



## 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. The light shields can also be used to directly dispense topical anaesthesia.

- Constructed from ultra-smooth, biocompatible PVA sponge
- Lint and fibre free
- Supplied sterile, 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

EYETEC® LASIK Shields are used specifically to protect and moisten the superior flap during the procedure. They can also be used with a nasal hinge.

### 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<sub>25</sub> Method Max testing.

### Instructions for Use

No instructions for use are provided as this device can be used safely without.

### 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.