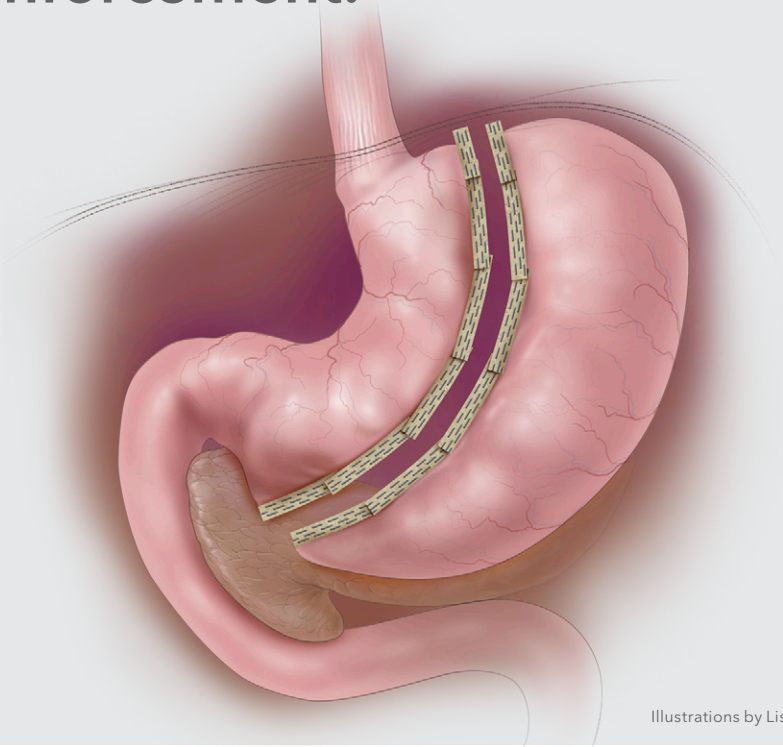


Move beyond to
strong, simple
reinforcement.



Illustrations by Lisa Clark

Biodesign[®]
ADVANCED TISSUE REPAIR



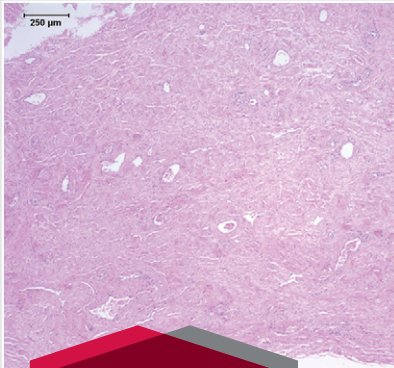


Move Beyond
to the next generation



BIODESIGN[®]
ADVANCED TISSUE REPAIR

Move beyond to advanced tissue repair.



Non-cross-linked

Biodesign material has been designed to maintain strength throughout the remodeling process, so there is no need for cross-linking. And because Biodesign material is remodeled completely into strong, vascularized tissue, it can provide a strong repair without a permanent material.

Non-dermis-based

Biodesign material is non-dermis-based, so it does not contain meaningful amounts of elastin.³ As a result, the body completely remodels Biodesign material into patient tissue that is not prone to overstretching.

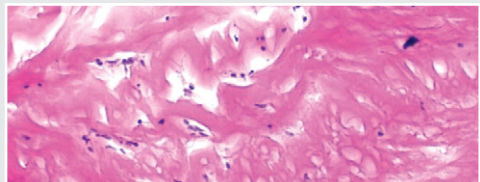
Biodesign is a non-cross-linked, non-dermis-based biologic graft technology that is completely remodeled into strong, well-vascularized tissue.¹

Cross-linked

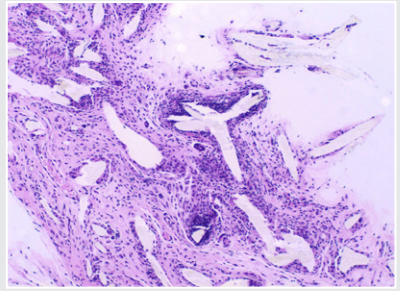
Cross-linked biologic grafts do inhibit remodeling and vascular ingrowth, and have been associated with chronic inflammation and encapsulation.²

Dermis-based

Dermis-based grafts contain high amounts of elastin. Over time, this elastin remains in the patient's body. A dermis-based graft can stretch and possibly lead to recurrence.⁴



Bioabsorbable synthetic mesh



Bioabsorbable synthetic mesh

Bioabsorbable synthetic mesh resorbs in the body over time. While bioabsorbable mesh leaves behind no permanent material, the body cannot remodel this mesh into new vascularized tissue.

