



FP0005-1H

COOK®



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SURGISIS AND SURGISIS ES (Enhanced Strength)
SOFT-TISSUE GRAFT, FREEZE-DRIED

INTENDED USE:

Used for implantation to reinforce soft tissue. 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.
Single-layer device should not be used in applications requiring high strength.
SURGISIS ES may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs.
Ensure that device is rehydrated prior to suturing or stapling.
Device performance has not been evaluated with suture spacing greater than 2 mm.
Ensure that all layers of SURGISIS ES are secured when suturing or stapling.

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical graft materials. If any of these conditions occur, the device should be removed.

- Infection
Acute or Chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.)
Allergic reaction

STORAGE: This device should be stored in a clean, dry location at room temperature.

STERILIZATION: This device has been sterilized with ethylene oxide.

NOTE: SURGISIS sheets have a microscopically rough and smooth side. With hole in upper right hand corner, rough side of the sheet is facing up. The functional difference between sides is minimal, but cell culture studies suggest that epithelial cell growth is moderately favored on the smooth side.



SUGGESTED INSTRUCTIONS FOR USING SURGISIS:

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: at least 50 mL of room temperature sterile saline or sterile lactated Ringer's solution for each SURGISIS sheet.
Using aseptic technique, remove the SURGISIS inner pouch from its outer bag, and place the inner pouch in the sterile field.
Open the inner pouch carefully, and aseptically remove the SURGISIS sheet with the sterile forceps.
Place the SURGISIS sheet into the sterile dish in the sterile field. (Multiple SURGISIS sheets may be rehydrated simultaneously in the same dish.)
Add to the dish at least 50 mL of the rehydration fluid for each SURGISIS sheet.
Allow SURGISIS sheets to rehydrate for at least three minutes. Allow SURGISIS ES sheets to rehydrate for at least ten minutes.
Prepare the graft site using standard surgical techniques.
Using aseptic technique, trim the SURGISIS sheet to fit the site, providing a small allowance for overlap. (Note: An alternative method is to cut the SURGISIS sheet to size prior to rehydration. If this method is selected, be sure to rehydrate the SURGISIS sheet prior to suturing or stapling it into place. See step 5.)
Using aseptic technique, transfer the SURGISIS sheet to the graft site and suture or staple into place, avoiding excess tension. (Note: Surgical experience indicates that suturing or stapling SURGISIS sheets with close tissue approximation produces better outcomes.)
Complete the standard surgical procedure.
Discard any unused portions of the SURGISIS sheet.

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