure contact closure.
- Apply shoe and tighten laces (Fig. 5). Readjust the device as necessary for maximum comfort and support.

#### Device Removal

Unfasten the straps to remove the device.

#### Cleaning and care

- Wipe with a damp cloth and mild soap.
- Air dry, do not expose to direct heat.

Note: Do not machine-wash, tumble dry, iron, bleach, or wash with fabric softener.

Note: Avoid contact with salt water or chlorinated water. In case of contact, rinse with fresh water and air dry.

#### DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

#### LIABILITY

Össur does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

#### DEUTSCH

### SYMBOLE



Medizinprodukt

### VERWENDUNGSZWECK

Das Produkt ist zur Stützung des Knöchels vorgesehen

### Indikationen

Verletzungen, die Inversions-/Eversionsbeschränkungen erfordern. Hierzu zählen:

- Leichte bis schwere Verstauchung des Sprunggelenks
- Chronische Instabilität des Sprunggelenks
- Unterstützung nach Ablegen eines Gipsverbandes oder eines Walkers.
- Posttraumatische Rehabilitation des Sprunggelenks und/oder postoperative Anwendung

Keine bekannten Kontraindikationen.

### WARNUNGEN UND VORSICHTSHINWEISE:

- Immer einen absorbierenden Strumpf unter dem Produkt tragen.
- Untersuchen Sie die Haut unter dem Kontaktbereich des Produkts vor und nach jeder Anwendung.

### ALLGEMEINE SICHERHEITSHINWEISE

Lesen Sie diese Einweisung vor dem Gebrauch sorgfältig durch. Bewahren Sie sie zur späteren Verwendung auf.

Jeder schwerwiegende Vorfall in Bezug auf das Produkt muss dem Hersteller und den zuständigen Behörden gemeldet werden.

Der Patient sollte die Verwendung des Produkts einstellen und einen Arzt aufsuchen:

- Wenn sich die Funktionalität des Produkts verändert oder verloren geht oder wenn das Produkt Anzeichen von Beschädigung oder Verschleiß aufweist, die seine normalen Funktionen beeinträchtigen.
- Wenn bei der Verwendung des Produkts Schmerzen, Hautreizungen oder ungewöhnliche Reaktionen auftreten.

Dieses Produkt ist nur für die mehrfache Anwendung am einzelnen Patienten bestimmt.

### VERWENDUNG

#### Produktanwendung

Dieses Produkt ist zum Tragen über Sportstrümpfen vorgesehen. Das Produkt für eine sichere Verwendung und einen optimalen Halt in einem geschürten Sportschuh tragen.

- Die Klettverschlüsse lösen.
- Die seitlichen Elemente spreizen und das Produkt steigen. Die seitlichen Elemente mittig am Unterschenkel und Knochen ausrichten (Abb. 1).
- Die Seitenelemente am Bein festhalten und gleichzeitig den unteren Klettverschluss fest um das Produktwickeln (Abb. 2). Klettverschluss schließen.

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1. Undo the contact closure straps.

2. Spread the side stirrups and step into the device. Center the sides along the lower leg and ankle (Fig. 1).

3. Hold the stirrups up against the leg while wrapping the lower contact closure strap snugly around the device (Fig. 2). Secure contact closure.

4. If required, adjust the heel width by peeling back the bottom layer and reapply by engaging the hook and loop where the brace is snug (Fig. 3). Position the bottom of the stirrups to be at or slightly above the bottom of the foot.

5. Wrap the contact closure top strap snugly around device (Fig. 4). Secure contact closure.

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- Bien enrouler la sangle supérieure de la fermeture à contact autour du dispositif (Fig. 4). Fixer la fermeture à contact.
- Appliquer la chaussure et serrer les lacets (Fig. 5). Réajuster le dispositif au besoin pour un maximum de confort et de soutien.

The device is for single patient – multiple use.

### USAGE

#### Retrait du dispositif

Détailler les sangles pour retirer le dispositif.

### Nettoyage et entretien

- Nettoyer avec un chiffon humide et un savon doux.
- Sécher à l'air libre, ne pas exposer à la chaleur directe.

Remarque : ne pas laver en machine, sécher en séche-linge, repasser, utiliser d'eau de javel ou laver avec un assouplissant.

