





### **Product Overview**

The NETCELL® PVA Ear Wicks are specifically designed to facilitate instant delivery of antibiotics into the ear canal, in order to provide fast pain relief when treating Otitis Externa.

- Manufactured from ultra-smooth, biocompatible PVA sponge
- Available as fenestrated option to enable aeration
- 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	Standard	50	30-300
9 mm dia x 15	Fenestrated	50	30-305
9 mm dia x 24	Standard	10	30-310
9 mm dia x 24	Fenestrated	10	30-315

## **Material Specification**







Product Component	Specification
Ear Wick	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Metalized Film /Film
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

#### **Intended Use**

PVA Ear Wicks are designed for delivering antibodies into the ear canal when treating Otitis Externa. The pack creates instant patient relief when hydrated with medicated otic drops.

### **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.

#### 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.

# **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



7 I D a n a