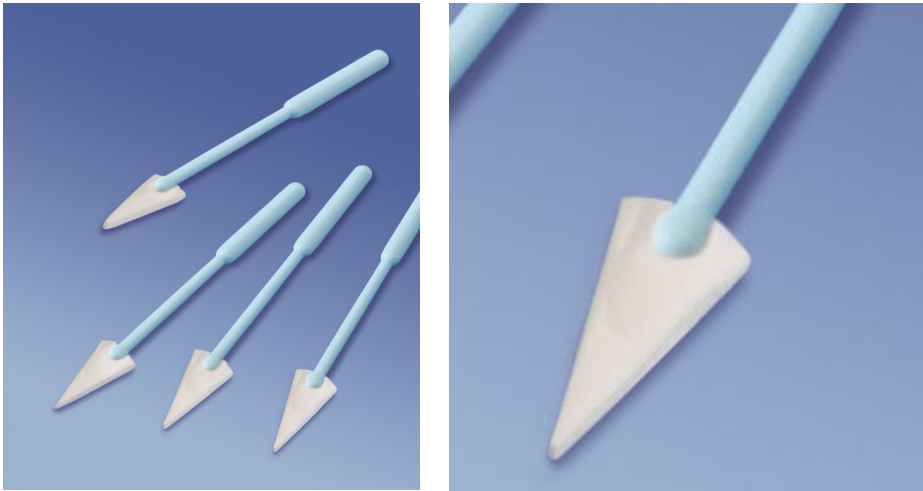




Cellulose Eye Spears and Points Specification Sheet



Product Overview

High quality and performance Cellulose Eye Spears and Points for the management of fluids during ophthalmic procedures:

- Constructed from medical grade biocompatible cellulose
- Highly absorbent
- Supplied sterile, single use only, declared 5 year shelf life

Cellulose Eye Spear and Point Options

Product	Pack Size	Product Code
Cellulose Spears	Pack of 5 box of 100	40-410
Cellulose Points	Pack of 5 box of 100	40-411
Cellulose Spears	Pack of 10 box of 200	40-415
Cellulose Points	Pack of 10 box of 250	40-416



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Material Specification

Product Component	Specification
Eye Spear/Point	100% Cellulose
Eye Spear Handle	Medical Grade Polypropylene
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron Printed White Boxboard

Intended Use

PVA and Cellulose ophthalmic sponge products are designed to staunch blood loss and absorb fluids from and around the eye during ophthalmic procedures. The PVA and Cellulose sponge reacts quickly to absorb blood and body fluids.

Intended Purpose

Cellulose spears:

A body and/or body orifice contact, single-use triangular piece of medical grade, highly absorbent cellulose supplied with attachment to a polypropylene handle. 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. Can also be used for tissue manipulation. They have a cumulative transient use of less than 60 minutes on the conjunctiva (mucous membrane of the eye), cornea and/or surrounding tissue. They are contraindicated for patients undergoing LASIK surgery.

Cellulose points:

A body and/or body orifice contact, single-use triangular piece of medical grade, highly absorbent cellulose. 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. Can also be used for tissue manipulation. They have a cumulative transient use of less than 60 minutes on the conjunctiva (mucous membrane of the eye), cornea and/or surrounding tissue. They are contraindicated for patients undergoing LASIK surgery..

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) the 25 kGy dose is substantiated by VD₂₅ Method Max testing.



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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® Cellulose 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.