



Product Overview

The NETCELL® PVA Microspheres have been specifically developed to control haemostasis during ENT micro surgery.

- Compressed microspheres can be hydrated with medication, and directly applied to the surgical area
- Manufactured from ultra-smooth, biocompatible PVA sponge
- Also suitable for use during middle ear procedures, to remove particles and control haemostasis
- Supplied sterile, single use only, declared 5 year shelf life

PVA Microsphere Size Options

Product Size (mm)	Format	Pack Size	Product Code
3 mm dia	Small	10 Per Pack/ Box of 10 Packs	30-380
5 mm dia	Large	10 Per Pack/ Box of 10 Packs	30-382

Material Specification

Product Component	Specification
Microspheres	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Metalized Film/Film (30-380) Tyvek/Film (30-381, 30-382)
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

PVA Microspheres are specifically intended for use in the middle ear cavity to control haemostasis and for the removal of wound tissue, during osteoplasty and stapedectomy procedures. The PVA Microspheres are suitable for the direct application of medication to the operating site.

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 VD₂₅ Method Max testing.

Instructions for Use

Instructions for Use are not supplied with this product as it can be used safely without.

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.