



NOBAMED Paul Danz AG

NOBAOPHTHALM[®] eye spears

REF 646110 (as of LOT 138392)

Product Description, Intended use, Application

NOBAOPHTHALM[®] eye spears consist of an absorbent polyvinyl acetal sponge spear attached to a high-density plastic handle. The eye spears are designed to absorb fluids and remove debris from the operative field or instruments during ophthalmic surgery. After absorbing liquid, a wedge shape is formed.

Composition

polyvinyl acetal, polypropylene

Contraindications

Do not use product on any patients who may be allergic to any of its ingredients.

Notes

Do not use in a dry state for refractive surgery (Lasik etc.). Do not resterilize. Consult instructions for use

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical Device according to MDD 93/42/EEC, MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH.

Sterilization of the product complies with DIN EN ISO 11137.

Packaging

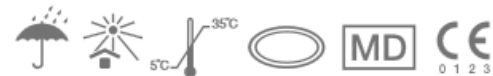
Primary packaging: aluminum

Secondary packaging: film-paper

Tertiary packaging: carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417.

Storage and Transport

Store at ambient temperature and protect from moisture

Check the expiry date before use. Do not use the product after the expiry date.

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact. Do not use if individual package is damaged or open.

Single use device

Single use device: The reuse of single use devices may lead to a microbiological hazard. Treatment for reuse may adversely affect the performance of the product.

Disposal

In accordance with the requirements of the applicable local legislation and with the standards for the prevention of infections.