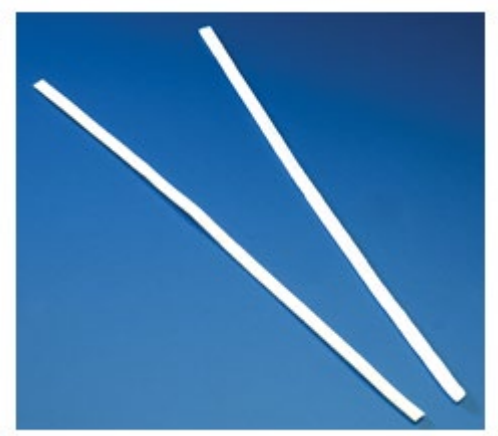
PVA Eye Wicks Specification Sheet
PROCEDURE PACK (BULK) PRODUCT



Product Overview

The EYETEC® PVA Eye Wick range has been specifically designed for the quick and efficient management of fluids during ophthalmic procedures.

- Constructed from ultra-smooth, biocompatible PVA sponge
- Ultra-fast wicking
- Available sterile or non-sterile for direct inclusion in procedure packs
- Single use only, declared 5 year shelf life

PVA Eye Wick Options

Product	Pack Size	Unit of Sale	Product Code
Eye Wick (bulk, non-sterile)	Bulk	Bag of 500pcs	1-431B
Eye Wick	Foil of 1	Bag of 50 packs	2-431
Wick and Wipe	Foil of 1	Bag of 50 packs	2-470

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SS_EYE_013 REV 06 04/21

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Material Specification

Product Component	Specification
Eye Wick	100% Polyvinyl Alcohol Sponge (PVA)
Instrument Wipe	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Metalized foil pouch (2-431, 2-470), Grip Seal Bag (1-431B)

Intended Use

The PVA Eye Wick range has been specifically designed for the quick and efficient management of fluids during ophthalmic procedures.

Intended Purpose

PVA wicks

A body or body orifice contact, single-use rectangular strip of medical grade, highly absorbent PVA used during ophthalmic surgical procedures. 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. 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 instrument wipe

A non-contact, single-use sheet of PVA intended to be used in a sterile condition by healthcare professionals to help clean medical devices prior to full decontamination. The instrument wipe is only to be handled with medical grade gloves and as such is non-contact with a cumulative transient use of less than 60 minutes. There are no known contraindications for this device. These devices are not intended to be used on a patient.

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Sterilisation

Sterile 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} Max Method testing.

All products are suitable for inclusion in procedure packs sterilised by EO gas. It is the responsibility of the procedure pack manufacturer to validate that their specific Ethylene Oxide Cycle does not adversely affect product performance.

The bulk eye wick (1-431B) is also suitable for including inside procedure packs that are sterilised by gamma radiation (25-35kGy).

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 (the bulk eye wick, 1-431B, is classified as Class I non-sterile).

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