Biologic graft

Move beyond to easier assurance.

Biodesign staple line reinforcement is designed to add strength without increasing the difficulty of the procedure. Each strip has:

Fructose coating

The strips are easy to load into the stapler with fructose **self-adhesive**. 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 share a **uniform thickness** of 0.4 mm. They can compress down to 0.2 mm. The strips are designed to provide more predictable, effective staple line formation by offering consistent thickness, even in overlapping strips.

In an animal study, staple lines reinforced with Biodesign strips withstood more pressure than staple lines reinforced by either bioabsorbable synthetic material or bovine pericardium.⁵

An intraoperative look at the staple line

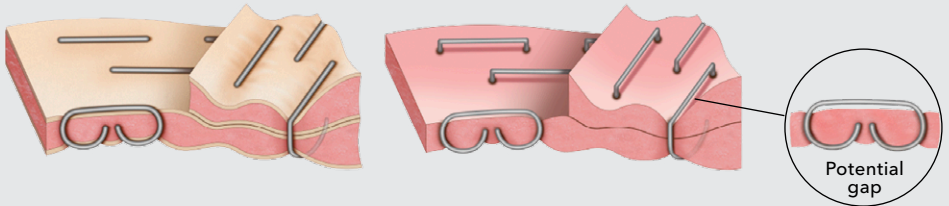
Biodesign

The uniform size of the Biodesign strips allow the staple line to form correctly at the time of resection. Over time, the patient's body will remodel the Biodesign material into healthy tissue that forms securely around the staple.



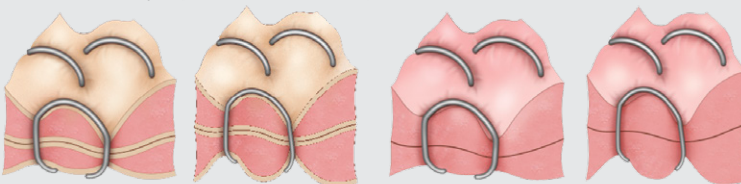
Bioabsorbable synthetic

The uniform size of the bioabsorbable synthetic reinforcement allows the staple line to form correctly at the time of resection. Over time, the synthetic material will be absorbed by the body. Gaps may form around the staples, in the place of the synthetic material.



Bovine pericardium

The bovine pericardium reinforcements have variable thickness. The staples may not form correctly around these reinforcements. Over time, the patient's body will remodel bovine pericardium into healthy tissue that forms securely around the staple.



Move beyond to Biodesign.



Biodesign® ADVANCED TISSUE REPAIR

An advanced tissue repair technology, Biodesign staple line reinforcement is designed to provide these benefits.

Easy loading

Biodesign staple line reinforcement is string-free and precoated with adhesive.

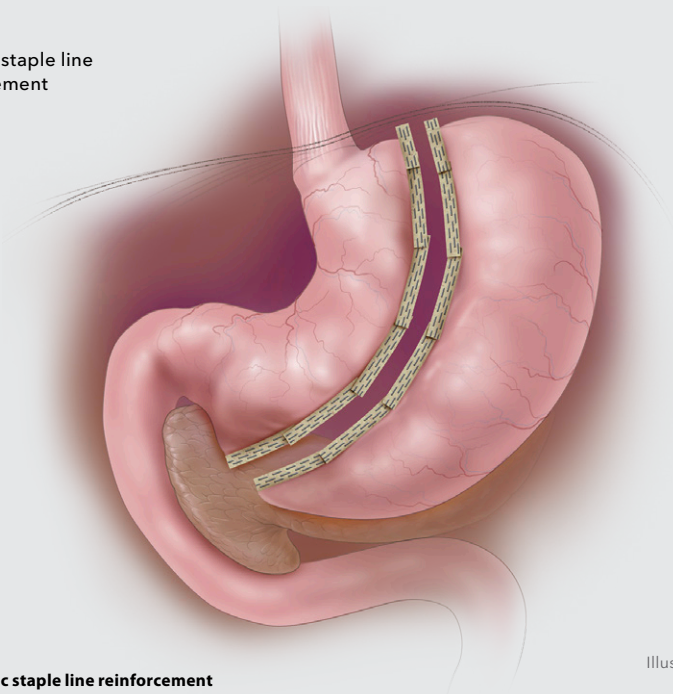
Consistent staple formation

Uniform strip thickness leads to better staple line formation.

