Product Information

Used for implantation to reinforce soft tissue. Supplied sterile in peel-open packages. Intended for one-time use.

Product	Size	Type	Order Number
SURGISIS Soft Tissue Graft	2x3 cm	1-ply	SLH-1S-2X3
	7x10 cm	1-ply	SLH-1S-7X10
	7x20 cm	1-ply	SLH-1S-7X20
SURGISIS ES Soft Tissue Graft	0.6x7 cm	4-ply (pledget)	SLH-4S-0.6X7
	4x7 cm	4-ply	SLH-4S-4X7
	7x10 cm	4-ply	SLH-4S-7X10
	7x20 cm	4-ply	SLH-4S-7X20

Delivered with COOK®'s outstanding customer service

SURGISIS Soft Tissue Graft is one of the family of SIS technology products from COOK, a name synonymous with medical innovation and outstanding customer service. Founded in 1963 with international headquarters in Bloomington, Indiana, COOK is the largest privately held medical device manufacturer in the world. COOK is a leading global developer, manufacturer and distributor of diagnostic and interventional devices for radiology, cardiology, radiation oncology, neurology, general surgery, gastroenterology, vascular access, wound care, urology, obstetrics and gynecology, critical care and endovascular procedures.

For more information, contact your COOK representative.

This product has the CE mark

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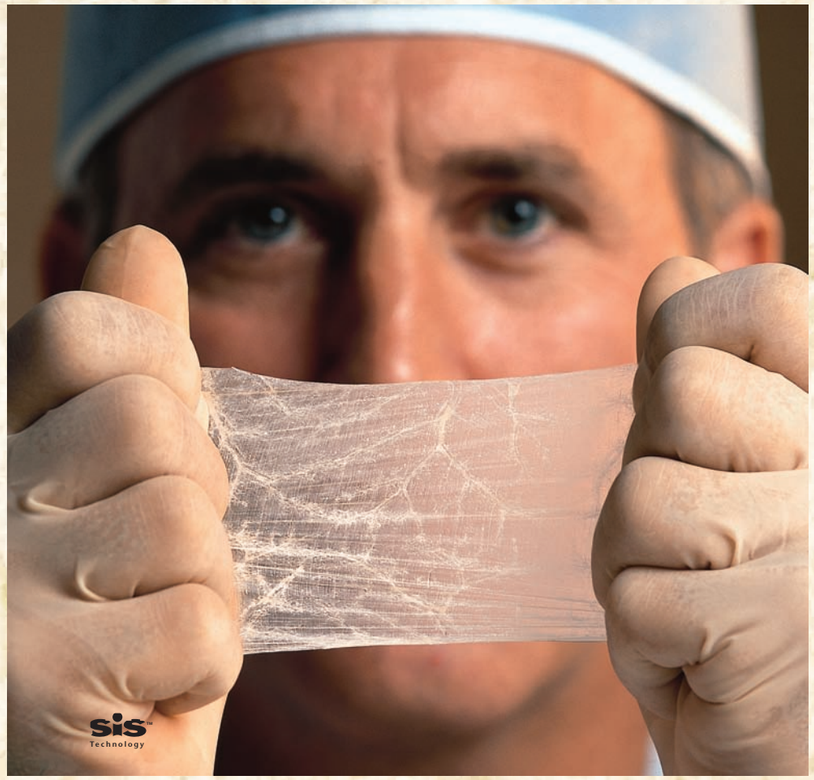
LIT009-2

SURGISIS® Soft Tissue Grafts

A revolutionary surgical mesh for tissue reinforcement.



SURGISIS® *A Revolutionary New Technology*

COOK®

SURGISIS® Soft-Tissue Graft

Indications

Used for implantation to reinforce soft tissue.
This device is supplied sterile in peel-open packages.
Intended for one-time use.

Applications

SURGISIS and SURGISIS ES Soft Tissue Grafts are used as a surgical mesh for implantation to reinforce soft tissue. Surgical meshes are generally used for:

- Abdominal wall repair
- Hernia repair (abdominal, inguinal, diaphragmatic, epigastric, gastroesophageal, hiatal, intermuscular, mesenteric, paraperitoneal, rectovaginal, retrocecal, uterine, and vesical)
- Prolapsed tissue support/repair
- Perforated tissue repair
- General tissue repair (pelvic floor, bladder, thoracic wall, etc.)

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 of SURGISIS.
- 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.
- 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.

Suggested Instructions for Use

NOTE: Always handle sheets using aseptic technique.

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 SURGISIS 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 SURGISIS sheet with the sterile forceps.
3. Place the SURGISIS sheet into the sterile dish in the sterile field. (Multiple SURGISIS sheets may be rehydrated simultaneously in the same dish.)
4. Add to the dish at least 50 mL of the rehydration fluid for each SURGISIS sheet. (Sufficient to completely cover SURGISIS sheet.)
5. Allow SURGISIS sheets to rehydrate for at least three minutes. Allow SURGISIS ES sheets to rehydrate for at least ten minutes.
6. Prepare the graft site using standard surgical techniques.
7. 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.
8. 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.
9. Complete the standard surgical procedure.
10. Discard any unused portions of the SURGISIS sheet.

Mechanical Properties

SURGISIS ES sheets have a thickness and mechanical strength that is several times that of a single-layer SURGISIS sheet. Nominal properties for SURGISIS ES and single-layer SURGISIS sheets are listed below:

	SURGISIS Single-Layer[a]	SURGISIS ES Enhanced Strength[b]
Nominal Thickness (mm)	0.20	0.42
Suture Retention Strength (g)*	303 ± 51	775 ± 196
Burst Force** (N)	23.1 ± 1.8 (N)	126.8 ± 30.2 (N)
(kg)	2.36 ± 0.18 (kg)	12.93 ± 3.08 (kg)

[a]Single-layer SURGISIS sheets are designed to tolerate the mechanical stresses associated with low-stress body systems.

[b]SURGISIS ES sheets are designed to tolerate the mechanical stresses associated with higher-stress body systems.

*5-0 suture with 2 mm bite depth

**9.5 mm diameter sphere