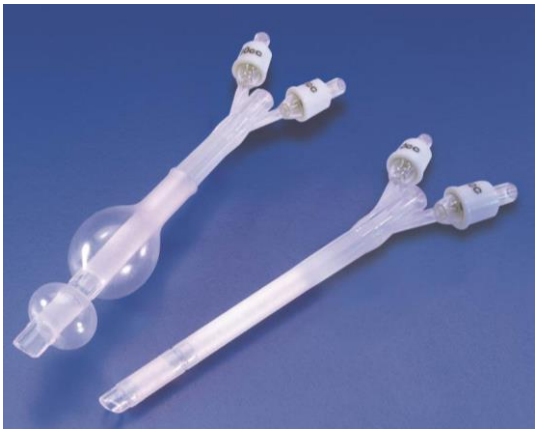
NETWORK ENT PRODUCTS

Epistaxis Balloon Catheter Range Specification Sheet



Product Overview

The NETWORK ENT® Epistaxis Balloon Catheter range has been specifically designed to stem serious posterior nasal bleeding (epistaxis), which cannot be stemmed by other methods.

- Independently inflatable cuffs to facilitate proper placement
- Airway tube feature to permit nasal breathing and access for suctioning
- Streamlined design to improve patient comfort during catheter insertion and removal
- Biocompatible-silicone construction supports conformation to the nasal structure.
- Available in two sizes: small and large
- Supplied sterile, single use only, one per box, declared 5 year shelf life

Epistaxis Balloon Catheter Size Options

Size	Length	Product Code
Large	120 mm	72- 3000
Small	97 mm	72-3001

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Material Specification

Product Component	Specification
Epistaxis Catheter	Silicone
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard

Intended Use

Epistaxis catheters are used to stem serious posterior nasal bleeding (epistaxis), which cannot be stemmed by other methods. Establishes posterior tamponade against the posterior choana by traction of the balloon.

Instructions for Use

The instructions for use and suggested surgical technique are supplied in the form of a multi-lingual leaflet with instructions given in diagram form where appropriate. The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product.

Sterilisation

Products are sterilised by Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1(current).

Conformity to the European Directives

Epistaxis Catheters listed in section 2.2 are disposable medical devices which are invasive in a body orifice (non-surgically) and intended for short term use. The Classification therefore is I according to rule 5 of Annex IX of the Medical Devices Directive 93/42/EEC.

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