Secure resection

The patient's body will remodel the Biodesign material. A staple line reinforced with Biodesign material can withstand significantly higher pressure than an unreinforced staple line.⁵

Bariatric staple line reinforcement



Illustrations by Lisa Clark

Bariatric staple line reinforcement

Order Number	Reference Part Number	Stapler
For Covidien Staplers		
G50656	C-SLRA-GIA30	Endo GIA® 30
G50868	C-SLRA-GIA45	Endo GIA 45
G50867	C-SLRA-GIA60	Endo GIA 60
G54251	C-SLRA-OPEN-GIA60	GIA® 60
G54252	C-SLRA-OPEN-GIA80	GIA 80
G25006	C-SLRA-TRI45	Tri-Staple® 45
G25007	C-SLRA-TRI60	Tri-Staple 60
For Ethicon® Staplers		
G50866	C-SLRA-TCT-TLC55	Proximate® TCT 55/TLC 55
G50865	C-SLRA-TCT-TLC75	Proximate TCT 75/TLC 75
G51746	C-SLRA-ECH45	Echelon™ 45
G50871	C-SLRA-ECH60	Echelon 60
G23201	C-SLRA-SC60	Echelon 60

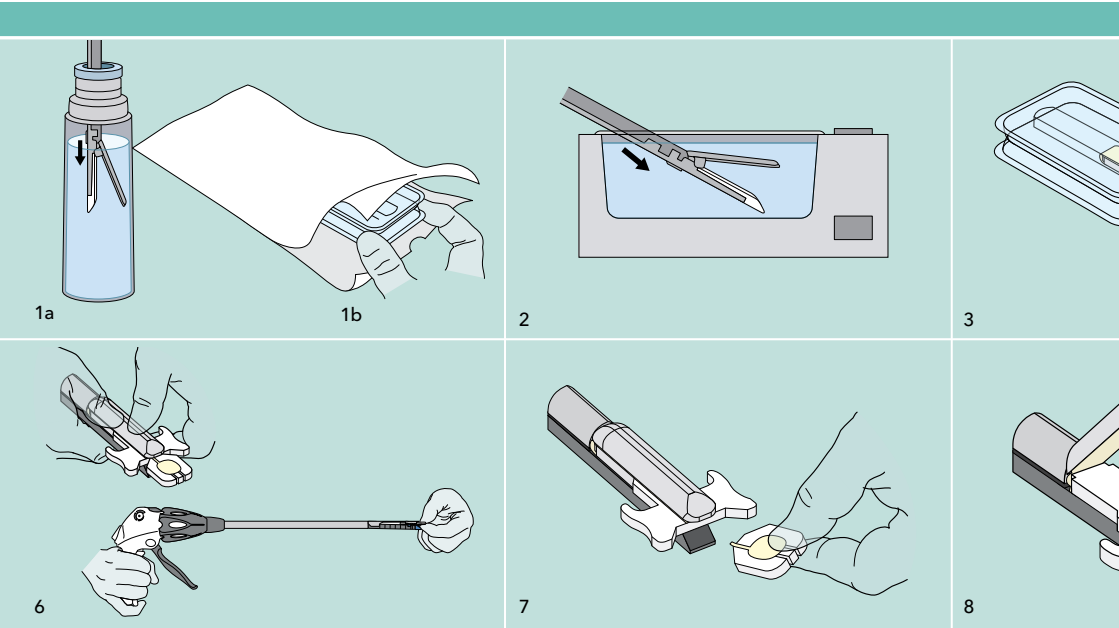
Note: All sold in boxes of 5.

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

Endo GIA, Tri-Staple, and GIA are registered trademarks of Covidien LP.

Echelon is a trademark of Johnson & Johnson.

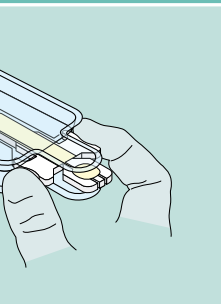
Proximate is a registered trademark of Johnson & Johnson.



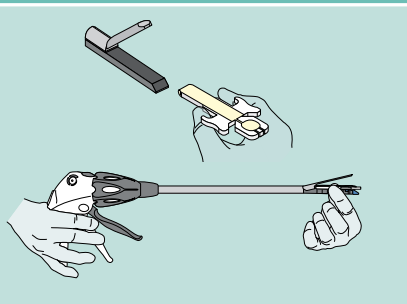
Procedural guide

Apply the staple line reinforcement with these simple steps.

