

HERNIA REPAIR FISTULA PLASTIC & REPAIR RECONSTR

PLASTIC & RECONSTRUCTIVE/ENT

STAPLE LINE REINFORCEMENT PEYRONIE'S REPAIR CONTINENCE RESTORATION DURAL I REPAIR I

PELVIC FLOOR REPAIR



# Experience a new category in tissue repair.

In response to physicians' needs, Cook Medical began developing a totally new kind of tissue repair graft material in the mid 1990s. According to physicians, an ideal graft would exhibit the properties of:

Remodeling

- Availability
- Resistance to infection
- Strength and durability
- Affordability and ease of use
- Reduced recurrence rates



Through continued evaluations, trials and advancements, Biodesign was born. This revolutionary technology is now available for use in **9 procedural areas**, has been distributed to **86 countries** and used in more than **one million patients**. To date, nearly **750 journal articles** have been published about the technology on which Biodesign is based. It is a breakthrough advancement in the evolution of tissue repair–a whole new category.

Cook Medical–Advancing tissue repair for better patient outcomes.



Biodesign has been designed to combine the best attributes of synthetic mesh and biologic grafts, creating a **whole new category** in tissue repair.



### **BIODESIGN** Advanced tissue repair

NOT FOR USE IN INFECTED FIELDS

POTENTIAL EROSION & SCARRING OF SURROUNDING TISSUE

LOW COST

WIDESPREAD AVAILABILITY

**VARIOUS SHAPES & SIZES** 

**READY TO USE** 

SIGNALS THE BODY RESISTANT TO INFECTION COMPLETE REMODELING LONG-TERM STRENGTH MODERATE COST WIDESPREAD AVAILABILITY VARIOUS SHAPES & SIZES READY TO USE



**RESISTANT TO INFECTION** 

NATURAL REMODELING

**POTENTIAL STRETCHING** 

HIGH COST

LIMITED AVAILABILITY

LIMITED SIZES

SOMETIMES REQUIRES SPECIAL STORAGE & PREPARATION

Previously, there were only two options for tissue repair-both with positive and negative attributes.



**RESISTANT TO INFECTION** 

**F**RIM

NATURAL REMODELING

**POTENTIAL STRETCHING** 

**HIGH COST** 

LIMITED AVAILABILITY

LIMITED SIZES

SOMETIMES REQUIRES SPECIAL STORAGE & PREPARATION

### Key benefits



Unlike some biologic grafts, Biodesign communicates with the body, signaling surrounding tissue to grow across the scaffold, allowing the body to restore itself.



### Resistant to Infection

Biodesign remodels into vascularized host tissue, allowing the body's own defense mechanisms to reach and respond to infection. This ability to remodel provides the basis for infection resistance.

The progression of remodeling is clear in these images. Initial placement of the graft is shown first, and in the next three images, the graft is gradually replaced by vascularized tissue.





### Complete Remodeling

The remodeling process starts quickly and creates strong, fully vascularized tissue. Biodesign is undetectable once healing is complete, providing a permanent repair without a permanent material.



Over time, Biodesign becomes as strong as the patient's own tissue and does not leave behind meaningful amounts of elastin that could stretch and make the repair prone to failure.



Photos courtesy of W. Scott Helton, MD

### Tissue repair's most versatile tool



Biodesign is available in a **variety of shapes and sizes** designed specifically to fit the patient's anatomy for common tissue repairs. Its ability to communicate with surrounding tissue translates into use in many procedural areas, including:



Hernia Repair Fistula Repair Peyronie's Repair Plastic & Reconstructive/ENT Staple Line Reinforcement Abdominal Wall Reconstruction Dural Repair Pelvic Floor Repair Continence Restoration



### Restore long-term strength.

The Biodesign Hernia Graft is a scaffold that lends support while helping damaged or infected tissue restore itself quickly.

Biodesign signals the body to promote rapid and complete remodeling, is resistant to infection and encapsulation, and offers reduced early complications. Over time, it becomes strong, fully vascularized tissue that creates a lasting repair.

As a tension-free repair tool available in large sizes, Biodesign provides a more stable solution and quicker patient recovery than primary repair methods.





Global		
Product	Order	Size
Number	Number	cm

### Ventral/Incisional Hernia

### Hernia Graft

G36032	C-SLH-8H-13X15	13 x 15
G46600	C-SLH-8H-13X22	13 x 22
G36033	C-SLH-8H-20X20	20 x 20
G48216	C-SLH-8H-20X30	20 x 30



SURGISIS® HIATAL HERNIA GRAFT

### Restore strength and function.

For complete and natural hiatal hernia repair, look no further than the Biodesign Hiatal Hernia Graft.

