

Epistaxis PVA Nasal Packs Specification Sheet



Product Overview

The NETCELL® Epistaxis PVA Nasal Pack range, provides an immediate and effective solution for controlling bleeding.

- Specifically designed to quickly contain and restrict blood loss
- Rapid absorption of fluid creates a taponading effect to stem bleeding
- Available in long version to quickly pack entire nasal cavity or small version to treat anterior epistaxis
- Layered pack option allows thickness to be customised to individual requirement
- Manufactured from ultra-smooth, biocompatible PVA sponge for improved patient comfort
- Supplied sterile, single use only, declared 5 year shelf life

Epistaxis PVA Nasal Pack Size Options

Product Size (cm)	Format	Pack Size	Product Code
10.0 x 1.5 x 2.5	Long	10	10-140
10.0 x 1.0 x 2.5	Slimpack Long	10	10-141
10.0 x 1.5 x 2.5	Long Layered	10	10-141L
8.0 x 1.5 x 2.5	Medium	10	10-145
8.0 x 1.0 x 2.5	Medium	10	10-146
5.5. x 1.5 x 2.5	Short	20	10-150









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Material Specification

Product Component	Specification
Nasal Pack	100% Polyvinyl Alcohol Sponge (PVA)
String	Braded Spring Polyester – Medical - Dacron ® Polyester Fibre
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

ENT PVA sponge products are designed to staunch blood loss after invasive surgery or traumatic injury in ENT surgery. The PVA sponge reacts quickly to absorb blood and body fluids. PVA is biocompatible and in some instances can be used for post-operative tissue support and to carry medication to the operative site (where specified in the Instructions for Use).

The long and medium Epistaxis Packs are intended for simple and quick packing of the entire nasal cavity, the most efficient way to contain and restrict blood loss. Fluid absorption causes the pack to expand producing a tamponading effect. The short Epistaxis Pack is intended for the quick, convenient treatment of anterior epistaxis.

Sterilisation

Products are sterilised by Gamma irradiation from a Cobalt 60 source in accordance with a validated 25 kGy cycle. Sterilisation is carried out in accordance with the requirements of ISO 11137-1 (current) and ISO 11137-2 (current) and the 25 kGy dose is substantiated by VD_{25} Method Max testing.

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.

Conformity to the European Directives

The range of PVA sponge products is supplied sterile and intended for short-term use in the nasal cavity. Therefore, classification is Class I Sterile, (rule 5, Annex IX, 93/42/EEC Medical Devices Directive). Classification is therefore Class I STERILE

