Use reinforcement strips that completely remodel.¹

Biodesign® Staple Line Reinforcement is designed to add strength without increasing the difficulty of the procedure. Each strip is designed to provide these benefits.

**Complete remodeling¹**
Biodesign is a biologic graft technology that is completely remodeled into strong well-vascularized tissue.¹
In an animal study of lung resection, staple lines reinforced with Biodesign material withstood more pressure than staple lines reinforced by either bioabsorbable synthetic material or bovine pericardium.²

**Fructose coating**
Coated with fructose self-adhesive, the strips are easy to load into the stapler. No strings or glue are needed. Once loaded, the strips stay in place until the stapler fires.

**Thin design**
The combined top and bottom strips have a nominal thickness of 0.5 mm. They can compress down to 0.3 mm thick.³ The strips are designed to offer consistent thickness, even in overlapping strips.

3. These measurements represent the four-layer strips. Data on file at Cook Biotech.
Apply the staple line reinforcement with these simple steps.

1. Prepare a basin of warm* sterile water or sterile saline. The basin should be deep enough to accommodate the length of the stapler’s jaws. Prepare the basin of warm liquid no more than five minutes before step two. Pull the tray out of the sterile pouch. Place the tray in a sterile field.

2. Completely submerge the stapler’s jaws into the basin for three seconds to allow the stapler to become moist and warm. Lift the stapler’s jaws from the liquid and tap the stapler to remove excess liquid.

3. Remove the staple line reinforcement from the tray by holding the finger grips on the wings of the foam applicator. Do not grab or hold the strip by the tail. Do not touch the strip.

4. Place the foam applicator inside the wet jaws of the stapler. Align the edges of the foam applicator with the edges of the cartridge jaw. Gently insert the foam applicator to the back of the stapler’s jaws, where notches in the foaml applicator provide a stop.

5. Close the jaws of the stapler on the strip and foam applicator.

6. Compress the jaws tightly with your fingers or compress the handle on the stapler for at least five seconds to allow the liquid to activate the adhesive.

7. While holding the jaws closed, grip the tail of the foam applicator and use a side-to-side motion to detach it. Discard the tail.

8. Slowly open the jaws of the stapler. Remove the remainder of the foam applicator and discard it.

9. Inspect the alignment of the device to ensure complete coverage of the cartridge side and the anvil side of the stapler’s jaws.

10. The stapler is ready to use. Ensure that the strip fully adheres to the jaws. If the strip falls off the stapler, avoid reapplying it. Discard that strip and apply a new one.

Note: The strip must be used within 10 minutes after being applied to the stapler. Between every use with Ethicon® staplers, wipe the anvil side clean.

Recommended for use with Medtronic or Ethicon stapling devices. For more information, contact your Cook Medical representative.

Ethicon is a registered trademark of Johnson & Johnson.

The techniques presented in this guide are recommendations that should help you achieve optimum results, but this guide is not meant to be a substitute for the IFU.

4. The liquid should be between 104-120 ºF (40-49 ºC).

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*Bisected® Staple Line Reinforcement

**INTENDED USE:** The Bisected® Staple Line Reinforcement is intended for use as a prosthesis for the construction of soft tissue anastomoses as an appositional staple line. The Staple Line Reinforcement may be used for the repair/reinforcement and reinforcement of staple lines during long mucosectomy, wedge resection, bronchectomy, lobectomy, culdectomy, partial resection of the liver and hepaticojejunostomy. The Staple Line Reinforcement can be used for the reinforcement of the cartridge staple line following endoscopic, transoral, or thoracic ductal ligation, and for placement of staple lines during peritoneum, mesenteric, or pericardial suture. This staple line reinforcement may be used in an aseptic environment with non-sterile, non-vacuum, or non-active staplers. It is intended for use by a trained surgeon or trained medical professional. This device is supplied sterile in multi-dose form, single use.

**CONTRAINDICATIONS:** This device is contraindicated for use by a patient in whom there is a potential to create a perforation in the stapler. The Staple Line Reinforcement contains a small amount of material that may cause an allergic reaction, which should not be used in patients with known sensitivity to this material. This device is contraindicated for use in patients with severe allergies to the product.

**PRECAUTIONS:** This device is designed for single use only. It is intended for use by a trained surgeon or trained medical professional. The device is not intended to be used in the event of a perforation. The surgeon should use the appropriate surgical technique to ensure proper placement of the device. The device is not intended for use in procedures that require a staple line in addition to the staple line reinforcement. Any attempt to use this device beyond its intended use may result in injury to the patient.

**ADVERSE REACTIONS:** There have been no adverse reactions reported for the use of the Bisected® Staple Line Reinforcement. However, it is possible that there may be a risk for the development of an allergic reaction to the material. The risk of an allergic reaction is low, and it is not expected to occur in the majority of patients. The risk of an allergic reaction may be higher in patients with a history of allergies.

**POTENTIAL COMPLICATIONS:** This device is intended for use in procedures where it is safe to use a staple line reinforcement. If the device is used in a manner that is not intended, it may cause complications such as perforation or tissue damage.

**REFERENCES:**


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