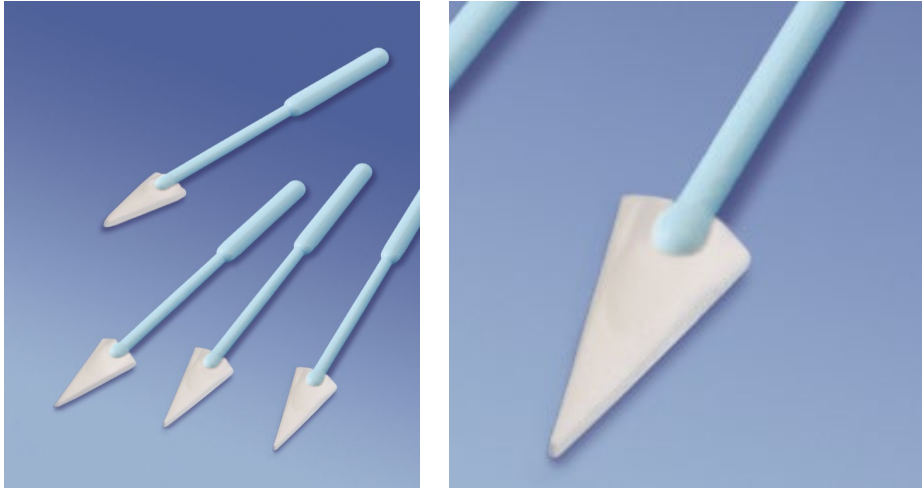




Cellulose Eye Spears and Points Specification Sheet PROCEDURE PACK (BULK) PRODUCT



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 non sterile for direct inclusion in procedure packs
- Single use only, declared 5 year shelf life

Cellulose Eye Spear and Point Options

Product	Pack Size	Unit of Sale	Product Code
Cellulose Spears	Pack of 5	Bag of 100 packs	1-410
Cellulose Spears	Pack of 10	Bag of 100 packs	1-415



Cellulose Eye Spears and Points Specification Sheet PROCEDURE PACK (BULK) PRODUCT

Material Specification

Product Component	Specification
Eye Spear/Point	100% Cellulose
Eye Spear Handle	Medical Grade Polypropylene
Pouch Packaging	Paper Glassine

Intended Use

Cellulose ophthalmic sponge products are designed to staunch blood loss and absorb fluids from and around the eye during ophthalmic procedures. The 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 non-sterile and suitable for inclusion in procedure packs sterilised by EO gas or Gamma irradiation (25-35kGy). It is the responsibility of the procedure pack manufacturer to validate that their specific Ethylene Oxide Cycle does not adversely affect product performance.



Cellulose Eye Spears and Points Specification Sheet PROCEDURE PACK (BULK) PRODUCT

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 non-sterile.