

The following should be read thoroughly read before use:

Important Notes:

This document is designed to provide instructions on how this product 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:

Intended to provide support to the neck spinal discs.

Indications For Use:

- Post-trauma e.g. Whiplash
- Cervical Spondylitis
- Cervical Spondylosis
- R/A and O/A cervical spine
- Herniated cervical disc
- General neck pain e.g. sprains and strains

Product Characteristics / Features:

A medium density soft collar for neck support, available in a choice of depths, with hook and loop closure for ease of use and secure fastening.

Key functional elements include:

- Covered with soft stockinette
- Hook and loop closure for ease of use and secure fastening
- Suitable for night-time use
- Available in 2½" and 3½" depth
- Hand washable
- Latex free

How it's supplied:

It is supplied non-sterile and ready for single patient use.

Devices Required For Use, And Interoperability

Requirements:

N/A

Storage Conditions:

Store in a cool and dry environment.

Care and Maintenance:

- Hand wash in warm water and mild soap.
- 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

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:

- Choose the correct size and depth of collar - Your chosen collar size needs to be at least 2" / 5cm longer than your neck circumference
- Open the hook and loop strap at the back of the collar
- Find the contoured part of the collar in the centre and place under the patient's chin
- Whilst holding the collar in place fold either sides of the collar around to the back of the neck and securely fasten together with the hook and loop fastening
- Please check that the collar is not restricting any air flow and causing any breathing difficulties

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	Collar Length		Depth	
	Inches	CM	2½"	3½"
X Small	14	35.5	SFC2-XS	SFC3-XS
Small	16	40.5	SFC2-S	SFC3-S
Medium	18	46	SFC2-M	SFC3-M
Large	20	51	SFC2-L	SFC3-L
X Large	22	56	SFC2-XL	SFC3-XL
XX Large	24	61	SFC2-XXL	SFC3-XXL

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

SFC IFU - Revision 6 - September 2024

 **CHANECO LTD**
4 Kilvey Road, Brackmills, Northampton, NN4 7BQ
T: 01604 709999 F: 01604 700057



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

