BIODESIGN® TISSUE GENERATION MATRIX

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 matrix is supplied sterile and is intended for use by trained medical professionals.

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

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COMPOSITION
The 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 fibronectins.¹ ² ³

CONTRAINdications
This matrix 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.
- Matrix is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard matrix if mishandling has caused possible damage or contamination, or if the matrix is past its expiration date.
- Ensure that the matrix is rehydrated prior to cutting or suturing.
- Matrix performance has not been evaluated with suture spacing greater than 2 mm.
- Ensure that all layers of the matrix are secured when suturing or stapling.
- No studies have been done to evaluate the reproductive impact with the clinical use of the matrix.
- The matrix may not have sufficient strength to support stressors 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 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 matrix should be stored in a clean, dry location at room temperature.

STERILIZATION
This matrix has been sterilized with ethylene oxide.

USE OF ANTIMICROBIALS
Because the matrix is at times used in surgical fields where sterility cannot be assured, the use of antimicrobials is common practice and may prevent infectious complications.¹ ² ³ These antimicrobials are not expected to prevent the growth of gram-negative bacteria and Peptostreptococcus species in the first 24 hours. If the antimicrobials are applied, allow the matrix to re-hydrate for at least 4 hours before suturing or stapling it into place. If the antimicrobials are used, be sure to re-hydrate the matrix prior to suturing or stapling it into place. See step 5.

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 matrix from the outer pouch, and place it in the sterile field.
2. Open the inner pouch carefully, and aseptically remove the matrix using sterile forceps.
3. Allow the 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.
4. IMPORTANT: Minimize manipulation of the matrix during rehydration to avoid denaturation.
5. Place the matrix into a sterile dish in the sterile field.
6. Add at least 50 mL of the hydration fluid to the dish for each matrix used.
7. Allow the 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.
8. IMPORTANT: Surgical experience indicates that suturing or stapling the matrix with close tissue approximation encourages cell in-growth, tissue remodeling and produces better outcomes.
9. Complete the standard surgical procedure.
10. Discard any unused portions of the matrix according to institutional guidelines for medical waste.

REFERENCES
3. Data on File, Cook Biotech, Inc.