NETCELL

Series 5000 PVA Nasal Packs Specification Sheet

Product Overview

The NETCELL® Series 5000 PVA Nasal Pack range, provides an immediate and effective solution for controlling post-operative bleeding. The unique design combines a non-stick outer surface with an ultra-smooth biocompatible PVA sponge to significantly reduce patient discomfort during removal.

- Specifically designed for use after septal, turbinate and rhinoplasty surgery
- Soft covered surface provides a non-stick interface against tissue in growth
- Remains hydrated for up to 7 days without rehydration
- Double compression for easy insertion (50% slimmer than competitor products)
- Outer coating can be used in conjunction with water or oil-based medication
- Provides gentle, equal pressure within the nasal cavity when stenting post-operative bleeding
- Independent clinical study identifies the Series 5000 nasal pack to facilitate the least trauma during removal
- Supplied sterile, single use only, declared 5 year shelf life

PVA Nasal Pack Size Options

Product Size (cm)	Format	Pack Size	Product Code
6.0 x 1.5 x 2.0	Standard	10	15-105
8.0 x 1.5 x 2.0	Standard	10	15-110
8.0 x 1.0 x 2.0	Slimpack	10	15-111

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Material Specification

Product Component	Specification
Nasal Pack	100% Polyvinyl Alcohol Sponge (PVA)
String	Braded Spring Polyester – Medical - Dacron ® Polyester Fibre
Outer Layer	Polyurethane Sheath
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. The Series 5000 range is intended as a single hydration pack that will remain moist for up to 7 days and requires no hydration prior to removal. The external pouch provides non-stick interface against tissue ingrowth which facilitates much easier removal and patient comfort.

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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