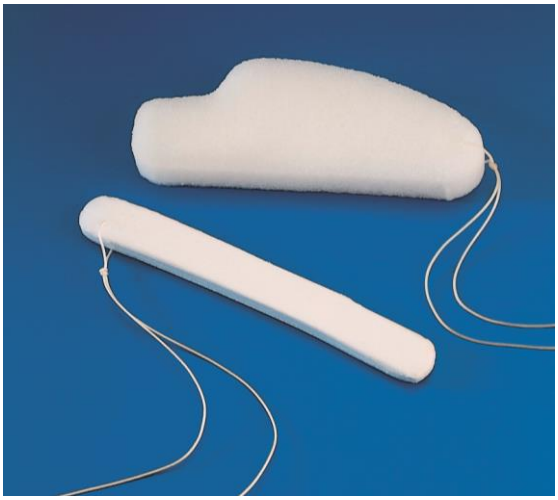
NETCELL

Anatomical PVA Nasal Packs Specification Sheet



Product Overview

The NETCELL® Anatomical PVA Nasal Pack range, provides an immediate and effective solution for controlling post-operative bleeding.

- Specifically designed for use after septal, turbinate and rhinoplasty surgery
- Anatomically shaped to fill the entire nasal cavity
- Provides gentle, equal pressure within the nasal cavity when absorbing post-operative bleeding
- Manufactured from ultra-smooth, biocompatible PVA sponge for improved patient comfort
- Available with Integral airway tube for improved venting and reduced risk of obstruction
- Slimpack option has been developed for use in conjunction with a nasal splint following septal surgery
- Supplied sterile, single use only, declared 5 year shelf life

Anatomical PVA Nasal Pack Size Options

Product Size (cm)	Format	Pack Size	Product Code
8.0 x 1.5 x 3.0	Standard	10	10-120
8.0 x 1.5 x 3.0	Standard with Airway Tube	10	10-120T
8.0 x 1.0 x 3.0	Slimpack	10	10-125

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Material Specification

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

Intended Use

PVA sponge ENT 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).

Nasal Packs are intended for use after septal, Turbinate and Rhinoplasty surgery and provide gentle equal pressure within the nasal cavity when absorbing post-operative bleeding. Patient comfort can be enhanced by using an airway tube. Anatomical Nasal Packs are clinically designed to fill the nasal cavity and provide gentle and equal support of the tissue and efficient absorption of postoperative bleeding. The slimpack version nasal pack has been developed for use in conjunction with a nasal splint following septal surgery.

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

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