



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:

To assist with foot elevation during walking and reduces the risk of trips and falls in patients affected by foot drop.

Indications For Use:

- Drop foot
- Stroke
- MS
- Neurological disorders

Product Characteristics / Features:

- Holds foot in neutral position and maintains true alignment
- Helps manage emerging spasticity
- Wearable day and night
- Includes pad set for additional comfort if required

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 a cool and dry environment.

Care and Maintenance:

- Remove the padding and wash periodically by hand in warm water and mild soap. Do not use fabric softener.
- 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.

Contraindications:

- Moderate to severe spasticity in the lower leg
- Sensory or circulatory disorders in the lower leg
- Moderate to severe oedema
- Moderate to severe foot deformities

Precautions / Warnings / Residual Risks:

If allergic skin rashes occur, please consult your healthcare professional. Wearing a sock underneath the orthosis to prevent chafing is advisable.

The Neuro-X AFO assists with toe clearance and ankle stability during walking. It is not intended to completely restrict motion or prevent contractures. Usage duration should be determined by a qualified healthcare provider.

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.

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.

Directions For Use / Fitting Instructions:

1. The plastic shell may be thermoformed using a heat gun, or trimmed and smoothed by a trained orthotist. Remove padding and avoid heating strap closures. Reapply padding after shaping.
2. Open out all the straps and gently place the foot into the orthosis, with the heel fully into the back section.
3. Fasten the upper strap around the front of the leg first using the integral plastic guide loop, then proceed to the strap over the toes, fastening securely with the hook and loop closure. Ensure snug but not constricting fit.
4. Thread the ankle strap diagonally from the outside of the foot through the integral plastic guide loop, fastening securely with the hook and loop closure but take care not to overtighten.
5. Stretch the functional elastic strap diagonally across the ankle and secure it using one of the holes to the hook in the calf section to create the desired tension.
6. Always wear the Neuro-X AFO with a closed, non-slip shoe. Walking or standing without appropriate footwear is not recommended.

Sizes & REF / Codes

Size	Shoe Size		Left	Right
	UK	Euro		
Small	4 - 5	35 - 37	AFO-NX-S-L	AFO-NX-S-R
Medium	5 - 6	37 - 39	AFO-NX-M-L	AFO-NX-M-R
Large	6 - 7	39 - 41	AFO-NX-L-L	AFO-NX-L-R
X-Large	7 - 10	41 - 44	AFO-NX-XL-L	AFO-NX-XL-R

EXPLANATION OF 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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