Biodesign®

SURGISIS® ABDOMINAL LOCK GRAFT

FP0035-1E

COOK® MEDICAL

Keep dry

Keep away from sunlight

MANUFACTURER

COOK BIOTECH
INCORPORATED
1425 Innovation Place
West Lafayette, IN 47906 U.S.A.
Phone: 812 339-2235
Toll Free: 800 457-4500
Toll Free Fax: (800) 554-8335

COOK (CANADA) INC.
111 Sandiford Drive
Stouffville, Ontario
L4A 7X5 CANADA
Phone: 905 640-7110
Toll Free: 800 668-0300

EC REPRESENTATIVE

COOK IRELAND
O'Halloran Road
National Technological Park
Limerick, IRELAND
Phone: +353 61 334440

WILLIAM A. COOK
AUSTRALIA PTY. LTD.
Brisbane Technology Park
12 Electronics Street
Eight Mile Plains
Brisbane, QLD 4113 Australia
Phone: +61 7 38 41 11 88

www.cookmedical.com

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BIODESIGN® SURGISIS® ABDOMINAL LOCK GRAFT

INTENDED USE

The Biodesign® Surgisis® Abdominal Lock Graft is used for implantation to reinforce soft tissue. 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.

SURGISIS® ABDOMINAL LOCK GRAFT This symbol means the following: Surgisis® Abdominal Lock 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 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.

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 postoperatively.[1]

The presence of certain antimicrobials may inhibit revascularization and/or infiltration of cells into the graft.[3-5] 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 forceps
- A sterile dish (kidney dish or other bowl)
- Rehydration fluid: room temperature, sterile saline or sterile lactated Ringer's solution

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. Allow the graft to rehydrate for at least five (5) minutes prior to cutting, suturing, stapling, or tacking.
6. Prepare the site using standard surgical techniques.
7. Using aseptic technique, trim the graft to fit the site, providing an allowance for a 2-3cm 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.
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.

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.
3. Petroutsos, G., et al., *Antibiotics and corneal epithelial wound healing*. Arch Ophthalmol, 1983. 101(11): p. 1775-8.
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.
5. Nelson, J.D., et al., *Corneal epithelial wound healing: a tissue culture assay on the effect of antibiotics*. Curr Eye Res, 1990. 9(3): p. 277-85.
6. Kjolseth, D., et al., *Comparison of the effects of commonly used wound agents on epithelialization and neovascularization*. J Am Coll Surg, 1994. 179(3): p. 305-12.
7. Nakamura, M., et al., *Effects of antimicrobials on corneal epithelial migration*. Curr Eye Res, 1993. 12(8): p. 733-40.
8. Petroutsos, G., et al., *The effect of concentrated antibiotics on the rabbit's corneal epithelium*. Int Ophthalmol, 1984. 7(2): p. 65-9.