Remarque : éviter tout contact avec de l'eau salée ou chlorée. En cas de contact, rincer à l'eau douce et laisser sécher à l'air.

### Entfernen des Produkts

Lösen Sie die Gurte, um das Produkt zu entfernen.

### MISE AU REBUT

Le dispositif et l'emballage doivent être mis au rebut conformément aux réglementations environnementales locales ou nationales en vigueur.

### RESPONSABILITÉ

Össur ne assume aucune responsabilité pour quanto segue:

- Dispositivo non mantenuto come indicato nelle istruzioni d'uso.

• Dispositivo montato con componenti di altri produttori.

• Dispositivo utilizzato in modo non conforme alle condizioni d'uso, dell'applicazione o dell'ambiente raccomandati.

### ELIMINACIÓN

El dispositivo y el envase deben eliminarse de acuerdo con las normas medioambientales locales o nacionales correspondientes.

### RESPONSABILIDAD

Össur no asumirá responsabilidad alguna ante las siguientes circunstancias:

- El dispositivo no se mantiene según lo indicado en las instrucciones de uso.

• Al dispositivo se le aplican componentes de otros fabricantes.

• El dispositivo se utiliza de forma distinta a las condiciones de uso, aplicación o entorno recomendados.

### ADVARSLER OG FORSIGIGHEDSREGLER

Ønsker ikke at bruge enheden under anordningen.

• Undersøg huden under enhedens kontaktområde før og efter hver brug.

### INDIKASJONER FOR BRUK

Situasjoner som krever begrensning av inversjon/eversjon. Dette kan omfatte:

- lett alvorlig ankelstøvring

• kronisk ustabil ankel

• støtte etter bruk av gips og walker

• rehabilitering av ankelskade og/eller postkirurgisk bruk

### ENTSORGUNG

Das Gerät und die Verpackung sind gemäß den vor Ort geltenden oder nationalen Vorschriften umweltgerecht zu entsorgen.

### HAFTUNG

Össur übernimmt in den folgenden Fällen keine Haftung:

- Das Gerät wird nicht gemäß der Gebrauchsanweisung gewartet.

• Das Gerät wird mit Bauteilen anderer Hersteller montiert.

• Das Produkt wird nicht gemäß den Empfehlungen in Bezug auf

Einsatzbedingungen, Anwendung oder Umgebung verwendet.

### FRANÇAIS

### SYBOLES



Dispositif médical

Potilaan pitää lopettaa laitteen käytö ja ottaa yhteyttä terveydenhuollon ammattihenkilöön:

- jos laitteen toiminta muuttuu tai huonontuu tai jos laitteessa näkyy vaurioita tai kulumista, jota estäävät sen normaaleja toimintoja
- jos laitteen käytön yhteydessä ilmenee kipua, ihässäistystä tai epätavallisia reaktioita.

Laitte on tarkoitettu yhden potilaan käyttöön, ja se on kestokäytöinen.

### KÄYTÖ

**Laitteen pukeaminen**

Tämä laite on suunniteltu käytettäväksi urheilusukan päällä. Käytä laitetta nauhaillisten urheilukien sisällä turvallisen käytön ja optimoisen tuen varmistamiseksi.

- Aava kaikki tarrakiihnityshihnat
- Levitä sivutukilevät ja astu laitteeseen. Keskitä sivut säären alaosaa ja nalkkaa pitkin (**kuvा 1**).
- Pidä sivutukilevät vasten samalla, kun kiedot alemman tarrakiihnityshihnan tiukasti laitteen ympärille (**kuvा 2**). Kiinnitä tarrakiihnityshihna.
- Voit tarvittaessa säätää kantapään leveyttä irrottamalla poljakerroksen ja panemalla laitteen uudelleen palkalleen kiinnittämällä tarrakiihnityshuuan jalkeaan, jossa tuki on tiukasti kiinni (**kuvा 3**). Pane sivutukilevjen alareuna jalkapohjan korkeudelle tai hieman sitä korkeammalle.
- Kiedot ylempänä tarrakiihnityshihnaa tiukasti laitteen ympärille (**kuvा 4**). Kiinnitä tarrakiihnityshihna.
- Vedä kenkä jalkaan ja sidu nauhat (**kuvा 5**). Säädä laitetta tarvittaessa, kunnes se tuntuu mukavalta ja tukee hyvin.

