



Bioengineered Eyelid Spacer Graft

Reorder No: TS-81040

SMOOTH SIDE

MANUFACTURED FOR:



Katena Products, Inc.
6 Campus Drive, Suite 310
Parsippany, NJ 07054 USA

Phone: 973-989-1600
Toll Free: 800-225-1195
FAX: 973-989-8175

www.katena.com

1x4cm
(Actual size)

INTENDED USE: The tarSys bioengineered eyelid spacer graft is intended for implantation to reinforce and aid reconstruction of the eyelid.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS: This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

PRECAUTIONS:

Do not resterilize. Discard all open and unused portions.

- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Eight-layer laminated device is designed for maximum elasticity and structural support.
- Ensure that device is rehydrated in sterile solution for at least 20 minutes prior to suturing in place.
- Ensure that all layers of tarSys are secured when suturing.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical graft materials. If any of these conditions occur, the device should be removed.

- Infection
- Allergic reaction
- Acute or Chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)

STORAGE: This device should be stored in a clean, dry location at room temperature.

STERILIZATION: This device has been sterilized with ethylene oxide.

NOTE: tarSys graft sheets consists of eight layers of laminated membrane tissue of porcine origin. The functional difference between sides is minimal, but cell culture studies suggest that epithelial cell growth is moderately favored on the smooth side.

Rehydrate for at least 20 minutes

SUGGESTED INSTRUCTIONS FOR USING PROSTHETIC EYELID SPACER GRAFTS: These recommendations are designed to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

NOTE: Handle using aseptic technique, minimizing contact with latex gloves.

REQUIRED MATERIALS:

- Sterile forceps
- A sterile dish with a capacity of at least 10mL
- Rehydration fluid: at least 5mL of room temperature sterile saline, sterile lactated Ringer's solution or sterile ocular irrigating solution for each tarSys graft.

1. Using aseptic technique, remove the tarSys inner pouch from its outer bag, and place the inner pouch in the sterile field.
2. Open the inner pouch carefully, and aseptically remove the tarSys graft with the sterile forceps.
3. Place the tarSys graft into the sterile dish in the sterile field. (Multiple grafts may be rehydrated simultaneously in the same dish.)
4. Add to the dish at least 5mL of the rehydration fluid for each graft. Antibiotic may be added to rehydration solution.
5. **Allow the tarSys grafts to rehydrate for at least twenty minutes.**
6. Prepare the graft site using standard surgical techniques.
7. Using aseptic technique, trim the tarSys graft to fit the site, providing a small allowance for overlap. (Note: An alternative method is to cut the device to size prior to rehydration. If this method is selected, be sure to rehydrate the tarSys graft prior to suturing into place. See step 5.)
8. Using aseptic technique, transfer the tarSys graft to the graft site and suture into place, avoiding excess tension. (Note: Surgical experience indicates that suturing tarSys grafts with close tissue approximation produces better outcomes.)
9. Orient the device to place the smoother surface towards the eye. The smooth surface may be identified by tactile comparison of both sides or visual inspection of each surface. The smooth side will appear shinier in the hydrated state.
10. Complete the standard surgical procedure and discard any unused portions of the tarSys graft.