



Product Overview

The EYETEC[®] PVA LASIK Eye Drain range has been specifically designed for the quick and efficient management of fluids during LASIK procedures.

- Constructed from ultra-smooth, biocompatible PVA sponge
- Ultra-fast wicking
- Supplied sterile, single use only, declared 5 year shelf life

LASIK EYE Drain Size Options

Product	Pack Size	Product Code
42 x 17 x 11.5mm Opening	Pack of 1 box of 20	40-830
40 x 14 x 10.5mm Opening	Pack of 1 box of 20	40-831



1 | Page



Material Specification

Product Component	Specification
LASIK Eye Drain	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Tyvek /Film
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

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

Intended Purpose

A body and/or body orifice contact, single-use rectangular strip of medical grade, highly absorbent PVA which drains into an attached polythene bag which has a self-adhesive strip to permit it to be secured to the drape 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 PVA portion of the drain has 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 VD_{25} 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 <u>https://www.networkmedical.co.uk/ifu-product-group</u>

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.

2 | P a g e



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