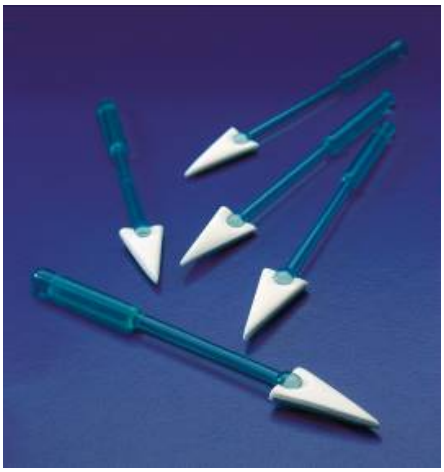
PVA Eye Spears Specification Sheet
PROCEDURE PACK (BULK) PRODUCT



Product Overview

High quality and performance PVA Eye Spears 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

NETWORK MEDICAL PRODUCTS LTD
Coronet House, Kearsley Road, Ripon, North Yorkshire, HG4 2SG, UK
Tel: +44 (0)1765 609555 Fax: +44 (0)1765 608476
info@networkmedical.co.uk | www.networkmedical.co.uk

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PVA Eye Spear Options

Product	Pack Size	Unit of Sale	Product Code
PVA Eye Spears	Pack of 5	Bag of 500 packs	2-400

Material Specification

Product Component	Specification
Eye Spear	100% Polyvinyl Alcohol Sponge (PVA)
Eye Spear Handle	Medical Grade K-Resin
Pouch Packaging	Metalised Foil Pouch

Intended Use

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

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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 11137-2 (current) and the 25 kGy dose is substantiated by VD_{25} Max Method testing.

Please note that PVA material is adversely affected by direct exposure to EO gas, therefore we supply these products inside a barrier foil that is sterilised by gamma irradiation. This allows the products to be included inside the procedure packs that are sterilised by EO and maintains the optimum performance for the end-user.

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.

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