

**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:

Wedge Footwear to relieve pressure from heel and promote faster healing

Indications For Use:

- Neuropathic heel ulcerations
- Post-surgical weight relief
- Heel off-loading post-fracture

Product Characteristics / Features:

- Black nylon mesh upper
- Wedged design to remove pressure from the heel by shifting weight to the mid and forefoot
- Square toe design offers more space for toes
- Moulded thermoplastic rubber sole
- Secure hook and loop fastening
- Open toe and closed heel design
- Heel retaining strap to reduce shear

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:

If allergic skin rashes occur, please consult your healthcare professional

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.

Directions For Use / Fitting Instructions:

- Open all the straps as fully as possible
- Carefully insert the foot into the footwear making sure the heel is at the back of the shoe
- Close the straps securely but comfortably

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.



Sizes & REF / Codes

Size	Sole Length (CM)	Shoe Size		Code
		UK	EU	
X Small	22	<3	<35	HOS-XS
Small	24	3½ - 5	36 - 38	HOS-S
Medium	26	5½ - 7½	39 - 41	HOS-M
Large	28	8 - 9	42 - 43	HOS-L
X Large	30	9½ - 11	44 - 46	HOS-XL

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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