

ENGLISH



Medical Device

INTENDED USE

The device is intended to keep the foot/ankle in a neutral position

Indications for use

Conditions that may benefit from resting with the ankle in a neutral position, such as:

• Plantar fasciitis

• Achilles tendinopathy

Contraindications

Plantar flexion contracture greater than 10°, severe uncontrollable plantar flexion spasticity.

Warnings and Cautions:

• Do not walk or attempt to place weight on the foot while using the device. This is not a weight-bearing device.

• Care should be taken not to overstretch the device.

• Patients with already compromised blood circulation in their extremities, like those with diabetes or peripheral vascular disease, should be extra careful and are advised to consult with a healthcare professional before using the device. If you experience pain, swelling, sensation changes, or if your extremity shows signs of insufficient blood flow (turns blue, white, or cold) while using this device, discontinue the use immediately and consult with a healthcare professional.

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.

Never wear the device directly over an open wound.

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.

DEUTSCH



Medizinprodukt

VERWENDUNGSZWECK

Das Produkt ist dafür vorgesehen, den Fuß/Knöchel in einer neutralen Position zu halten

Kontraindikationen

Plantarflexionskontraktur von mehr als 10°, schwere unkontrollierbare Spastik der Plantarflexion.

Indikationen

Zustände, bei denen es von Vorteil sein kann, den Knöchel in einer neutralen Position zu lagern, etwa bei:

USAGE

Device Application

The device should be applied while seated.

An athletic sock may be worn on foot for additional comfort.

1. Open all 3 buckles (Fig. 1).

2. Place foot inside the soft liner, ensuring that the heel is all the way to the back of the device and the toes should not extend past the end. The ankle should be at 90° when the device is properly positioned.

3. Fasten the buckles. Fasten ankle (Fig. 2), foot (Fig. 3), and calf strap (Fig. 4) in this order. If necessary, adjust the buckles to ensure a secure and comfortable fit (Fig. 5).

4. Release the hook and loop straps on each side of the device (Fig. 6). Pull up the straps to increase plantar fascia stretch and lower the straps to decrease plantar fascia stretch.

Device Removal

Loosen the hook and loop straps and open all 3 buckles to remove the device from the foot.

Accessories and Replacement Parts

Please refer to the Ossur catalog for a list of available replacement parts or accessories.

Cleaning and care

• Hand-wash using mild detergent and rinse thoroughly.

• Air dry.

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

Ossur 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.

Contra-indications

Contracture bloquée en flexion plantaire supérieure à 10°, spasticité sévère en flexion plantaire incontrôlable.

Avertissements et mises en garde :

• Ne pas marcher et ne pas essayer de mettre du poids sur le pied pendant l'utilisation du dispositif. Il ne s'agit pas d'un dispositif de mise en charge.

• Il faut bien faire attention à ne pas trop serrer le dispositif.

• Les patients souffrant de problèmes de circulation sanguine aux extrémités, comme ceux ayant du diabète ou une maladie vasculaire périphérique, doivent prendre les précautions nécessaires et consulter un professionnel de santé avant d'utiliser le dispositif. Pendant le port du dispositif, si vous ressentez une douleur, un gonflement ou une sensation inhabituelle, ou si votre extrémité montre des signes d'une circulation sanguine insuffisante (elle devient bleue, blanche ou froide), retirez immédiatement le dispositif et consulter un professionnel de santé.

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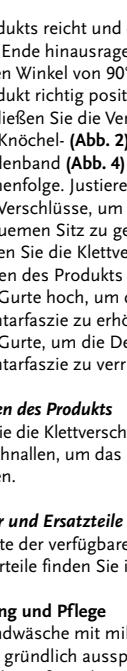
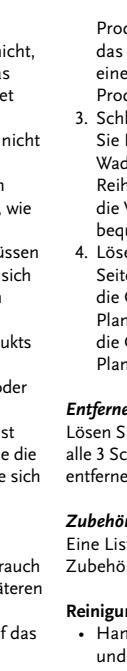
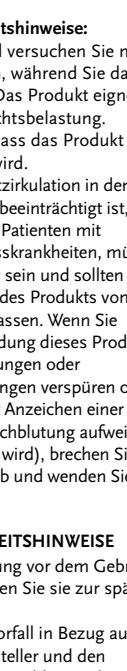
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