



MODE OF ACTION AND DEVICE DESCRIPTION

ologenTM Collagen Matrix is a device specifically configured to support physiologic repair processes in ocular connective tissue and epithelium when there is tissue damage, weakness or disorganization. ologenTM Collagen Matrix prevents scar formation and provides a dynamic physical and physiological reservoir system to restore and maintain functionality. The collagen is obtained from porcine hide and the matrix structure has a porous configuration made of cross-linked lyophilized type I atelocollagen and glycosaminoglycans (GAG).

Eventually, ologenTM Collagen Matrix is biodegraded around 90 days depending on stress tissue site, predetermined intrinsic inflammatory and remodeling mechanisms.

THERAPEUTIC INDICATIONS

Glaucoma:

ologenTM Collagen Matrix is primary designed to create the subconjunctival space (bleb) and modulate the wound healing physiologically for trabeculectomy, non-penetrating deep sclerotomy, bleb revision or drainage implantation surgery. The host tissue-collagen matrix interaction may optimize and stabilize the structure and composition of ocular tissues, creating a mature bleb structure and prevent scar formation.

Other ophthalmic surgeries:

ologenTM Collagen Matrix may be used in other ophthalmic surgeries in which a physiological and reinforced structure is required like strabismus surgery, ocular surface reconstruction, graft donor sites, pterygium excision or ocular plastic surgery. The use of ologenTM Collagen Matrix for other ophthalmic procedures not mentioned in this instruction for use must be based on surgical criteria, mode of action, location, prognosis, and potential benefit-risk ratio.

DIRECTIONS FOR USE

1. ologenTM Collagen Matrix is supplied in sterile double-bagged pack. Before use, peel open the pouch, take out the foil bag and remove the product.
2. ologenTM Collagen Matrix does not need prior preparation and is ready to use. ologenTM Collagen Matrix can be trimmed prior surgery to adjust to different indications or surgical needs.
3. No learning curve is required as traditional glaucoma surgeries (trabeculectomy, non-penetrating deep sclerotomy or drainage implantation surgery) or other ophthalmic surgeries. Simply place ologenTM Collagen Matrix on the intended area securing to adjacent tissues.
4. In glaucoma surgery (after perform trabeculectomy, non-penetrating deep sclerotomy or drainage implantation) it is recommended suture the sclera flap loosely with one or two single stitches (figure 1) and then place ologenTM Collagen Matrix on the top of the sclera flap (figure 2). After this, suture the conjunctiva and reform anterior chamber.

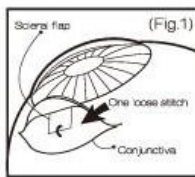


Fig. 1

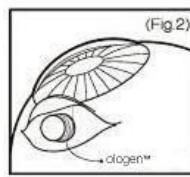


Fig.2

AFTERCARE

- The surgeon shall carefully evaluate tissue condition and ocular physiological parameters post operatively.
- If needed, appropriate therapy-medication may be prescribed by the physician according to patients and treatment needs.

PRECAUTIONS

- Do not re-sterilize. Do not re-use!
- Discard the opened and unused parts.
- Do not use if the package seal is broken or expiry date is overdue.
- Discard device if mishandling has caused possible damage or contamination.
- Always handle under sterile and aseptic conditions.

CONTRAINDICATIONS

ologenTM Collagen Matrix is contraindicated in patients with known hypersensitivity to porcine collagen.



WARNINGS

- The implant of ologenTM Collagen Matrix may cause a normal mild and localized immune reaction. However, if uncontrolled immune reaction occurs, the implant must be retrieved.
- The safety of ologenTM Collagen Matrix for use during pregnancy or in infant and children has not been established.

INTERACTIONS

Any medication that interferes the porous structure or the cross linking configuration of ologenTM Collagen Matrix may change the rate of absorption and degradation.

SHELF-LIFE AND STORAGE

ologenTM Collagen Matrix has a shelf-life of 36 months. The expiry date is stated on the package. ologenTM Collagen Matrix must be stored at room temperature. Avoid heat greater than 40°C or direct sunlight.

Product Model

Model	Specification
830601	6 mm (D) × 2 mm (H)
830621	7.5 mm (D) × 2 mm (H)
830661	7 mm (D) × 4 mm (H)
830681	7.5 mm (D) × 4.5 mm (H)
830691	10 mm (D) × 5 mm (H)
862051	12 mm (D) × 1 mm (H)
861051	12/20 mm (ID/OD) × 1 mm (H)
870041	5 mm (W) × 10 mm (L) × 4 mm (H)
870051	10 mm (W) × 10 mm (L) × 2 mm (H)
870061	10 mm (W) × 10 mm (L) × 4 mm (H)

SYMBOL DEFINITIONS

	Sterilized Using Irradiation		Serial Number
	Do Not Reuse		Manufacturer
	Caution, Consult Accompanying Documents		Date of Manufacture
	Use By		Temperature Limitation
	Lot Number		Consult Instructions for Use



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