

# Surgisis® Biodesign™

VAGINAL EROSION REPAIR GRAFT

FP0055-01A



## Manufacturer:

Cook Biotech Incorporated  
1425 Innovation Place  
West Lafayette, IN 47906 U.S.A.  
Phone: (812) 339-2235  
Toll Free: 1-800-457-4500  
Toll Free Fax: 800-554-8335  
www.cookmedical.com

**INTENDED USE:** Surgisis® Biodesign™ Vaginal Erosion Repair Graft is intended to be implanted to reinforce soft tissues where weakness exists in the gynecological anatomy, including the repair of erosions of the vaginal wall. The Vaginal Erosion Repair 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.**

This product is intended for use by trained medical professionals.

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

### **PRECAUTIONS:**

- **Do not sterilize.** Discard all open and unused portions of the device.
- The Vaginal Erosion Repair Graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Ensure that the device is rehydrated prior to cutting or suturing.
- Ensure that all layers of the Vaginal Erosion Repair Graft are secured when suturing.
- Place the device in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling.
- Suturing more than one device together may decrease device performance.
- No studies have been conducted to evaluate the reproductive impact of the clinical use of the Vaginal Erosion Repair Graft.
- Extended rehydration or excessive handling could lead to partial delamination of the superficial layers of the Vaginal Erosion Repair Graft.
- The device performance has not been evaluated with suture spacing greater than 2 mm.
- Users should exercise good surgical practice for the management of contaminated or infected wounds.
- The potential for infection of the device material following implantation may be reduced by the use of prophylactic antibiotics.
- Users should exercise caution to avoid vessel, bowel, and bladder perforation.
- **IMPORTANT: Users should counsel patients on abstaining from heavy lifting, strenuous exercise, vaginal insertions (e.g. tampons) and sexual intercourse for a period of four (4) to six (6) weeks after surgery.**

### **USE OF ANTIMICROBIALS**

Because the Vaginal Erosion Repair Graft is 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 device 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*. Typical vaginal and genitourinary flora can be expected to include a variety of aerobic, anaerobic and facultative anaerobic organisms such as *Bacteriodes spp.* and *Enterococcus spp.* 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 Vaginal Erosion Repair Graft [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 Vaginal Erosion Repair Graft.

### **POTENTIAL COMPLICATIONS:**

The following complications are possible with the use of surgical graft materials: bleeding, infection, adhesions, erosion, extrusion, exposure, sterile effusion, chronic inflammation, allergic reaction, and delayed or failed incorporation of device. If conditions of infection, inflammation, or allergic reaction cannot be resolved, consider removal of the device.

**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 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 Vaginal Erosion Repair Graft using aseptic technique, minimizing contact with latex gloves.**

### **REQUIRED MATERIALS:**

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

### **PREPARATORY:**

1. Remove the packaging containing the Vaginal Erosion Repair Graft from the envelope.
2. Remove the inner pouch containing the Vaginal Erosion Repair 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 Vaginal Erosion Repair Graft with a sterile instrument. Place the Vaginal Erosion Repair Graft into the sterile dish in the sterile field.
4. Add enough rehydration fluid to the dish to fully submerge the Vaginal Erosion Repair Graft. Allow the Vaginal Erosion Repair Graft to rehydrate, fully submerged, for 2-5 minutes. (See Use of Antimicrobials)
5. Prepare the patient and surgical site using standard surgical techniques appropriate for vaginal erosion repair.

#### PROCEDURAL:

1. Size the Vaginal Erosion Repair Graft approximately 20-30% larger than the defect.

**NOTE: If the device is too small for the defect, excess tension may result in recurrence of the original tissue defect or development of a defect in the adjacent tissues.**

2. Using aseptic technique, transfer the Vaginal Erosion Repair Graft to the surgical site. Tuck the edges of the Vaginal Erosion Repair Graft under the margins of the defect and suture into place, avoiding excess tension.

**NOTE: Surgical experience indicates that suturing the Vaginal Erosion Repair Graft with close tissue approximation produces better outcomes. Fundamental surgical principles suggest a suture spacing approximately equal to suture bite depth.**

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

3. Close the edges of the vaginal epithelium over the Vaginal Erosion Repair Graft.

**NOTE: If the vaginal epithelium does not cover the Vaginal Erosion Repair Graft, leaving the device exposed, consider placing the patient on estrogen cream. Additionally, a vaginal dilator or mold can be utilized post-operatively to keep the vaginal canal open.**

4. Complete the standard surgical procedure.
5. Discard any unused portions of the Vaginal Erosion Repair Graft according to institutional guidelines for disposal of 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.
3. Petroustos, 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.
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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. Petroustos, G., et al., *The effect of concentrated antibiotics on the rabbit's corneal epithelium*. Int Ophthalmol, 1984. 7(2): p. 65-9.