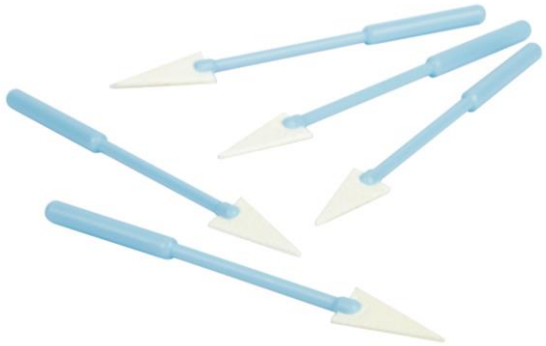
Cellulose Eye Spears and Points Specification Sheet



Product Overview

The EYETEC® Cellulose Eye Spear and Points range provides unrivalled quality and performance for the management of fluids and tissue manipulation during ophthalmic procedures.

- Constructed from 100% medical grade biocompatible cellulose
- Highly absorbent
- Lint and fibre free
- 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

Cellulose sponge ophthalmic products are designed for the management of fluids and to staunch blood loss after invasive surgery or traumatic injury in the areas of ophthalmic surgery. Cellulose sponge is biocompatible.

A spear's wicking time is directly related to its ability to expand. The EYETEC® Cellulose Spears and Points are supplied compressed but expands immediately upon contact with body fluids, saline or balanced salt solution, wicking 10-15 times its own weight away from the operative site.

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 VD_{25} 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® 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.

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