

Surgisis® Biodesign™

STAPLE LINE REINFORCEMENT

Self-Adhesive Freeze-Dried Sheet

FP0050-01D



Manufacturer:

Cook Biotech Incorporated

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INTENDED USE:

The Surgisis® Biodesign™ Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The device may be used for buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers.

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 device is supplied sterile and is intended for one-time use.

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CONTRAINDICATIONS:

- This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine materials.
- This device contains fructose and should not be used in patients with known sensitivity to fructose.

PRECAUTIONS:

- Do not resterilize. Discard open and unused portions.
- Device is sterile if the package is dry, unopened, and undamaged. Do not use if package seal is broken.
- Discard device if mishandling has caused possible damage or contamination or if device is past its expiration date.

NOTE: Device may get damaged if foam applicator is folded.

- Follow the manufacturer's instructions regarding the use of the stapler, including precautions regarding use with staple reinforcement materials.
- Use stapler loads that allow for combined thickness of tissue and the Staple Line Reinforcement.*
- Use only specified staplers with appropriate sized Staple Line Reinforcement.
- Ensure that prior to firing the surgical stapler the entire active portions of stapler jaws are covered by the reinforcement device.
- Fire the stapler within 20 minutes after applying the Staple Line Reinforcement. Otherwise, it may be difficult to dislodge the device from the stapler jaws after firing.
- Avoid dropping the tray-device assembly from the pouch onto the sterile field as it might fall off the sterile field.
- Avoid using the tail to remove the Staple Line Reinforcement device from the tray as it could lead to premature detachment from the foam applicator.
- Avoid trying to re-adhere the Staple Line Reinforcement device to the stapler if it comes off.
- Avoid excessive manipulation of tissue with a stapler loaded with the Staple Line Reinforcement device.
- Avoid dipping the Staple Line Reinforcement device in water/saline to prevent loss of adhesive. Dip the stapler jaws instead.

POTENTIAL COMPLICATIONS:

- Infection
- Acute or chronic inflammation (Initial application of 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:

The Staple Line Reinforcement has been sterilized using E-beam radiation.

* The average total nominal thickness (anvil+cartridge side including adhesive) of the product is 0.53 mm.

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.

REQUIRED MATERIALS:

- Compatible surgical stapler
- Warm sterile water or saline
- Sterile scissors
- Sterile basin
- Sterile gauze or sponge

NOTE: Always handle the Staple Line Reinforcement using aseptic technique, minimizing contact with latex gloves.

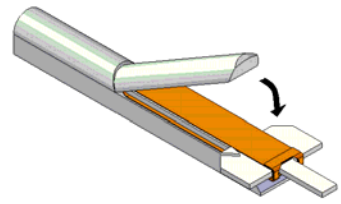
1. Aseptically remove the tray from inside the pouch using sterile gloved hands and place into the sterile field.
2. Pull the Staple Line Reinforcement out of the tray by the wings of the foam applicator.
3. Wet the jaws of the surgical stapler or re-load by compressing the jaws across a piece of gauze (or a sponge) that has been soaked with sterile water or saline.



NOTE: Liquid can be warmed up to 38°C (100°F) to enhance adhesion.

An alternate wetting method is to quickly dip the jaws of the surgical stapler or re-load in sterile water or saline and allow any excess water to drip off.

4. Place the applicator inside **the wet jaws of the surgical stapler**. Visually or palpably align the parallel edges of the applicator with the edges of the stapler jaws. Insert the applicator fully to ensure that the device will cover all staples in the cartridge. The perforated portion of the device with the tail should extend beyond closed staple jaws.



5. Close the stapler on the applicator. **Keep tightly closed for at least 10 seconds.**
6. Grip the tail of the foam applicator close to its base and detach it to allow the device to be released from the foam applicator. **Discard the tail of the applicator.**
7. Open the stapler jaws, **remove and discard the foam applicator**. Inspect device alignment to ensure complete coverage of both cartridge and anvil stapler jaws. Inspect the adhered Staple Line Reinforcement to ensure that none of the foam applicator parts are stuck. If required, using sterile scissors, cut off any excess length of the Staple Line Reinforcement strip that protrudes from the tip of the stapler jaws, being certain not to dislodge the strip from the stapler jaws.

NOTE: IF THE STAPLER IS A TWO-PART STAPLER, USE STERILE SCISSORS TO CUT THE REINFORCEMENT DEVICE AT THE HINGED FOLD LYING BETWEEN THE TWO STAPLER JAWS.

8. Move the stapler or re-load to the operative site and continue with the procedure. Use caution to avoid displacing the Staple Line Reinforcement from the stapler jaws. **Use the stapler within 20 minutes after applying the Staple Line Reinforcement to the stapler.**

NOTE: BEFORE APPLYING A NEW Staple Line Reinforcement WIPE THE STAPLER JAWS WITH A DRY PIECE OF GAUZE OR STERILE CLOTH.

9. Discard any unused portions of the device following standard technique for disposal of medical waste.

