PVA Corneal Light Shield

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
- Supplied sterile, single use only, declared 5 year shelf life

PVA Corneal Light Shield Size Options

Product	Pack Size	Product Code
7mm Diameter	Pack of 1 box of 20	40-420
8mm Diameter	Pack of 1 box of 20	40-421
10mm Diameter	Pack of 1 box of 20	40-423

Material Specification

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

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EYETEC

PVA Corneal Light Shield

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 1117-2 (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 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.

NETWORK MEDICAL PRODUCTS AN INNOVIA MEDICAL COMPANY

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