**Laitteen irrottaminen**

Irrota hihnat laitteen irrottamiseksi.

**Puhdistus ja hoito**

- Puhdista kostealla liinalla ja miedolla saippualla.
- Anna kuivua, älä altista suoralle lämmölle.

**Huomautus:** Älä pese pesukoneessa, älä rumpukuivaa, silitä, valkaise tai käytä huuhdelluina nettaa.

**Huomautus:** Vältä kosketusta suolaveden tai kloorin veden kanssa. Jos laite joutuu kosketukseen tälläisten aineiden kanssa, huuhtele se raikkaalla vedellä ja anna kuivua.

**HÄVITTÄMINEN**

Laite ja pakkaus on hävitettävä paikallisten tai kansallisten ympäristömääräysten mukaisesti.

**VASTUU**

Össur ei ole vastuussa seuraavista:

- Laitetta ei ole huollettu käytöönhisissä neuvottulla tavalla.
- Laitteen kokoonpanossa käytetään muiten valmistajien osia.
- Laitteen käytössä ei noudataa suosittelua käyttöolosuhdetta, käytökköhdettä tai käyttöympäristöä.

**ΕΛΛΗΝΙΚΑ**

**Indications voor gebruik**

Omstandigheden die een beperking van inversie/versies vereisen. Bijvoorbeeld:

- Lichte tot ernstige enkelverstuiking
- Chronische instabiliteit van de enkel
- Ondersteuning na een gipsverband en walker
- Gebruik na operatie en/of tijdens revalidatie van enkelletsel

**ΣΥΜΒΟΛΑ**

**MD** Iatrotechneologikό προϊόν

**ΠΡΟΒΛΕΠΟΜΕΝΗ ΧΡΗΣΗ**

To proiόn proořízetai για υποστήριξη του αστράγαλου

**Ενδείξεις χρήσης**

Καταστάσεις κατά τις οποίες απαιτείται περιορισμός αναστροφής/εκστροφής. Σε αυτές ενδέχεται να διαβάστε μαζί μας στην αστράγαλο:

- Η πιά έως ασφαρά διαστρέματα στον αστράγαλο
- Χρόνια ασθεία του αστράγαλου
- Υποστήριξη μετά από γύρο και μετά από περιπατητή
- Αποκατάσταση τραυματισμού στον αστράγαλο /και μετεγειρητική χρήση

Δεν υπάρχουν γνωστές αντενδείξεις.

**Προειδοποιήσεις και προφυλάξεις:**

- Να φοράτε πάντα μια απορροφητική κάτω από το προiόν.
- Ελέγχετε το δέρμα κάτω από την περιοχή επαφής με το προiόν πριν και μετά από κάθε χρήση.

**ΓΕΝΙΚΕΣ ΟΔΗΓΙΕΣ ΑΣΦΑΛΕΙΑΣ**

Διαβάστε προεπική τις παρόύσες οδηγίες πριν τη χρήση. Φυλάξτε τις για μελλοντική αναφορά.

Οποιοδήποτε σοβαρό συμβόλο σε σχέση με το προiόν πρέπει να αναφέρεται στον κατασκευαστή και στις αρμόδιες αρχές.

Ο ασθενής πρέπει να σταματήσει να χρησιμοποιεί το προiόν και να επικοινωνήσει με επαγγελματία υγείας:

- Έναν παραπρότερη ή απώλεια της λειτουργικότητάς του προiόντος ή έναν το προiόν εμφανίζει ίχνη βλάβης ή φθοράς που εμποδίζουν τις κανονικές λειτουργίες του.
- Έναν εμφανιστεί οποιοδήποτε πόνος, ερεθισμός του δέρματος ή ασυνήθιστη αντίδραση με τη χρήση του προiόντος.

To proiόn proořízetai για πολλαπλές χρήσεις από έναν μόνο ασθενή.

**ΧΡΗΣΗ**

**Εργασμού η προiόντος**

Αυτό το προiόν έχει σχεδιαστεί για να φορεθεί πάνω από αθλητική κάτω. Για ασφαλή χρήση, δεν πρέπει να φορεται σε αθλητικό παπούτσι δεμένο με κορδόνια.

