BIODESIGN™
TISSUE GENERATION MATRIX

FP0066-01B

COOK® MEDICAL

Manufacturer:

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INTENDED USE:
The BIODESIGN™ Tissue Generation Matrix is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

COMPOSITION:
The Tissue Generation Matrix is an extracellular membrane derived from porcine Small Intestinal Submucosa (SIS) from qualified animal production facilities. SIS is obtained using a process that retains the natural composition of matrix molecules such as collagen (Types I, III, VI), glycosaminoglycans (hyaluronic acid, chondroitin sulfate A and B, heparin, and heparan sulfate), proteoglycans, growth factors (FGF-2, TGF-β), and fibronectin.[1,2,3]

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.
- Ensure that the device is rehydrated prior to cutting or suturing.
- Device performance has not been evaluated with suture spacing greater than 2 mm.
- Ensure that all layers of the device are secured when suturing or stapling.
- No studies have been done to evaluate the reproductive impact of the clinical use with the Tissue Generation Matrix.
- The Tissue Generation Matrix may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs.
- Patients undergoing radiation therapy may not experience normal wound healing.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical graft materials. If any of these complications occur and cannot be resolved, consider the removal of the Tissue Generation Matrix:
- Infection
- Acute or Chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Seroma formation

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

STERILIZATION: This device has been sterilized with ethylene oxide.

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

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

REQUIRED MATERIALS:
- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Rehydration fluid: At least 50 mL of room temperature sterile saline or sterile lactated Ringer's solution for each sheet.

1. Using aseptic technique, remove the inner pouch containing the Tissue Generation Matrix from the outer pouch, and place it in the sterile field.
2. Open the inner pouch carefully, and aseptically remove the Tissue Generation Matrix using sterile forceps.
3. Place the Tissue Generation Matrix into a sterile dish in the sterile field.
4. Add at least 50 mL of the hydration fluid to the dish for each Tissue Generation Matrix used.
5. Allow the Tissue Generation Matrix to re-hydrate until desired handling characteristics are achieved. Rehydration longer than 1 minute is not required and not recommended to exceed 4 minutes.

   IMPORTANT: Minimize manipulation of the Tissue Generation Matrix during rehydration to avoid delamination.

6. Prepare the graft site using standard surgical techniques.
7. Using aseptic technique, trim the Tissue Generation Matrix to fit the site, providing a small allowance for overlap.

   Note: An alternative method is to cut the Tissue Generation Matrix to size prior to rehydration. If this method is selected, be sure to re-hydrate the device prior to suturing or stapling it into place. See step 5.

8. Using aseptic technique, transfer the Tissue Generation Matrix to the graft site. Suture or staple into place, ensuring that all layers are captured and avoiding excess tension.

   IMPORTANT: Surgical experience indicates that suturing or stapling the Tissue Generation Matrix with close tissue approximation encourages cell in-growth, tissue remodeling, and produces better outcomes.

9. Complete the standard surgical procedure.

   IMPORTANT: For breast procedures, the liberal use of drains is recommended until output is less than 15 cc in 24 hours.

10. Discard any unused portions of the Tissue Generation Matrix according to institutional guidelines for medical waste.

REFERENCES:

1. Hodde J, Janis A, Ernst D, Zopf D, Sherman D, Johnson C. Effects of sterilization on an extracellular matrix scaffold: Part I. Composition and matrix architecture. *J Mater Sci Mater Med* 2007;18:537-543
2. Hodde JP, Badylak SF, Brightman AO, et al. "Glycosaminoclygan Content of Small Intestinal Submucosa: A Bioscaffold for Tissue Replacement." *Tissue Engineering*, 1996;2:209-217.
3. Data on File, Cook Biotech, Inc.