

⚠ Instructions for Use – This leaflet contains important product use and safety information. Please read carefully and retain these instructions for future reference.

Product Name:
Eye Plaque Applicator Kit

Description/ Indications for Use:

Eye Plaque Applicator Kits are concave devices made of a gold alloy and/or silastics (silicone inserts) shaped in such a way, which the various diameters follow the curvature of the eye. (See Fig. 1: COMS EYE PLAQUE APPLICATOR KIT; Fig. 2: EYE PLAQUE APPLICATOR KIT, below).

During ordering, a physician must specify the brand, size, shape and/or style required, so that the appropriate Eye Plaque Applicator Kit is provided.

Figure 1: COMS EYE PLAQUE APPLICATOR KIT



Figure 2: EYE PLAQUE APPLICATOR KIT



Instructions for Safe Use:

The Eye Plaque Applicator Kit is used by a physician within surgical markets to better treat individual patients' needs. The COMS and Eye Plaque Applicator Kit's Dummy Ring (Templates) may be used to align placement for accuracy and optimum results of the Eye Plaque Applicator Kit. The COMS and Eye Plaque Applicator Kit's Dummy Ring (Templates) must be removed prior to placement of the Eye Plaque Applicator.

⚠ **CAUTION:** Do not autoclave the COMS Eye Plaque Applicator Kit's Dummy Ring (Template), acrylic – it may deform at the temperatures employed.

Eye Plaque Applicator Kit

The Eye Plaque Applicator Kit can be either Steam or EO sterilized.

Contraindications:

- Do not use non-sterile product.

Steam Sterilization:

The COMS and Eye Plaque Applicator Kits are shipped non-sterile. Customers should sterilize the COMS Eye Plaque Applicator and Eye Plaque Applicator Kit Dummy Ring (Template) prior to using. We recommend following the moist heat guidance document in accordance with ANSI/AAMI/ISO 17665-1:2006 "Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices."

Ethylene Oxide Sterilization:

COMS Eye Plaque Applicator Kit and Eye Plaque Applicator Kit can be sterilized using ethylene oxide; The Eye Plaque Applicator Kit's Dummy Ring (Template) and COMS Eye Plaque Applicator Kit's Dummy Ring (Template), acrylic can be sterilized using ethylene oxide; and we recommend that the devices are validated in accordance with ANSI/AAMI/ISO 11135:2007 "Sterilization of health care products—Ethylene Oxide—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices".

(Eye Physics) Eye Plaque Applicator Kit's Dummy Ring (Template)

An Eye Plaque Applicator Kit's Dummy Ring (Template) may be used for alignment and is to be removed prior to placement of the Eye Plaque Applicator.

COMS Eye Plaque Applicator Kit's Dummy Ring (Template) Acrylic:

A COMS Eye Plaque Applicator Kit's Dummy Ring may be used for alignment and is to be removed prior to placement of the COMS Eye Plaque Applicator.

Unpacking, Handling and Accidental Damage:

Before use, thoroughly inspect the package for seal integrity and damage that could affect the integrity of the product. A damaged package may indicate that the Eye Plaque Applicator Kit has been compromised.

- Check the correct labeling, and completeness of the contents.
- Follow aseptic procedures while removing the product from the pouch and when handling the Eye Plaque Applicator Kit.

- Proper sterile techniques should be applied upon handling, which will ensure that the product's sterility is not compromised

After removing the product from the packaging, inspect it for any damage, such as bending of the Eye Plaque Applicator Kits or broken eyelets.

⚠ **WARNING** Do not use the Eye Plaque Applicator Kit if the eyelets or Eye Plaque Applicator Kit is bent or appears damaged. A damaged product may not function correctly.

⚠ **WARNING** Do not use the product if there is suspicion that the product is damaged.

⚠ **WARNING** Do not separate the COMS Eye Plaque Applicator Kit's Dummy Ring (Template) Acrylic from the COMS Eye Plaque Applicator Kit's Dummy Ring.

	Caution: Consult Accompanying Documents
	Do Not Reuse
	Consult Instructions for Use
	Ethylene Oxide Sterilization
	Steam Sterilization
	Use by Date
	Catalog Number
	Do not Resterilize
	Date of Manufacture
	Biohazard
	Do not use if package is damaged

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