PVA LASIK Eye Shield Specification Sheet

Product Overview

The EYETEC ® PVA LASIK Eye Shield range has been specifically designed to keep the surface of the cornea moist and cool during LASIK procedures, whilst shielding the retina from intense operating light.

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

LASIK EYE Shield Size Options

Product	Pack Size	Product Code
9mm Diameter/7mm Edge	Pack of 1 box of 20	40-820
8mm Diameter/6mm Edge	Pack of 1 box of 20	40-821
4mm Edge/8mm Edge	Pack of 1 box of 20	40-822

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Material Specification

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

Intended Use

The PVA LASIK Eye Shields range has been specifically designed to keep the surface of the cornea moist and cool during LASIK procedures, whilst shielding the retina from intense operating light.

Intended Purpose

A body orifice contact, single-use strip of medical grade and highly absorbent PVA. It is intended to be used by healthcare professionals in a sterile condition on any patient for keeping the surface of the cornea moist and cool during LASIK procedures, and for shielding the retina from intense operating light. They have a cumulative transient use of less than 60 minutes on the conjunctiva (mucous membrane of the eye) and/or the cornea. There are no known contraindications for these devices.

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} Method Max testing.

All products are suitable for including inside procedure packs that are sterilised by EO gas.

The bulk eye shield (1-821) is suitable for including inside procedure packs that are sterilised by gamma irradiation and e-beam. These devices are non-sterile and are suitable for sterilisation at 25-35kGy.

It is the responsibility of the procedure pack manufacturer to validate that their specific Ethylene Cycle does not adversely affect product performance. Network Medical can undertake product testing of customer sterilised product if required.

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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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