

SURGISIS® IHM™

INGUINAL HERNIA MATRIX

FP0023-1F

COOK®

sis
Technology

Manufacturer:

Cook Biotech Incorporated

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INTENDED USE: SURGISIS® Inguinal Hernia Matrix is implanted to reinforce soft tissues in the inguinal floor to repair inguinal hernias.

SURGISIS® Inguinal Hernia Matrix is supplied sterile 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 in patients with known sensitivity to porcine material.

PRECAUTIONS:

- **Do not resterilize.** Discard all open and unused portions of the device.
- SURGISIS® Inguinal Hernia Matrix 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.
- **Ensure that device is rehydrated prior to cutting, suturing, stapling, or loading of the device laparoscopically.**
- Care should be taken to avoid damaging the device when loading laparoscopically. It is recommended to load through a 10 mm or larger port.
- Ensure that all layers of SURGISIS® Inguinal Hernia Matrix are secured when suturing or stapling.
- Suturing or stapling more than one device together may decrease device performance.
- No studies have been conducted to evaluate the reproductive impact of the clinical use of SURGISIS® Inguinal Hernia Matrix

POTENTIAL COMPLICATIONS:

Possible adverse reactions with the use of any prosthesis may include, but are not limited to, infection, pain, inflammation, adhesion, fistula formation, seroma formation, hematoma, and recurrence of tissue defect.

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 USING SURGISIS® Inguinal Hernia Matrix

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 SURGISIS® Inguinal Hernia Matrix using aseptic technique, minimizing contact with latex gloves.

Required Materials

- Sterile scissors (if cutting required)
 - Rehydration fluid: room temperature, sterile saline or sterile lactated Ringer's solution.
 - Sterile tray
1. Using aseptic technique, remove the inner pouch from the outer pouch and place it in the sterile field.
 2. Open the inner pouch carefully. Use a tray to rehydrate the device by adding room temperature, sterile saline or sterile lactated Ringer's solution.
 3. Allow SURGISIS® Inguinal Hernia Matrix to rehydrate for at least ten (10) minutes prior to cutting, suturing, stapling, or loading the device laparoscopically.
 4. Prepare the hernia repair site using standard surgical techniques.
 5. Using aseptic technique, trim SURGISIS® Inguinal Hernia Matrix to fit the site, providing a small allowance for overlap.
 6. Using aseptic technique, transfer SURGISIS® Inguinal Hernia Matrix to the surgical site and suture or staple into place, avoiding excess tension.
 7. Complete the standard surgical procedure.
 8. Discard any unused portions.

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