- Λύντε τους πάνες επαρφή.
- Απλώντε τα πλευρικά στηριγμάτα και εισάγετε το πόδι σας στο προiόν. Κεντράρετε τις πλευρές κατά μήκος του κάτω μέρους του ποδού και του αστράγαλου (**Εικ. 1**).
- Κρατήστε τα στηριγμάτα επάνω στο κάτω μέρος της πλευρικής ώμου του προiόντος (**Εικ. 2**). Ασφαλίστε την επαρφή.
- Εάν απαιτείται, ρυθμίστε το πλάτος της πτέρυγας αποκλείστας το κάτω στρώμα και επαντοποιήστε τα συνδεότας το άνωτρο και το βρόχο όπου ο νότρικος είναι σημιτένος (**Εικ. 3**). Τοποθετήστε το κάτω μέρος των στηριγμάτων έπου στο κάτω στρώμα του πάνου όπου το κάτω μέρος του πλευρικού είναι σημιτένος (**Εικ. 4**).
- Ασφαλίστε την επαρφή.
- Τοποθετήστε το πάνο στο κάτω μέρος των στηριγμάτων έπου στο κάτω στρώμα του πάνου όπου το κάτω μέρος του πλευρικού είναι σημιτένος (**Εικ. 5**). Ρυθμίστε ξανά το προiόν όπως απαιτείται για μέγιστη άνεση και υποστήριξη.

**Hulpmiddel verwijderen**

Maak de riemen los om het apparaat te verwijderen.

**Reinigen en onderhoud**

- Reinigen met een vochtige doek en milde zeep.
- Aan de lucht laten drogen, niet blootstellen aan directe hitte.

**Opmerking:** Niet in de machine wassen, in de droogtrommel drogen, strijken, bleken van water met wasverzachter.

**Opmerking:** Vermijd contact met chloor- of zout water. Bij contact afspoelen met schoon water en aan de lucht laten drogen.

**AFVOEREN**

Het hulpmiddel en de verpakking moeten worden afgevoerd volgens de betreffende plaatselijke of nationale milieuvorschriften.

**AANSPRAKELIJKHED**

Össur aanvaardt geen aansprakelijkheid voor het volgende:

- Hulpmiddel is niet onderhouden zoals aangegeven in de gebruiksaanwijzing.
- Hulpmiddel is samengesteld uit componenten van andere fabrikanten.
- Hulpmiddel is niet gebruikt volgens de aanbevolen gebruiks-, toepassings- of omgevingsomstandigheden.

**ΑΠΟΡΡΙΨΗ**

To προiόν και η συσκευασία θα τρέπεται να απορρίπτονται σύμφωνα με τους αντίστοιχους τοπικούς ή εθνικούς περιβαλλοντικούς κανονισμούς.

**ΕΥΘΥΝΗ**

H Össur δεν αναλαμβάνει καμία ευθύνη για τα ακόλουθα:

- Με συντήρηση του προiόντος με τις οδηγίες χρήσης.
- Συναρμόλωση του προiόντος με εξαρτήματα άλλων κατασκευαστών.
- Χρήση του προiόντος εκτός ουσιοτύπων συνθηκών χρήσης, εφαρμογής ή περιβάλλοντος.

**PORTUGUÊS**

**SÍMBOLOS**

**MD** Dispositivo médico

**UTILIZAÇÃO PREVISTA**

O dispositivo destina-se a apoiar o tornozelo

**Indicações de utilização**

Situações que requerem restrição de inversão/versão. Estas podem incluir:

- Entorses do tornozelo leigeras a graves
- Instabilidade crónica do tornozelo
- Suporrt pós-gesso e pós-andarilho
- Reabilitação de lesões no tornozelo e/ou utilização pós-cirúrgica

**NEDERLANDS**

**SYMBOLEN**

**MD** Medisch hulpmiddel

**BEOOGD GEBRUIK**

Het hulpmiddel is bedoeld voor ondersteuning van de enkel

**Indicaties voor gebruik**

Omstandigheden die een beperking van inversie/versies vereisen. Bijvoorbeeld:

- Light tot ernstige enkelverstuiking
- Chronische instabiliteit van de enkel
- Ondersteuning na een gipsverband en walker
- Gebruik na operatie en/of tijdens revalidatie van enkelletsel

**Avisos e precauções:**

- Utilizar sempre uma meia absorvente por baixo do dispositivo.
- Inspecionar a pele sob a área de contacto do dispositivo antes e depois de cada utilização.

