



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:

Supports wrist and hand in resting position

Indications For Use:

- Severe contractures at wrist / PMC / Phalanges
- Cerebral Palsy
- Brain / Spinal Cord Injury
- Degenerative neuromuscular disorders

Product Characteristics / Features:

Resting Hand Splint

Key functional elements include:

- Full length hand & thumb support plate in heat mouldable thermoplastic
- Can be re-moulded to gradually improve position
- Removable and washable soft cushioning cover
- Wide, soft & padded wraparound straps with secure hook & loop closure
- Latex free

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 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 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 safety checked by the providing service and/or user every 6 months.

Contraindications:

None

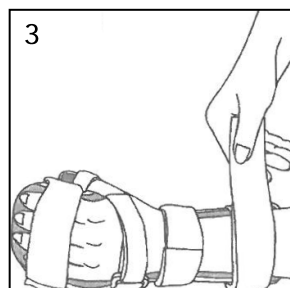
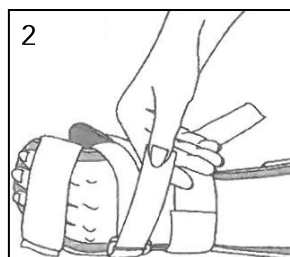
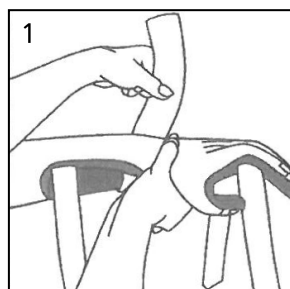
Precautions / Warnings / Residual Risks:

If allergic skin rashes occur, please consult your healthcare professional

Possible Adverse Reactions:

None

Directions For Use / Fitting Instructions:



1. Pre-position fingers and thumb by manually extending fingers while placing them in the orthosis
2. Firmly place the wrist in the orthosis and attach wrist strap (Figure 1)
3. Attach finger strap and optional MP strap over hand (Figure 2)
4. Secure thumb strap around thumb
5. Secure remaining forearm strap (Figure 3)
6. Check thumb and fingertips for excessive pressure

Continued overleaf...

Directions For Use / Fitting Instructions cont'd:

Heat Moulding:

Remove orthosis from patient. Remove liner and straps. Hold heat gun 2-4 inches over areas to be moulded and heat evenly for approximately 30 seconds. Bend thermoplastic to desired shape and allow to cool. Reheat and adjust if necessary.

How to apply the Foam Liner:

- Attach the liner to adhesive strips on the orthosis
- Attach optional MP strap to the adhesive strip provided on the back side of the orthosis in the palmar area with loop away from the thumb
- Secure all the straps sewn to the liner around the back of the orthosis and over the remaining adhesive strips

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.

Sizes & REF / Codes

Size	Palm Width		Code
	Inches	CM	
X Small	Up to 2½	Up to 6.5	BRHO-XS
Small	2½ - 3	7 - 8	BRHO-S
Medium	3 - 3¾	8.5 - 9.5	BRHO-M
Large	3¾+	10+	BRHO-L

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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