



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:

Immobilises and stabilises the wrist.

Indications For Use:

- Post-surgery / cast removal
- Post-injury e.g. sprains and strains
- Carpal Tunnel Syndrome

Product Characteristics / Features:

- Palmar and dorsal stays immobilise and support the wrist, preventing flexion and extension
- Breathable foam material
- Anatomically-contoured aluminium palmar splint
- Low contour at palmar crease allows full finger function
- Contact closure for easy application

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 a cool and dry environment.

Contraindications:

None

Care and Maintenance:

- Remove the metal stay from the brace before washing
- Wash in cold water, gentle cycle and mild soap
- Use a towel to absorb most of the dampness and then allow to dry at room temperature.
- Do not expose to alcohol, ointments or solvents.
- The device should be safety checked by the providing service and/or user every 6 months.

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:

1. Measure the patient's wrist and select the correct size
2. Undo the Velcro straps and open up the wrist brace fully
3. Position the wrist within the brace
4. Finally close the Velcro straps and check that the brace is not too tight and adversely affecting the patient's circulation

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.
















Disposal

Discard and dispose of as common waste according to national guidelines.


Sizes & REF / Codes

Size	Wrist Circumference		Code	
	Inches	CM	Left	Right
Small	4 - 5.5	11 - 14	PWS-S-L	PWS-S-R
Large	5.5 - 7	14 - 17	PWS-L-L	PWS-L-R

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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