



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 provide support to the ankle joint following injury or post-surgery.

Indications For Use:

- Ankle sprains and strains
- Chronic ankle ligament instability
- Post-surgical ankle rehabilitation

Product Characteristics / Features:

- Provides mediolateral ankle stability to promote healing
- Figure of 8 strapping for secure fitting
- "Powerdial" closure system for ease of adjustment
- Two supportive and hand-mouldable aluminium stays to conform to patient's ankle anatomy for better fit
- Hand washable

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 in warm water with a mild soap
- Rinse thoroughly
- 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
- Ensure the brace is fully dry before reapplying
- 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:

Contains latex.

If allergic skin rashes occur, please consult your healthcare professional.

Possible Adverse Reactions:

Pressure, moisture, heat and dirt can cause redness and soreness of your skin. To avoid skin breakdown, keep the skin clean, dry, and cool. If you notice redness (that remains after the brace has been off for 15-30 minutes) or skin breakdown, remove the brace and consult with your GP or healthcare professional as soon as possible. At least once a day, take off the brace to wash your skin and check for redness and areas of pressure.

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.

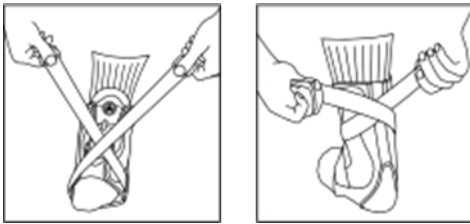
Serious Incident Reporting

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:

- Unfasten all the straps as fully as possible and ensure the powerdial closure system is loose by pulling out the knob to release the cable.
- Slide the brace onto the foot ensuring that the powerdial is facing forwards and adjacent to the shin.
- Tighten the ankle brace by pressing in the powerdial so that an audible click is heard and then turning it clockwise to pull in the cable and tighten the brace.
- If required, remove the two side stays from the side pockets and hand-mould to fit body contours. Once the desired shape is achieved, replace the stays via the top back corners of the side pockets.
- With the foot held in a right-angled or slightly dorsi-flexed position, pull one of the elastic figure of 8 straps tightly over the top of the foot and attach it to the top of the brace on the opposite side. Repeat this with the other strap. It does not matter which strap is fastened first. The firmer these straps are tightened, the more support the ankle brace will provide.

Size	Shoe Size		Code
	UK	EU	
Small	3 - 5	<38	XCA-S
Medium	6 - 8	38 - 42	XCA-M
Large	9 - 12	43 - 47	XCA-L
X Large	12+	47+	XCA-XL



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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CHANECO LTD
4 Kilvey Road, Brackmills, Northampton, NN4 7BQ
T: 01604 709999 E: info@chaneco.co.uk



Ukalia Ltd
Clockwise River, 48-60 King St,
Belfast, BT1 2BE
Northern Ireland
info@ukalia.com

