Biodesign®

SURGISIS® UMBILICAL HERNIA GRAFT

FP0053-01C

COOK® MEDICAL

Keep dry

Keep away from sunlight

MANUFACTURER

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Biodesign® Surgisis® Umbilical Hernia Graft

INTENDED USE

Cook® Biodesign® Surgisis® Umbilical Hernia Graft is intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a body wall defect including umbilical hernias. The graft 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.

SURGISIS® UMBILICAL HERNIA GRAFT This symbol means the following: Surgisis® Umbilical Hernia 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

- **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 the graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date.
- Ensure that the graft is rehydrated prior to cutting, suturing, stapling, or tacking.
- Ensure that all layers of the graft are secured when suturing, stapling, or tacking.
- Place the graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling.
- 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.
- Extended rehydration or excessive handling could lead to partial delamination of the superficial layers of the graft.

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
- 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.

USE OF ANTIMICROBIALS

Because the graft 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] In these cases both antibiotic prophylaxis of the patient and antimicrobial soaking of the graft have been used. Typical flora can be expected to include a variety of aerobic and facultative anaerobic organisms, including, but not limited to, *Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa,* and *Escherichia coli.* Therefore, the following points should be considered:

- Antimicrobials, if used topically or systemically, should provide coverage against a wide spectrum of aerobic and anaerobic organisms.[2]
- Antibacterial prophylaxis, if chosen, should be started prior to surgery and continued post-operatively.[1]

The presence of certain antimicrobials may inhibit revascularization and/or infiltration of cells into the graft matrix.[3,4,5] For example, gentamicin is known to hinder neovascularization, epithelialization, and keratinocyte growth,[4] while povidone iodine,[6] bacitracin,[3,6] polymyxin B,[7] and vancomycin[8] have all been reported to slow or inhibit wound healing. However, no studies have been conducted to evaluate the combination of antimicrobials with the graft.

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

REQUIRED MATERIALS

- Sterile dish (kidney dish or other bowl)
- Sterile forceps
- Sterile hemostats
- Rehydration fluid: room temperature, sterile saline or sterile lactated Ringer's solution
- Suitable resorbable suture, such as 2-0 or 0 polyglycolic acid

PREPARATORY

1. Remove the packaging containing the graft from the envelope.
2. Remove the inner pouch containing the graft from the outer package using aseptic technique. Place the inner pouch in the sterile field.
3. Using sterile gloved hands, open the inner pouch carefully, and aseptically remove the graft with a sterile instrument. Place the graft into the sterile dish in the sterile field.
4. Add enough rehydration fluid to the dish to fully submerge the graft. Allow the graft to rehydrate, fully submerged, for 2-5 minutes.
5. Prepare the patient and surgical site using standard surgical techniques appropriate for umbilical hernia repair.

PROCEDURAL

1. Attach the graft circumferentially to the fascia, keeping in mind that sutures should be passed in such a way that the graft is oriented in a subfascial/underlay position. A suggested method to achieve this is as follows:
   a. Pass a suitable resorbable suture through the anterior fascia and into the posterior space approximately 2 cm from the edge of the defect. Bring the needle end of the suture through the defect.
   b. Take an adequate bite of the graft. Holes are provided in the graft to serve as a guide for suture spacing along the periphery of the graft.
   c. Pass the suture from the posterior space anteriorly back through the fascia, again allowing for approximately a 2 cm margin from the edge of the defect.
   d. Cut the needle from the suture and secure the ends without tying using a hemostat.
   e. Repeat Steps a-d a minimum of three times around the periphery.
2. Insert the graft under the hernia defect into the posterior space.
3. Pull up on all pairs of suture to open the graft flat against the fascia.
4. Tie both ends of each suture together.
5. Close the hernia defect primarily.
6. Complete the standard surgical procedure.
7. Discard any unused portions according to institutional guidelines for medical waste.

REFERENCES

1. Mangram, A., et al, *Guideline for prevention of surgical site infection,* 1999. Centers for Disease Control and Prevention (CDC). 1999.
2. Aldridge, K.E., et al., *Multicenter survey of the changing in vitro antimicrobial susceptibilities of clinical isolates of Bacteroides fragilis group, Prevotella, Fusobacterium, Porphyromonas, and Peptostreptococcus species*. Antimicrob Agents Chemother, 2001. 45(4): p. 1238-43.
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4. Bang, K., et al., *Gentacoll hampers epithelialisation and neovascularisation in excisional wounds in hairless mice*. Scand J Plast Reconstr Surg Hand Surg, 1998. 32(2): p. 129-33.
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