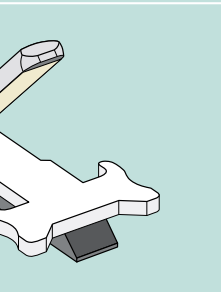
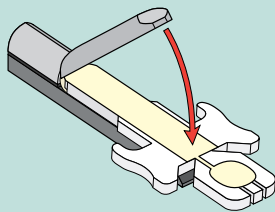
- 1a. Prepare a basin of warm sterile water or sterile saline. The liquid should be no warmer than 40 °C-49 °C (104 °F-120 °F). The basin should be deep enough to accommodate the length of the stapler jaws. Prepare the basin of warm liquid no more than five minutes before step two.
- 1b. Pull the tray out of the sterile pouch. Place the tray in a sterile field.
2. Completely submerge the stapler jaws into the basin for three seconds to allow the stapler to become moist and warm. Lift the stapler 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 applicator inside the wet jaws of the stapler. Align the edges of the applicator with the edges of the cartridge jaw. Gently insert the applicator to the back of the stapler jaws, where notches in the applicator provide a stop.
5. Close the jaws of the stapler on the strip and foam applicator.



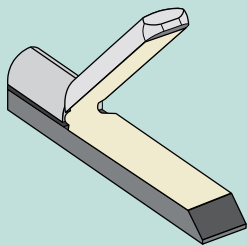
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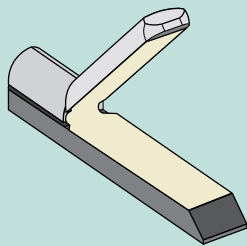
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9



10



6. Compress the jaws tightly with your fingers or compress the handle on the stapler for at least 5 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 jaws.
NOTE: Between every use with Ethicon® staplers, wipe the anvil side clean.
10. The stapler is ready to use. Ensure that the strip fully adheres to the jaws. If the strip is not lined up or fully adhered to the stapler, reinsert and compress the handle on the stapler for a further 10-20 seconds. If the strip is still not fully adhered, remove it, discard it, and apply a new strip. **NOTE:** The strip must be used within 10 minutes after being applied to the stapler.

Recommended for use with Covidien or Ethicon stapling devices. For more information, contact your Cook Medical representative. Ethicon is a registered trademark of Johnson & Johnson.

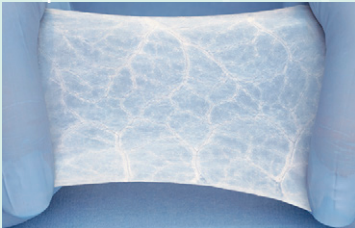
Move beyond to continual improvement.

Biodesign material is the evolution of a technology that started a revolution in tissue repair.

Advancing staple line reinforcement

Early versions of small intestinal submucosa (SIS) reinforcement strips were not self-adhesive. As we created Biodesign staple line reinforcement, we continually improved the strips' handling and ability to be remodelled.

1988



Discovery of SIS

Small intestinal submucosa (SIS) is used as an aortic replacement in a canine model. Remarkably, the SIS is fully remodeled into vascular tissue.

January 2008



SLRA-ECH60

We release the first version of our staple line reinforcement to be self-adhesive and use Biodesign technology.

October 2008



SLRA-ECH60

We release a version of our staple line reinforcement that is more compressible. We widen the foam tip to make the strip easier to hold.

2010



SLRA-OPEN-GIA80

We release versions of our staple line reinforcement that are made for open staplers.

Move beyond to Biodesign.

10 reasons to choose Biodesign material over other reinforcement technology.

- ✓ Biodesign strips have a uniform thickness and can result in smoother staple lines than other reinforcement material.
- ✓ Biodesign strips are coated with fructose and self-adhere to the stapler jaws. No gel or strings are needed.
- ✓ The body remodels Biodesign material into vascularized tissue that can surround and secure the staple.
- ✓ The patient's body remodels Biodesign material into strong, vascularized patient tissue. A staple line reinforced with Biodesign material can withstand significantly higher pressure than an unreinforced staple line.
- ✓ Biodesign reinforcement strips are designed to be thin. You can get a predictable, consistent staple line formation even when the staple line overlaps.
- ✓ Biodesign reinforcement strips can be used alongside a wide variety of stapling devices in bariatric surgery.
- ✓ Biodesign is a non-cross-linked biologic material, so no residual cross-linked material is left behind to encapsulate, erode, or become infected.
- ✓ An intact extracellular matrix, Biodesign material is processed in a way that preserves its natural structure, supporting tissue remodeling.
- ✓ Biodesign is a proven technology that has been demonstrated to be effective in more than 1,000,000 patient treatments.
- ✓ Biodesign material is based on a technology that has been the subject of more than 1,000 peer-reviewed journal articles and 10 randomized controlled trials.

