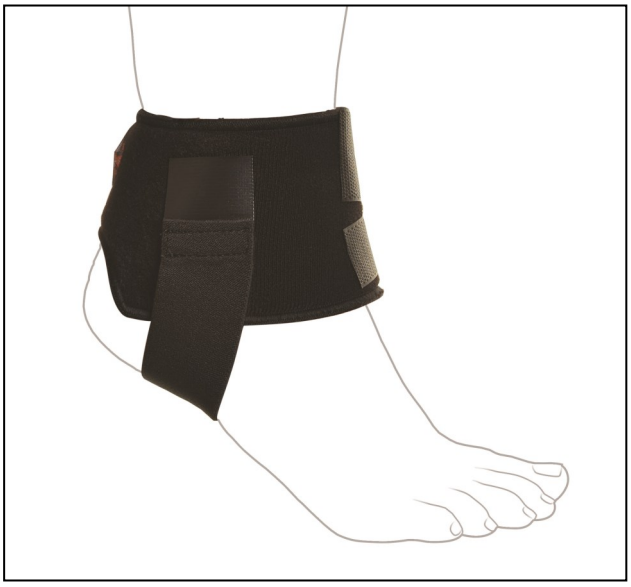
Plantar Fasciitis Strap - Instructions for Use

REF PFS



The following should be read thoroughly read 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 a suitably trained healthcare professionals in a healthcare establishment

Intended Purpose:
To reduce the pain caused by Plantar Fasciitis.

Indications For Use:
- Plantar Fasciitis.

Product Characteristics / Features:
Provides continuous elastic tension and pressure to reduce pain.

Key functional elements include:
- Fits easily into most types of footwear,
- Can be worn day or night
- Effective whilst walking or at rest

How it's supplied:
It is supplied non-sterile, ready for single patient multiple 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.

Contraindications:
Not suitable for people with severe circulatory impairment or other medical conditions where the elastic band could further reduce circulation or cause problems related to excess pressure.

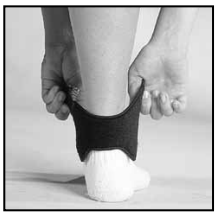
Care and Maintenance:
Wash periodically by hand with a damp cloth and mild soap
Use a towel to absorb most of the dampness and then allow to dry at room temperature.
Do not hang up, or iron and do not expose to direct heat sources such as stoves, heaters, radiators, direct sunlight etc
Do not expose to alcohol, ointments or solvents.
The device should be checked regularly for signs of damage or wear. If in doubt, always consult your healthcare professional

Precautions / Warnings / Residual Risks:
Do not dry clean or tumble dry - allow to dry naturally away from direct heat sources
Do not expose to alcohol, ointments or solvents
Do not use if package is damaged or broken.
Keep dry and away from direct sunlight and heat sources in a cool and dry environment.
If allergic skin rashes occur, please consult your healthcare professional

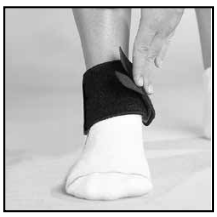
Possible Adverse Reactions:
None

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:

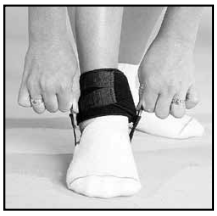


1. Centre the cutaway notch of the foam wrap over the Achilles tendon with the upper edge of the wrap above the ankle at the smallest point of the leg.



2. Wrap the long end of the foam piece around the front of the ankle, using the short end of the foam to overlap. Use the two Velcro hook closures to fasten. If necessary, the long end may be trimmed with scissors. Tension the wrap comfortably snug around the ankle.

3. Remove the singular elastic band from the foam wrap in preparation for application.



4. Wrap the elastic band under the back edge of the arch and pull up and back with both ends . Press the hook ends onto the foam wrap to fasten. The elastic band should be applied to provide pressure just forward of the heel at the back of the arch. The tension from the elastic should be up and slightly back (about 15 degrees from vertical).

5. To adjust for pronation, detach the elastic band from the medical side, pull to desired tension and secure against the foam material.

PFS IFU - Revision 4 - January 2024

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UK CA CE

MD NON STERILE LATEX

BHTA British Healthcare Trades Association

APPROVED CODE TRADINGSTANDARDS.GOV.UK

nqa. ISO 13485 MEDICAL DEVICES

nqa. ISO 14001 ENVIRONMENTAL MANAGEMENT

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Patient Guide:

Daytime Wear - The elastic band should be tensioned as much as comfortably possible and should be worn during any walking, always following the directions from your healthcare professional.

Night-time Wear - During the first month, it can be helpful to wear the device at night with the tension of the elastic band reduced to prevent discomfort whilst sleeping. Please consult your healthcare professional as to whether this is recommended for you.

Disposal
Discard 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 & Codes

Size	Shoe Size		Code
	UK	EURO	
Small	<5	<37	PFS-S
Medium	5 - 8	37 - 40	PFS-M
Large	<9	>41	PFS-L

Labelling Symbology - EN ISO 15223-1:2021, unless otherwise stated			
	EC REP	REF	LOT
Manufacturer	Authorized representative in the European Community	Catalogue number	Batch code
LATEX	GB		
Contains Latex.	Manufactured in the United Kingdom of Great Britain and Northern Ireland on date	Caution	Consult *Instructions For Use*
MD	UDI	CE	UK CA
Medical device	Unique Device Identifier	CE Mark - EU Regulation 2017/745	UKCA Mark - UK Regulation SI 2002 No 618
		NON STERILE	1
Keep away from sunlight	Keep dry	Non-sterile	Single patient—multiple use
QTY			
Quantity - abbreviation	Warning, flammable material - Regulation ISO 7010—W021		Do not use if package is damaged and consult *Instructions For Use*

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