

PVA AND CELLULOSE PRODUCTS FOR OPHTHALMIC APPLICATIONS

PRODUCT INFORMATION AND INSTRUCTIONS

1

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PVA AND CELLULOSE PRODUCTS FOR OPHTHALMIC APPLICATIONS GB - Instructions for Use

Product Description:

The PVA and Cellulose Spears, Points, Drains and Wicks are a complete line of sponge products used for the management of fluids during ophthalmic procedures. Our PVA and Cellulose sponge products are used during cataract and other refractive surgeries. The PVA products are manufactured from 100% biocompatible PVA sponge and supplied in various shapes and sizes according to use. The Cellulose sponge products are manufactured from biocompatible Cellulose (approx. 78%) and Pulp (approx. 22%) and supplied in various shapes and sizes according to use.

The **PVA Shields** are placed on the cornea when it is necessary to moisten the cornea and shield the retina from intense operating light during ophthalmic surgery. These products are manufactured from 100% PVA Sponge in various sizes. Two variants are offered – for general ophthalmic procedures (Eye Shield) and for Lasik Procedures (Lasik Shield).

PVA Instrument Wipes are manufactured from 100% biocompatible PVA sponge in sheet form in various sizes. They are used to help clean medical devices after use.

Intended Population / Patient Target Groups:

Instrument wipes are not intended to be used on patients. All other devices are intended to be used on patients undergoing ophthalmic procedures. Cellulose sponge products however are contraindicated on patients undergoing (LASIK) procedures. There are no other restrictions on patient population. Medical assessment is necessary and due care is to be exercised in cases of eye infections and injuries to the cornea.

Intended Users:

Healthcare professionals only; trained ophthalmic surgeons and ophthalmic theatre staff including trained decontamination professionals.

Intended Purpose:

Statement for Intended purpose for PVA spears:

A body and/or body orifice contact, single-use triangular piece of medical grade, highly absorbent PVA 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. There are no known contraindications for these devices.



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