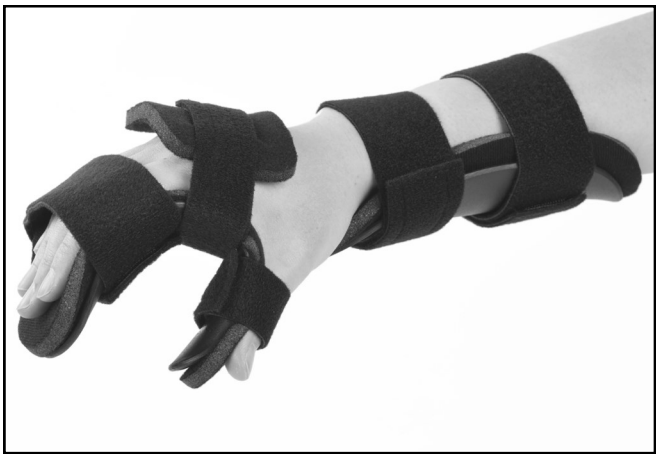
Basic Resting Hand Orthosis- Instructions for Use

REF BRHO



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 swelling and pain whilst offering support and immobilisation of the wrist and hand.

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 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.

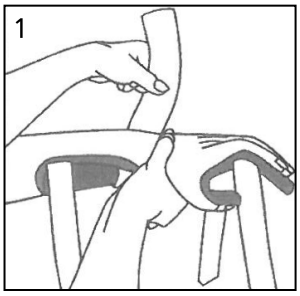
Contraindications:
None

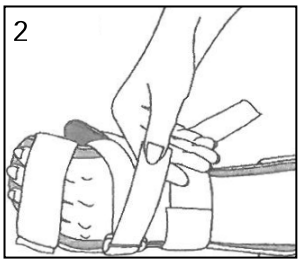
Precautions / Warnings / Residual Risks:
Do not dry clean or tumble dry - allow to dry naturally away from direct heat sources
Do not expose to alcohol, ointments or solvents
Do not use if package is damaged or broken.
Keep dry and away from direct sunlight and heat sources in a cool and dry environment.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

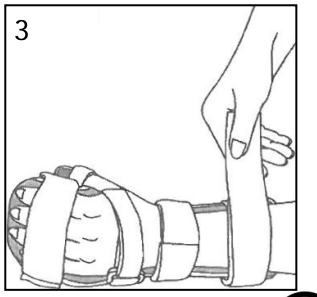
Possible Adverse Reactions:
None

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. 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...

BRHO IFU—Version No: 5 - January 2024

CHANECO LTD
4 Kilvey Road, Brackmills, Northampton, NN4 7BQ
T: 01604 709999 F: 01604 700057
www.chaneco.co.uk

UK CA CE

MD NON STERILE LATEX

BHTA British Healthcare Trades Association

tsi APPROVED CODE TRADINGSTANDARDS.GOV.UK

nqa. ISO 13485 MEDICAL DEVICES

nqa. ISO 14001 ENVIRONMENTAL MANAGEMENT

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

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 & 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 15223-1:2020, 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 use
QTY			
Quantity - abbreviation	Not Fire Retardant		Do not use if package is damaged

BRHO IFU—Version No: 5 - January 2024

CHANECO LTD
4 Kilvey Road, Brackmills, Northampton, NN4 7BQ
T: 01604 709999 F: 01604 700057
www.chaneco.co.uk

UK CA CE

MD NON STERILE LATEX

BHTA

APPROVED CODE TRADINGSTANDARDS.GOV.UK

nqa. ISO 13485 MEDICAL DEVICES

nqa. ISO 14001 ENVIRONMENTAL MANAGEMENT