The graft is a scaffold that restores the crura's strength and function and is not prone to the erosion into the esophagus that synthetic mesh can cause. Following placement, Biodesign communicates with the tissue around it, signaling the body to restore itself.

When finished, it leaves behind healthy tissue that is strong enough to function normally.





Global Product Number	Order Number	Size cm	Comments		
Hiatal Hernia Graft					
G31455	C-PHR-7X10-U	7 x 10	(preshaped)		
G51578	C-PHR-7X10	7 x 10	(standard)		
4-Layer Tissue Graft					
G12580	C-SLH-4S-7X10	7 x 10			





### Restore a quality of life that was once unattainable.

The Biodesign Fistula Plug treats difficult fistulas without causing muscle damage that can lead to incontinence. With Biodesign, you can help your patients return to normal life, free from the pain and embarrassment fistulas can cause.

Biodesign provides fistula repair that is completely natural, making it stronger and more resistant to rejection or relapse than other treatment options. Biodesign is a scaffold that communicates with your patient's anatomy, signaling the body to close the gap on its own. And patients can experience immediate relief without lifelong discomfort and drainage.





Global		
Product	Order	Size
Number	Number	cm

### Anal Fistula

Fistula Plu	ıg		
G36226	C-AFP-0.6X9.5	0.6 x 9.5	
G48651	C-RVP-0.2	0.2 (with button	
G48652	C-RVP-0.4	0.4 (with button	
G48653	C-RVP-0.7	0.7 (with button	
4-Layer Tissue Graft			
G13181	C-SLH-4S-4X7	4 x 7	

### Fistula Set

Includes Biodesign Fistula Plug (without button); Cook Medical Fistula Brush for tract identification, preparation and placement of the plug; flushing catheter; syringe; 2-0 PGA sutures on a UR-6 needle; and a silk tie.

G53614 C-AFPS-0.6X9.5 0.6 x 9.5 cm (plug size)





### Provide relief from difficult symptoms.

Women suffering from rectovaginal fistulas experience painful and embarrassing symptoms that completely alter their quality of life. Many of these women do not come forward with their condition and are unaware there is a simple solution, the Biodesign Fistula Plug. Biodesign communicates with your patient's body, signaling surrounding cells to grow across the scaffold. The result is fully remodeled, vascularized tissue and complete fistula closure so patients can enjoy normal functioning.



Global Product Number	Order Number	Size cm		
Rectovaginal Fistula				
Fistula Plug	g			
G48651	C-RVP-0.2	0.2		
G48652	C-RVP-0.4	0.4		
G48653	C-RVP-0.7	0.7		
4-Layer Tissue Graft				
G13181	C-SLH-4S-4X7	4 x 7		

### **Fistula Brush**

The only specially designed device for fistula tract identification, preparation and placement of the Biodesign Fistula Plug.

G48527 J-FB-100 46 cm length





### <u>coo</u>к Biodesign™ SURGISIS® STAPLE LINE REINFORCEMENT

### Prevent leaks while strengthening tissue.

**Biodesign Staple Line Reinforcement** does more than guard against leaks; it makes the staple line stronger.

That's because once it secures the line, Biodesign communicates with the body, signaling surrounding tissue to grow across the scaffold.

Biodesign completely remodels into strong, fully vascularized tissue, providing a natural, strong seal that's resistant to infection. And because its thin profile is string free and precoated with watersoluble adhesive, it's remarkably easy to apply.





Illustrations by Lisa Clark

### **Staple Line Reinforcement**

### U.S. Surgical

 G50656
 C-SLRA-GIA30

 G50868
 C-SLRA-GIA45

 G50867
 C-SLRA-GIA60

 G50872
 C-SLRA-GIA80

### Ethicon™

G50866	C-SLRA-TCT-TLC55
G50865	C-SLRA-TCT-TLC75
G50870	C-SLRA-EZ45
G51746	C-SLRA-ECH45
G50871	C-SLRA-ECH60

#### **Fits Stapler**

Endo GIA<sup>™</sup> 30 Endo GIA 45 Endo GIA 60 and GIA 60 GIA 80

### **Fits Stapler**

Proximate™ TCT 55/TLC 55 Proximate TCT 75/TLC 75 EZ 45 Echelon™ 45 Echelon 60

Note: All staple line reinforcement strips sold in boxes of 5.



Echelon, Ethicon and Proximate are trademarks of Johnson & Johnson. Endo GIA is a trademark of United States Surgical Corporation.

