

Biodesign™

SURGISIS® HIATAL HERNIA GRAFT

FP0032-3B



Manufacturer:

Cook Biotech Incorporated

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Biodesign™ Surgisis® Hiatal Hernia Graft

INTENDED USE:

Used for implantation to reinforce soft tissue where weakness exists, including repair of paraesophageal/hiatal hernias. This device is supplied sterile in peel-open packages and is intended for one-time use.

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.
- The Hiatal Hernia Graft may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs.
- Ensure that the device is rehydrated prior to cutting or suturing.
- Ensure that all layers of the Hiatal Hernia Graft are secured when suturing or stapling.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical graft materials.

- Infection
- Acute or Chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Adhesion
- Fistula formation
- Seroma formation
- Hematoma
- Recurrence of tissue defect

The following complications are associated with use of graft materials in hiatal hernia repair.

- Esophageal erosion
- Stricture formation
- Perforation

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 USING THE HIATAL HERNIA GRAFT:

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: room temperature sterile saline or sterile lactated Ringer's solution

1. Using aseptic technique, remove the Hiatal Hernia Graft 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 Hiatal Hernia Graft with the sterile forceps.
3. Place the Hiatal Hernia Graft into the sterile dish in the sterile field. (Multiple Hiatal Hernia Grafts may be rehydrated simultaneously in the same dish.)
4. Add to the dish at least 50 mL of the rehydration fluid for each Hiatal Hernia Graft.
5. Rehydrate the Hiatal Hernia Graft in the rehydration fluid until the desired handling characteristics are achieved. A rehydration time of greater than 1 minute is not required.
6. Prepare the graft site using standard surgical techniques.
7. Using aseptic technique, trim the Hiatal Hernia Graft to fit the site, if necessary, providing a small allowance for overlap.

NOTE: An alternative method is to cut the Hiatal Hernia Graft to size prior to rehydration. If this method is selected, be sure to rehydrate the Hiatal Hernia Graft prior to suturing or stapling it into place. See step 5.

8. Using aseptic technique, transfer the Hiatal Hernia Graft to the graft site and suture or staple into place, avoiding excess tension.

NOTE: The Hiatal Hernia Graft with pre-cut U has a larger hole in the corner to identify graft orientation. It is recommended that the larger hole should be placed at the patient upper left.

NOTE: Surgical experience indicates that suturing or stapling the Hiatal Hernia Graft with close tissue approximation produces better outcomes.

9. Complete the standard surgical procedure.
10. Discard any unused portions of the Hiatal Hernia Graft.

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