

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:

Cervical support. Movement restriction.

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 box, away from direct sunlight and heat sources in a cool and dry environment.

Care and Maintenance:

Hand wash in warm water and mild soap.
Do not dry clean or tumble dry - allow to dry naturally away from direct heat sources.
Do not use bleach.
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.

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 & Codes

Size	Collar Length		Depth	
	Inches	CM	2½"	3½"
X Small	13	33.	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	23	59	SFC2-XL	SFC3-XL
XX Large	24	61	SFC2-XXL	SFC3-XXL

Labelling Symbology - EN ISO 15223-1:2020, unless otherwise stated

			
Manufacturer	Authorized representative in the European Community	Catalogue number	Batch code
			
Contains Latex.	Manufactured in the United Kingdom of Great Britain and Northern Ireland on date	Caution	Consult Instructions For Use
			
Medical device	Unique Device Identifier	CE Mark - EU Regulation 2017/745	UKCA Mark - UK Regulation SI 2002 No 618
			
Keep away from sunlight	Keep dry	Non-sterile	Single patient use
QTY			
Quantity - abbreviation	Not Fire Retardant		Do not use if package is damaged

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