Randomized controlled trials that include Biodesign devices

- Analoni L, Catena F, D'Alessandro L. Prospective randomized, double-blind, controlled trial comparing Lichtenstein's repair of inguinal hernia with polypropylene mesh versus Surgisis gold soft tissue graft: preliminary results. *Acta Biomed.* 2003;74(suppl 2):10-14.
- Mostow EN, Haraway GD, Dalsing M, et al. Effectiveness of an extracellular matrix graft (OASIS Wound Matrix) in the treatment of chronic leg ulcers: a randomized clinical trial. *J Vasc Surg.* 2005;41(5):837-843.
- Niezgoda JA, Van Gils CC, Frykberg RC, et al. Randomized clinical trial comparing OASIS Wound Matrix to Regranex Gel for diabetic ulcers. *Adv Skin Wound Care.* 2005;18(5, pt 1):258-266.
- Oelschlager BK, Pellegrini CA, Hunter J, et al. Biologic prosthesis reduces recurrence after laparoscopic paraesophageal hernia repair: a multicenter, prospective, randomized trial. *Ann Surg.* 2006;244(4):481-490.
- Romanelli M, Dini V, Bertone M, et al. OASIS wound matrix versus Hyaloskin in the treatment of difficult-to-heal wounds of mixed arterial/venous aetiology. *Int Wound J.* 2007;4(1):3-7.
- Landsman A, Roukis TS, DeFronzo, DJ, et al. Living cells or collagen matrix: which is more beneficial in the treatment of diabetic foot ulcers? *Wounds.* 2008;20(6):111-116.
- Analoni L, Catena F, Coccolini F, et al. Inguinal hernia repair with porcine small intestine submucosa: 3-year follow-up results of a randomized controlled trial of Lichtenstein's repair with polypropylene mesh versus Surgisis Inguinal Hernia Matrix. *Am J Surg.* 2009;198(3):303-312.
- Romanelli M, Dini V, Bertone MS. Randomized comparison of OASIS wound matrix versus moist wound dressing in the treatment of difficult-to-heal wounds of mixed arterial/venous etiology. *Adv Skin Wound Care.* 2010;23(1):34-38.
- Feldner PC Jr, Castro RA, Cipolotti LA, et al. Anterior vaginal wall prolapse: a randomized controlled trial of SIS graft versus traditional colporrhaphy. *Int Urogynecol J.* 2010;21(9):1057-1063.
- Bejjani GK, Zabramski J; Durasis Study Group. Safety and efficacy of the porcine small intestinal submucosa dural substitute: results of a prospective multicenter study and literature review. *J Neurosurg.* 2007;106(6):1028-1033.
- van Koperen PJ, Bemelman WA, Gerhards MF, et al. The anal fistula plug treatment compared with the mucosal advancement flap for cryptoglandular high transsphincteric perianal fistula: a double-blinded multicenter randomized trial. *Dis Colon Rectum.* 2011;54(4):387-393.
- Sung VW, Rardin CR, Raker CA, et al. Porcine subintestinal submucosal graft augmentation for rectocele repair: a randomized controlled trial. *Obstet Gynecol.* 2012;119(1):125-133.
- Sarr MG, Hutcher NE, Snyder S, et al. A prospective, randomized, multicenter trial of Surgisis Gold, a biologic prosthetic, as a sublay reinforcement of the fascial closure after open bariatric surgery. *Surgery.* 2014;156(4):902-908.
- Robert M, Girard I, Brennand E, et al. Absorbable mesh augmentation compared with no mesh for anterior prolapse: a randomized controlled trial. *Obstet Gynecol.* 2014;123(2, Pt 1):288-294.

Citations

1. Franklin ME Jr, Trevino JM, Potillo G, et al. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up. *Surg Endosc.* 2008;22(9):1941-1946.
2. Novitsky YW, Rosen MJ. The biology of biologics: basic science and clinical concepts. *Plast Reconstr Surg.* 2012;130:9s-17s.
3. Heise RL, Inanova J, Parekh A, et al. Generating elastin-rich small intestinal submucosa-based smooth muscle constructs utilizing exogenous growth factors and cyclic mechanical stimulation. *Tissue Eng Part A.* 2009;15(12):3951-3960.
4. Gupta A, Zahriya K, Mullens PL, et al. Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm. *Hernia.* 2006;10(5):419-425.
5. Downey DM, Harre JG, Pratt JW. Functional comparison of staple line reinforcements in lung resection. *Ann Thorac Surg.* 2006;82(5):1880-1883.

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