Bioengineered Eyelid Spacer Graft

Natural tarsus is specialized tissue that is neither purely fibrous nor cartilaginous in composition. The tissue functions as the skeletal structure for the delicate mechanical properties of the lid. Substitute materials necessary to correct lid function are limited due to the hybrid composition of this unique tissue type.

- Engineered specifically for the repair of lid retraction.
- Biologic composition similar to tarsal plate.
- Compatible with superficial mucosa.
- Vertical support, no excess bulk.
- Integrates with host tissue.
- No graft site morbidity.

**References:**


**tarSys** is manufactured from decellularized xenogeneic membrane. The membrane consists of collagen types I, III and VI, with a glycosaminoglycan profile similar to tarsal plate. The manufacturing process configures the material into a dense elastic matrix suitable for structural repair of superficial mucosa.
**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.

**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 graft 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. Complete the standard surgical procedure.
10. Discard any unused portions of the tarSys graft.

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