Biodesign®

INCISION GRAFT

FP0075-01D

COOK® MEDICAL

MANUFACTURER

ATTENTION, SEE INSTRUCTIONS FOR USE

TEMPERATURE LIMIT

KEEP DRY

USE-BY DATE

STERILE EO STERILIZED USING ETHYLENE OXIDE

DO NOT RE-USE

MANUFACTURER

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BIODESIGN® INCISION GRAFT

INTENDED USE

The Biodesign® Incision Graft is intended for implantation to reinforce soft tissues where weakness exists. Indications for use include the repair of a body wall defect. This graft is supplied sterile in peel-open packages 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.

INCISION GRAFT This symbol means the following: Incision Graft

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

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

PRECAUTIONS

- This device 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 of the graft.
- The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date.
- Ensure that graft is rehydrated prior to cutting, suturing, stapling, or tacking.
- Ensure that all layers of the graft are secured when suturing, stapling, or tacking.
- Suturing, stapling, or tacking more than one graft together may decrease graft performance.
- No studies have been conducted to evaluate the reproductive impact of the clinical use of the graft.
- Place graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling.

POTENTIAL COMPLICATIONS

Possible adverse reactions with the use of any prosthesis may include, but are not limited to:

- Infection
- Inflammation
- Adhesion
- Fistula formation
- Seroma formation
- Hematoma
- Allergic reaction
- Recurrence of tissue defect

Complications, such as delayed wound infection, hernia recurrence, and the need for re-operation, should be reasonably expected in patients who are critically ill or who have severely contaminated wounds.

STORAGE

This graft should be stored in a clean, dry location at room temperature.

STERILIZATION

This graft has been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- Sterile forceps
- A sterile dish (kidney dish or other bowl)
- Rehydration fluid: room temperature, sterile saline or sterile lactated Ringer's solution

NOTE: Always handle the graft using aseptic technique, minimizing contact with latex gloves.

1. Using aseptic technique, remove the inner pouch from its outer pouch and place the inner pouch in the sterile field.
2. Open the inner pouch carefully, and aseptically remove the graft using sterile forceps.
3. Place the graft into a sterile dish in the sterile field.
4. Add rehydration fluid.
5. Rehydrate the graft in room temperature, sterile saline or sterile lactated Ringer's solution until the desired handling characteristics are achieved. Rehydration time of greater than 1 minute is not required.
6. Prepare the site using standard surgical techniques.
7. Using aseptic technique, trim the graft to fit the site, providing an allowance for a 4cm overlap.
8. Using aseptic technique, transfer the graft to the surgical site and suture, staple, or tack into place, avoiding excess tension.

   NOTE: Surgical experience indicates that suturing, stapling, or tacking the graft with close tissue approximation produces better outcomes. Fundamental surgical principles suggest a suture spacing approximately equal to suture bite depth.
9. Complete the standard surgical procedure, including primary closure of the incision or body wall defect.
10. Discard any unused portions according to institutional guidelines for medical waste.

    NOTE: Interrupted sutures can provide additional security against recurrence of tissue defect in the event of suture failure.