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Neurotec Restorative Hand Orthosis

Instructions for Use



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Neurotec Restorative Hand Orthosis

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TalarMade Ltd is a UK-based manufacturer of Class I medical devices, committed to providing high-quality, safe, and effective products designed to support healthcare professionals and patients.

This Instruction for Use (IFU) document provides essential information for the correct and safe use of TalarMade products, in compliance with the requirements of the UK Medical Devices Regulations 2002 (as amended) and the EU Medical Device Regulation (EU) 2017/745 (MDR), as applicable.

All TalarMade medical devices are designed, manufactured, and distributed under a certified Quality Management System in accordance with ISO 13485:2016, ensuring that they consistently meet both regulatory and customer requirements for safety, performance, and reliability.

Prescribers and users are advised to read this document carefully before use. Proper

understanding and adherence to the instructions, warnings, and precautions outlined herein are essential to ensure optimal product performance and to minimise the risk of misuse or adverse events.

Product Details

Product Name: Neurotec Restorative Hand Orthoses

GMDN: 41457 – Hand orthosis

BASIC UDI-DI (if applicable): 50552043ULOWHOL8

Packaging contents (list what is included in the package): 1 x Neurotec Restorative Orthoses

Manufacturer Details

Manufacturers Registered Address

TalarMade Ltd. Edinburgh House, Millennium Way, Chesterfield, Derbyshire, S41 8ND

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Device Description

The Neurotec Restorative Orthosis is an upper limb resting splint with the following features:

- Heat mouldable thermoplastic full hand and thumb support plate
- Soft, padded removable and washable cover with Outlast® (thermo-regulating material) lining
- Wide, soft and padded wrap-around touch-and-close straps
- Numbered straps for easy application
- Removable finger separator for overlapping fingers

- Available in 3 sizes (Small, Medium and Large) - Left or Right
- This device is intended for **single patient use only** and not designed for multi

users

Intended Use

The Neurotec Restorative Orthosis is an adjustable resting splint designed to prevent and treat severe contractures at the wrist, hand or fingers.

It achieves this function by providing a progressive low-level stretch to the soft issues surrounding the contracted joint aiming to maintain or increase muscle and tendon length gradually over time.

Target users are healthcare professionals and laypeople, both in hospital/healthcare environments and at home. The Neurotec Restorative Orthosis should be used as guided by a healthcare professional and as outlined in the instructions for use.

Indications

- Treatment of severe contractures at Wrist/MCP/Phalanges
- Prevention of contractures and associated tissue viability risks
- Increased muscle tone/spasticity
- Reduced pain/discomfort associated with finger/wrist/hand contractures

Due to the above, some of the patients that need this orthosis may have the following diagnoses:

- Cerebral palsy
- Brain/spinal cord injury
- Degenerative neuromuscular disorders

Contraindications

- Patients with skin at risk of break down
- Gross fixed deformities
- Open wounds coming into contact with the device

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Excess local pressure or friction due to improper fit i.e. too loose	Skin irritation, blistering, callus, ulceration	Ensure correct application Discontinue use if redness, irritation, or skin breakdown re-occurs and seek professional advice
⚠ **Follow Instructions For Use**	User misapplication	Ineffective immobilisation, increased injury risk or skin breakdown	Read the IFU thoroughly before first use. Only use as directed by a healthcare professional.
⚠ **Consult a Healthcare Professional**	Device irritating hand, wrist or fingers	Skin breakdown injury	Do not use if active ulcer or wound present
⚠ **Warning**	Worn when wet	Skin irritation, blistering or persistent and undue redness	Ensure device is dry after laundering before continuing use
⚠ **Warning**	Odour, contaminated with body fluids	Infection, cross contamination	Ensure device is laundered frequently to maintain its conformability, hygiene and comfort
⚠ **Warning**	Heating	Skin injury Damage to device	If heating thermoplastic shell, remove all soft goods before doing so and allow thermoplastic to cool fully before re-applying

Precautions

- This device is for **single patient use only**. Re-use by another individual may increase the risk of cross-contamination, improper fit, or compromised device performance
- The device should be worn as instructed by the prescriber
- Inspect the device integrity before use
- Remove brace and cease use if the brace causes pain, redness or skin breakdown

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Instructions for Use

Preparation

- Remove packaging
- Inspect brace, making sure all parts are intact and without damage

Application

NOTE: Only use as directed by a Healthcare Professional. Do not overstretch any joint.

1. With all straps unfastened apply hand to splint to ascertain appropriateness of fit
2. With brace removed from hand, thermoplastic hand and thumb plate can be removed from padding and heated (low temperature heat gun/hair dryer) to change shape (do not overstretch)
3. Re-apply cover to thermoplastic plate once required position obtained
4. Apply adjusted brace to hand
5. If using finger separators, locate one separator between each finger. Move separator unit up or down the splint to reach desired position between fingers. Attach to each side of splint with touch-and-close fastening.
6. Secure brace in required position by securing the 4 soft numbered straps to maintain required resting position
7. Strap tension should be firm and not be uncomfortable for patient
8. Begin wear schedule at 30 minutes before removing brace to check skin. Gradually increase wear time, as tolerance allows, to no more than 6 hours at a time.

Removal

1. Release the touch-and-close straps
2. Remove Neurotec Restorative Hand Orthosis from fingers/hand/wrist
3. Inspect skin, checking for any signs of irritation, redness, or pressure marks.

During Use

- Wearing schedule - follow the duration and daily wear time recommended by your healthcare professional or medical care plan
- Monitoring:

- Periodically check skin condition and comfort.
- Adjust positioning/shaping of brace as needed

Cleaning & Maintenance

- Remove outer padding from thermoplastic plate (undo touch and close fastening on underside of brace)
- Thermoplastic plate can be wiped clean as required
- Outer padding can be hand washed in cool water with mild detergent
- Do not use bleach or chlorine-based cleaning products
- Not for use in washing machine or tumble dryer

Storage Conditions

- Store in a **cool, dry place**, protected from direct sunlight and heat

Disposal Instructions

Dispose of the device and its packaging in accordance with applicable local, regional, or national regulations.

Regulatory Compliance

EU REP

EUROPEAN AUTHORIZED REPRESENTATIVE

MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

SRN number: DE-AR-000000002

CH REP

SWISS AUTHORIZED REPRESENTATIVE

MedNet SWISS GmbH, D4 Platz 4, 6039 Root D4, Switzerland

CHRN: CHRN-AR-20000730

Warranty Information

The device is supplied under the manufacturer's warranty as outlined in the current Terms and Conditions available on our website. Users are advised to review these terms

prior to use.

Contact Information

We are committed to continuously improving our products.
Please scan the QR code to share your feedback with us.

No camera? Click here or on the QR code to open the product feedback form.

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