PVA Corneal Light Shield Specification Sheet
KITPACK (BULK) PRODUCT

Product Overview

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

- Constructed from ultra-smooth, biocompatible PVA sponge
- Suitable for inclusion in procedure packs sterilised by EO gas.
- Supplied sterile, single use only, declared 5 year shelf life

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 procedure packs that are sterilised by EO and maintains the optimum performance for the end-user.

PVA Corneal Light Shield Size Options

Product	Packaging	Unit of Sale	Product Code
Eye Shield 7mm	Pack of 1	100	1-420B
Eye Shield 8mm	Pack of 1	100	1-421B
LASIK Shield 8mm	Pack of 1	100	1-821

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Material Specification

Product Component	Specification
Corneal Light Shield	100% Polyvinyl Alcohol Sponge (PVA)
Pouch Packaging	Metalised foil pouch

Intended Use

The PVA Corneal Light Shield range has been designed to keep the surface of the cornea moist and cool during ophthalmic procedures, whilst shielding the retina from intense operating light.

Intended Purpose

A body orifice contact, single-use circular shaped piece 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 ophthalmic 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

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.

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.

Instructions for Use

The instructions for use are supplied in the form of a multi-lingual leaflet with instructions given.

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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

These 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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