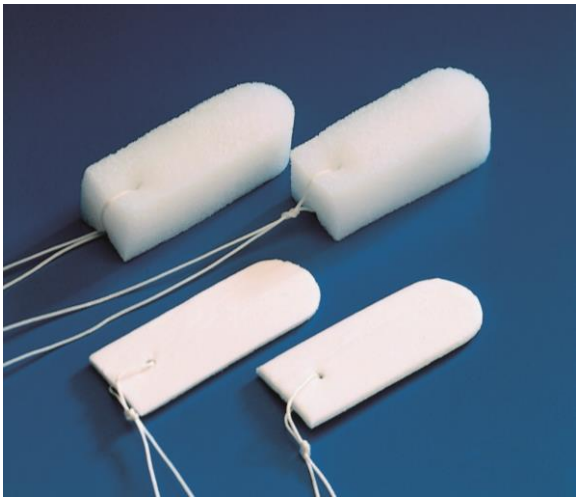
NETCELL

PVA Sinus Packs Specification Sheet



Product Overview

The NETCELL® PVA Sinus Pack is specifically developed for post-operative packing following an F.E.S.S procedure.

- Designed to prevent lateralization of the middle turbinates post-operatively
- Can be used to pack the Osteomeatal complex to leave the nasal passage clear for easier breathing
- Manufactured from ultra-smooth, biocompatible PVA sponge for improved patient comfort
- Supplied sterile, single use only, declared 5 year shelf life

PVA Nasal Pack Size Options

Product Size	Format	Pack Size	Product Code
2.5 x 1.20 x 2.0 cm	Standard	2 Per Pack/ Box of 10 Packs	20-200
3.5 x 1.20 x 1.2 cm	Standard	2 Per Pack/ Box of 10 Packs	20-210
3.5 x 0.90 x 1.2 cm	Medium	2 Per Pack/ Box of 10 Packs	20-211

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Material Specification

Product Component	Specification
Sinus Pack	100% Polyvinyl Alcohol Sponge (PVA)
String	Braded Spring Polyester – Medical - Dacron ® Polyester Fibre
Pouch Packaging	Tyvek/Film (20-210, 20-211) Metalized Film/Film (20-200, 20-212)
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).

Sinus Packs are intended for use as post-operative packing after functional endoscopic sinus surgery, to prevent pot-operative lateralisation of the middle turbinates. The packs can also be used to fill the osteomeatal complex to leave the nasal passage clear for easier breathing.

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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