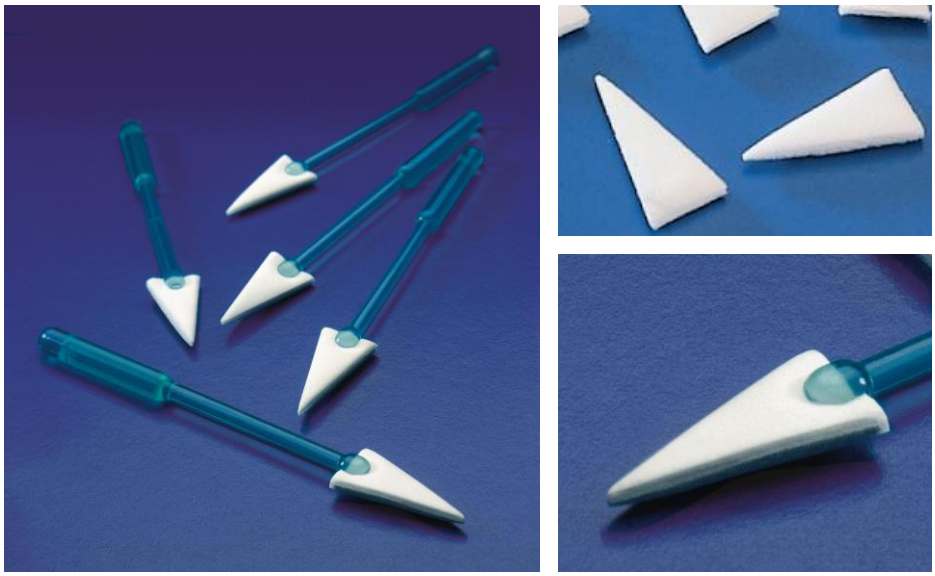
PVA Eye Spears and Points Specification Sheet



Product Overview

The EYETEC® PVA Eye Spear and Points range provides unrivalled quality and performance for the management of fluids during ophthalmic procedures.

- Constructed from ultra-smooth micropore PVA sponge
- Ultra-fast wicking action
- Lint and fibre free
- Suitable for tissue manipulation
- Supplied sterile, single use only, declared 5 year shelf life

PVA Eye Spear and Point Options

Product	Pack Size	Product Code
PVA Eye Spears	Pack of 5 box of 90	40-400
PVA Eye Spears	Pack of 5 box of 180	40-405
PVA Points	Pack of 10 box of 180	40-406

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Material Specification

Product Component	Specification
Eye Spear/Point	100% Polyvinyl Alcohol Sponge (PVA)
Eye Spear Handle	Medical Grade K-Resin
Pouch Packaging	Metalized Film /Film (40-400, 40-405) Tyvek/Film (40-406)
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

PVA sponge ophthalmic products are designed for the management of fluids and to staunch blood loss after invasive surgery or traumatic injury in the areas of ophthalmic surgery.

All spears and points are intended to absorb liquid, wicking it away quickly and efficiently from the operative site. A spear's wicking time is directly related to its ability to expand. The EYETEC® PVA spear is supplied compressed but expands immediately upon contact with body fluids, saline or balanced salt solution, wicking 10-15 times its own weight away from the operative 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 VD_{25} Method Max testing.

Instructions for Use

No instructions for use are provided as this device can be used safely without.

Conformity to the European Directives

EYETEC® PVA products are defined as invasive devices with respect to body orifices (Rule 5, Annex IX 93/42/EEC Medical Devices Directive) and are classified as Class I Sterile.

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