**INSTRUÇÕES GERAIS DE SEGURANÇA**

Leia atentamente estas instruções antes da utilização. Guarde-as para referência futura.

Qualquer incidente grave relacionado com o dispositivo deve ser comunicado ao fabricante e às autoridades competentes.

O paciente deve deixar de utilizar o dispositivo e entrar em contacto com um profissional de saúde:

- Em caso de alteração ou perda de funcionalidade do dispositivo, ou se o dispositivo apresentar sinais de dano ou desgaste que limitem o seu funcionamento normal.
- Em caso de dor, irritação cutânea ou reação invulgar após a utilização do dispositivo.

O dispositivo destina-se a utilização num único paciente – várias utilizações.

**UTILIZAÇÃO**

**Colocação do dispositivo**

Este dispositivo foi concebido para ser usado sobre uma meia desportiva. Para uma utilização em segurança e um apoio perfeito, utilizar o dispositivo com calçado atlético com atacadores.

- Desapertar as correias com fecho de contacto.
- Abrir os estribos laterais e colocar o dispositivo. Centrar os lados ao longo da perna e sobre o tornozelo esquerdo (**Fig. 1**).
- Segurar os estribos junto à perna enquanto envolve a correia com fecho de contacto inferior confortavelmente à volta do dispositivo (**Fig. 2**). Fixar o fecho de contacto.
- Se necessário, ajustar a largura do calcâncio ao remover a camada de baixo e replicar, encalhando o gancho e alça onde a ortótese está justa (**Fig. 3**).
- Posicionar a base dos estribos ao nível da base do pé ou ligeiramente acima. Enrolar a correia com fecho de contacto superior confortavelmente à volta do dispositivo (**Fig. 4**). Fixar o fecho de contacto.

**DEVISSINGEN EN MELDEN:**

- Draag altijd een absorberende sok onder het apparaat.
- Inspecteer de huid onder het contactgebied van het hulpmiddel voor en na elk gebruik.

**ALGEMENE VEILIGHEIDSINSTRUCTIES**

Lees deze gebruiksaanwijzing voor gebruik zorgvuldig door. Bewaar de gebruiksaanwijzing voor toekomstig gebruik.

Elk ernstig incident met betrekking tot het hulpmiddel moet worden gemeld aan de fabrikant en de relevante autoriteiten.

De patiënt moet stoppen met het gebruik van het hulpmiddel en contact opnemen met een professionele zorgverlener:

- Bijs. verandering of verlies van de functionaliteit van het hulpmiddel of als het hulpmiddel getekend is van beschadiging of slijtage vertoont die de normale functies belemmeren.
- als pijn, huidirritatie of ongewone reacties optreden bij gebruik van het hulpmiddel.

Het hulpmiddel is uitsluitend bedoeld voor meervoudig gebruik door één patiënt.

**GEBRUIK**

**Hulpmiddel aanbrengen**

Dit apparaat is speciaal ontworpen om het te dragen over een atletische sok. Draag het apparaat voor veilig gebruik en optimale ondersteuning in een sportschoen met veters.

- Mak de sluitbanden los.
- Spred de beugels aan de zijkant en stap in het apparaat. Centreer de zijkanten langs het onderbeen en de enkel (**afb. 1**).
- Maak de sluitbanden los.
- Spred de beugels aan de zijkant en stap in het apparaat. Centreer de zijkanten langs het onderbeen en de enkel (**afb. 1**). Fixar o fecho de contacto.
- Se necessário, ajustar a largura do calcâncio ao remover a camada de baixo e replicar, encalhando o gancho e alça onde a ortótese está justa (**Fig. 3**).
- Posicionar a base dos estribos ao nível da base do pé ou ligeiramente acima. Enrolar a correia com fecho de contacto superior confortavelmente à volta do dispositivo (**Fig. 4**). Fixar o fecho de contacto.

**De laarsjes en schoenen:**

- Wear the device over a sport sock.
- Wear the device with laces.
- Adjust the width of the calcaneal strap if it has been damaged or worn.
- If pain, skin irritation or unusual reactions occur during use of the device.

**De laarsjes en schoenen:**

- Wear the device over a sport sock.
- Wear the device with laces.
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