



The following should be read thoroughly before use:

Important Notes:

This document is designed to provide instructions on how this product/s is used. It is not a reference to clinical techniques, and does not replace local or national guidance or protocols.

Intended User:

For use by both suitably trained healthcare professionals in a healthcare establishment and 'Lay Users' in a home use environment.

Intended Purpose:

To relieve pain and inflammation to support healing.

Indications For Use:

- Plantar Fasciitis
- Achilles Tendonitis
- Heel Pain Management

Product Characteristics / Features:

- Provides gentle stretching of the plantar fascia and Achilles Tendon during sleep
- Maintains the foot at a therapeutic 90° angle
- Includes a repositionable toe wedge for added stretch
- Adjustable straps for customisable fit
- Soft, comfortable padding
- Fits both left and right

How it's supplied:

It is supplied non-sterile and ready for single patient use.

Devices Required For Use, And Interoperability Requirements:

None

Storage Conditions:

Store in box, away from direct sunlight and heat sources in a cool and dry environment.

Care and Maintenance:

- Wash periodically by hand with a damp cloth and a mild soap
- Use a towel to absorb most of the dampness and then allow to dry at room temperature
- Do not dry clean or tumble dry - allow to dry naturally away from direct heat sources
- Do not expose to alcohol, ointments or solvents
- The device should be safety checked by the providing service and/or user every 6 months.

Contraindications:

None

Precautions / Warnings / Residual Risks:

This product is to be used under the supervision of a medical professional. If you experience any pain, swelling, sensation changes, or any unusual effects while using this product, consult your medical professional immediately.

Possible Adverse Reactions:

None

Single Patient Use Precaution:

This device is designed and sold for single patient use only.

The effects of any unauthorised reuse can result in the following complications:

- Risk of Cross contamination;
- Risk of mechanical fatigue, and/or associated failure.

Disposal

Discard after single patient use and dispose of as common waste according to national guidelines.

Serious Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Directions For Use / Fitting Instructions:

- Apply the splint with the knee bent to maximise the angle of joint dorsiflexion.
- Place the foot into the splint, ensuring the heel is securely positioned at the back of the device and the foot is correctly aligned.
- Wrap the instep strap over the centre of the ankle joint and secure in place using the hook and loop closure. Once the instep strap is applied, straighten the leg and check strap tightness. NOTE: If the heel rises up within the splint, the instep strap may be too loose. Adjust as necessary.
- Secure the remaining straps snugly around the leg to ensure comfort and avoid pressure points.

Continued overleaf.

Directions For Use / Fitting Instructions Cont'd:

INSERTION OF WEDGE (If prescribed)

With the splint on, slide the foam wedge, (thin edge first) between the foot and splint securing with the attached hook and loop fastening. The thicker edge will rest under the toes.

CAUTION: Do not apply the foam wedge until instructed to do so by a physician or healthcare provider.

MODIFYING THE DEVICE (If required)

Remove the cover and fold the toe portion of the splint back. Separate the insert and slide it out from the cover.

Heat Mold the Insert:

To adjust the angle of the splint, manually bend or warm part of the insert. Use heat gun or hair dryer on moderate setting.

CAUTION: Do not overheat the insert. Overheating may damage the splint.

Allow insert to cool before reinserting into the cover and reattaching using the hook and loop fastening.

Sizes & REF / Codes

Size	Shoe Size		Code
	UK	EU	
Small	< 5	< 38	SNS-S
Medium	5 - 8½	38 - 42	SNS-M
Large	9 - 12	43 - 47	SNS-L

EXPLANATION OF LABELLING SYMBOLOGY
EN ISO 15223-1:2021, unless otherwise stated

	Manufacturer		Consult Instructions for Use		Unique Device Identifier
	Authorised representative in the European Community		Caution		Single Patient Use
	Medical Device		Non-Sterile		Quantity - Abbreviation
	Catalogue Number		CE Mark - EU Regulation 2017/745		Contains Latex
	Batch Code		UKCA Mark - UK Regulation SI 2002 No 618		Date of Manufacture

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