### Frequently asked questions

### Q: What is Biodesign?

A: Biodesign has been designed to combine the best attributes of synthetic mesh and biologic grafts, creating a whole new category in tissue repair. It is not prone to erosion or stretching, and it leaves behind strong, fully vascularized tissue that functions and moves naturally. Biodesign's key benefits-signals the body, resistant to infection, complete remodeling and long-term strength-make it the preferred material when compared to synthetic mesh and biologic grafts.

### Q: How is Biodesign different from biologic grafts?

A: Dermis-based biologic grafts contain elastin that is left behind in the body to stretch, sometimes resulting in a recurrence of the original tissue failure. Some are chemically cross-linked, creating a graft that will not fully remodel into tissue. Also, most biologic grafts are very limited in availability and size and can be cost-prohibitive.

Biodesign, on the other hand, is not chemically cross-linked and does not leave behind a significant amount of elastin that would make the patient prone to a recurrence. It signals the body to encourage complete remodeling, so it becomes strong, organized tissue. Conveniently, Biodesign is widely available for a moderate price in specially designed shapes and sizes.

### Q: What data is published about Biodesign?

A: Since development of Biodesign began in the mid 1990s, this new category of tissue repair material has been studied and written about extensively in medical journals. To date, more than 750 articles have been published about the material from which Biodesign is created (originally called Surgisis or SIS).

### Q: How is Biodesign different from synthetic mesh?

A: Synthetic mesh can lead to scarring and encapsulation, is contraindicated in infected fields, and has potential for erosion into surrounding tissue. It commonly needs to be removed after implant, requiring a second surgery.

Biodesign, however, signals the body to actually remodel itself, so the patient's own repair mechanisms act to heal the area rather than attack or encapsulate the graft. Thus, it is resistant to infection, encourages complete remodeling, and is not prone to erosion or encapsulation. Biodesign leaves behind strong, fully vascularized tissue that functions and moves naturally.

If you have additional questions, please contact your Cook Medical representative.

### References



### Signals the Body

#### Badylak SF, Park K, Peppas N, et al.

Marrow-derived cells populate scaffolds composed of xenogeneic extracellular matrix. *Exp Hematol*. 2001;29(11):1310-1318.

#### Hodde JP, Suckow MA, Wolter WR, et al.

Small intestinal submucosa does not promote PAIII tumor growth in Lobund-Wistar rats. *J Surg Res.* 2004;120(2):189-194.

#### Hodde JP, Ernst DM, Hiles MC, et al.

An investigation of the long-term bioactivity of endogenous growth factor in OASIS Wound Matrix. *J Wound Care*. 2005;14(1):23-25. **Niezgoda JA, Van Gils CC, Frykberg RG, 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.

#### 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.



## Resistant to Infection

### Franklin ME, Gonzalez JJ, Michaelson RP, et al.

Preliminary experience with new bioactive prosthetic material for repair of hernias in infected fields. *Hernia*. 2002;6(4):171-174.

#### Franklin ME Jr, Gonzalez JJ Jr, Glass JL.

Use of porcine small intestinal submucosa as a prosthetic device for laparoscopic repair of hernias in contaminated fields: 2-year follow-up. *Hernia*. 2004;8(3):186-189.

#### Helton WS, Fisichella PM, Berger R, et al.

Short-term outcomes with small intestinal submucosa for ventral abdominal hernia. *Arch Surg*. 2005;140(6):549-562.

#### Shell DH IV, Croce MA, Cagiannos C, et al.

Comparison of small-intestinal submucosa and expanded polytetrafluoroethylene as a vascular conduit in the presence of gram-positive contamination.

Ann Surg. 2005;241(6):995-1004.

### **Champagne BJ, O'Connor LM, Ferguson M, et al.** Efficacy of anal fistula plug in closure of cryptoglandular fistulas: long-term follow-up. *Dis Colon Rectum.* 2006;49(12):1817-1821.

### References

### Complete Remodeling

#### Wiedemann A, Otto M.

Small intestinal submucosa for pubourethral sling suspension for the treatment of stress incontinence: first histopathological results in humans. *J. Urol.* 2004;172(1):215-218.

#### Woo SL, Takakura Y, Liang R, et al.

Treatment with bioscaffold enhances the fibril morphology and the collagen composition of healing medial collateral ligament in rabbits. *Tissue Eng.* 2006;12(1):159-166.

#### Desai KM, Diaz S, Dorward IG, et al.

Histologic results 1 year after bioprosthetic repair of paraesophageal hernia in a canine model. *Surg Endosc.* 2006;20(11):1693-1697.

#### 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.

#### