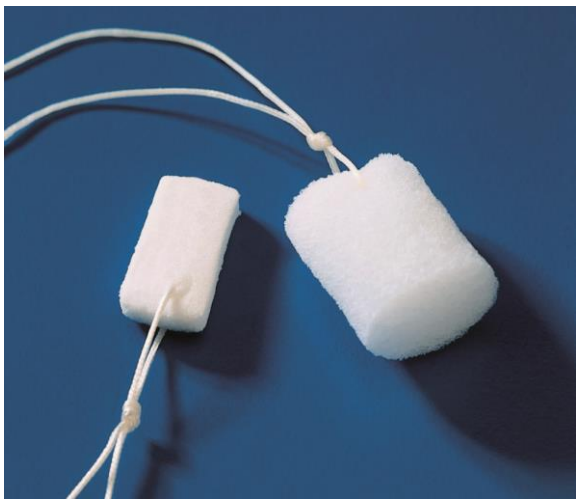
NETCELL

PVA Post-Operative Ear Packs Specification Sheet



Product Overview

The NETCELL® PVA Post-Operative Ear Packs are specifically designed to help prevent stenosis of the ear canal, post-surgery.

- PVA structure will not expand lengthways, allowing product to be used for graft tissue support following Tympanoplasty surgery
- Available with string (strung) or without (unstrung)
- Manufactured from ultra-smooth, biocompatible PVA sponge
- Supplied sterile, single use only, declared 5 year shelf life

PVA Ear Wicks Size Options

Product Size (mm)	Format	Pack Size	Product Code
9 mm dia x 15 mm	Strung (with string)	10	30-320
12 mm dia x 24 mm	Unstrung (without string)	10	30-340

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Material Specification

Product Component	Specification
Ear Pack	100% Polyvinyl Alcohol Sponge (PVA)
String	Braded Spring Polyester – Medical - Dacron ® Polyester Fibre
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).

PVA Post-Operative Ear Packs are used to prevent stenosis of the ear canal following surgery and will not expand lengthways making it suitable to support a graft following Tympanoplasty.

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 ear canal up to the eardrum. 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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