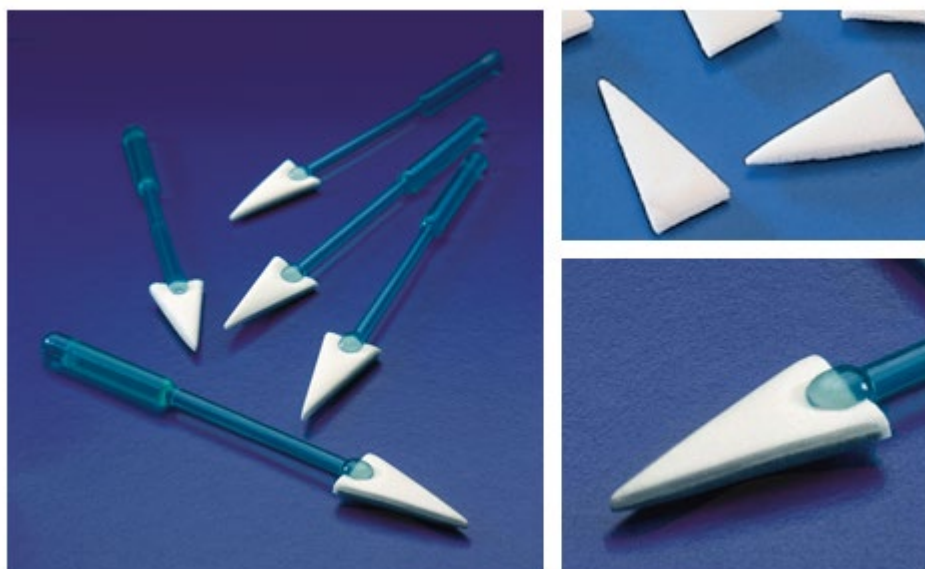


PVA Eye Spears and Points Specification Sheet



Product Overview

High quality and performance PVA Eye Spears and Points for the management of fluids during ophthalmic procedures:

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

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

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Intended Use

PVA and Cellulose ophthalmic sponge products are designed to staunch blood loss and absorb fluids from and around the eye during ophthalmic procedures. The PVA and Cellulose sponge reacts quickly to absorb blood and body fluids.

Intended Purpose

PVA spears:

A body and/or body orifice contact, single-use triangular piece of medical grade, highly absorbent PVA supplied with attachment to a polypropylene handle. Intended to be used in a sterile condition by healthcare professionals on any patient for the management of fluids, and to staunch blood loss after invasive surgery or traumatic injury in the areas of ophthalmic surgery. Can also be used for tissue manipulation. They have a cumulative transient use of less than 60 minutes on the conjunctiva (mucous membrane of the eye), cornea and/or surrounding tissue. There are no known contraindications for these devices.

PVA points:

A body and/or body orifice contact, single-use triangular piece of medical grade, highly absorbent PVA. Intended to be used in a sterile condition by healthcare professionals on any patient for the management of fluids, and to staunch blood loss after invasive surgery or traumatic injury in the areas of ophthalmic surgery. Can also be used for tissue manipulation. They have a cumulative transient use of less than 60 minutes on the conjunctiva (mucous membrane of the eye), cornea and/or surrounding tissue. There are no known contraindications for these devices.

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

The instructions for use are supplied in the form of a multi-lingual leaflet with instructions given. The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product and is also available to view and download at <https://www.networkmedical.co.uk/ifu-product-group>

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.