

STRATASIS[®]

URETHRAL SLING

FP0007-1H

COOK[®]

sis[®]
Technology

Manufacturer:

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INTENDED USE

Used to provide pubourethral support for the treatment of urinary incontinence resulting from hypermobility or intrinsic sphincter deficiency. STRATASIS[®] Urethral Sling is intended for implantation to reinforce soft tissues where weakness exists.

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 in patients with known sensitivity to porcine material.

PRECAUTIONS:

- **Do not resterilize.** Discard all open and unused portions of STRATASIS.
- 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.
- Ensure that device is rehydrated prior to securing the device to the surgical site with sutures, staples, or other fasteners.
- Device performance has not been evaluated with suture spacing greater than 2 mm.
- Ensure that all layers of STRATASIS are secured when fastening the device to the surgical site.
- Excess tension on the device may cause urinary retention in the device recipient when being treated for urinary incontinence

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. Do not resterilize.

NOTE: STRATASIS 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 STRATASIS
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 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 STRATASIS.
1. Using aseptic technique, remove the STRATASIS 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 STRATASIS with the sterile forceps.
 3. Place the STRATASIS into the sterile dish in the sterile field.
 4. Add to the dish at least 50 ml of the rehydration fluid for each STRATASIS.
 5. Allow STRATASIS to rehydrate for at least ten minutes.
 6. Prepare the surgical site using standard surgical techniques.
 7. Using aseptic technique, trim the STRATASIS to fit the surgical site. (Note: An alternative method is to cut the STRATASIS to size prior to rehydration. If this method is selected, be sure to rehydrate the STRATASIS prior to securing the device into place. See step 5.)
 8. Using aseptic technique, transfer the STRATASIS to the surgical site and secure the device into place, avoiding excess tension.
(Note: Surgical experience indicates that securing STRATASIS with close tissue approximation produces better outcomes.)
 9. Complete the surgical procedure.
 10. Discard any unused portions of the STRATASIS.

MECHANICAL PROPERTIES

The nominal properties for STRATASIS are listed below:

Property	STRATASIS
Nominal Thickness (mm)	0.42
Suture Retention Strength*	775 ± 196g 1.7 ± 0.4 lb
Burst Force**	12.9 ± 3.1 kg 28.4 ± 6.8 lb

* 5-0 suture with 2 mm bite depth

** 9.5 mm diameter sphere

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