Biodesign®

PLASTIC SURGERY MATRIX

FP0066-01I

COOK® BIOTECH

**Caution**

**Do not re-use**

**Keep dry**

MR **Magnetic resonance safe**

**Manufacturer**

STERILE EO **Sterilized using ethylene oxide**

**Temperature limit**

**Use-by date**

**MANUFACTURER**
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# BIODESIGN® PLASTIC SURGERY MATRIX

## DESCRIPTION

The Biodesign Plastic Surgery Matrix is a multi-layered sheet of extracellular collagen matrix derived from porcine small intestinal submucosa. The Biodesign Plastic Surgery Matrix is implanted by a trained medical professional during plastic and/or reconstructive surgery. The device is supplied sterile and packaged dry. Prior to use, the device is hydrated with saline or autologous body fluids such as blood, bone marrow aspirate, or blood concentrates such as platelet concentrate.

## INTENDED USE

The Biodesign Plastic Surgery 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 one-time use.

Rx ONLY This symbol means the following:

**CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.** This graft is intended for use by trained medical professionals.

## CONTRAINDICATIONS

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

## PRECAUTIONS

- The graft is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.
- **Do not resterilize.** Discard all open and unused portions.
- The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date.
- Ensure that the graft is hydrated prior to cutting or suturing.
- Graft perfomance has not been evaluated with suture spacing greater than 2 mm.
- Ensure that all layers of the graft are secured when sutuing.
- Suturing more than one graft together may decrease matrix performance.
- No studies have been conducted to evaluate the reproductive impact of clinical use of the graft.
- The graft 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.
- No studies have been done to examine the effect of concomitant radiation with graft placement.
- Place the graft in maximum contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling.

  **NOTE:** When implanting the graft in patients with thin skin, transient, post-operative redness may be seen.
- Hydration of ECM-based materials with autologous fluids has only been studied in animal models. Clinical benefit has not been established.

## 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 graft removal.

- Allergic reaction
- Infection
- Inflammation
- Seroma formation

Use of autologous body fluid may introduce other potential complications. Please consult the Instructions for Use of the autologous fluid preparation device.

## STORAGE

Store the graft in a clean, dry location at room temperature.

## STERILIZATION

The graft has been sterilized with ethylene oxide.

## INSTRUCTIONS FOR USE

### Required Materials

- Sterile basin
- Sterile forceps
- Hydration fluid: room temperature sterile saline, sterile lactated Ringer's solution, or autologous body fluids, such as blood, bone marrow aspirate, or blood concentrates such as platelet concentrate.

**NOTE: Consult autologous fluid preparation device labeling for instructions on how to prepare the autologous fluid.**

1. Remove the packaging containing the graft from the envelope.
2. Using aseptic technique, open the outer pouch and pass the inner pouch containing the graft onto the sterile field.
3. Place the graft into the sterile basin in the sterile field.
4. Place enough hydration fluid in the basin to completely cover the graft.
5. Hydrate the graft in the fluid until the desired handling characteristics are achieved. A hydration time of greater than one minute is not required.

   **IMPORTANT:** Minimize manipulation of the graft during hydration to avoid delamination.
6. Prepare the graft site using standard surgical techniques.
7. If necessary, trim the graft to fit the patient's anatomy, providing a small allowance for overlap with the adjacent tissues.

   **NOTE:** The graft may be trimmed prior to hydration to fit the patient's anatomy. Be sure to hydrate the graft prior to suturing it into place. See step 5.
8. Suture the graft into place, avoiding excess tension.
9. Complete the standard surgical procedure.

   **IMPORTANT:** The use of drains is recommended until output is less than 15 cc in 24 hours.
10. Discard any unused portions of the graft according to institutional guidelines for medical waste.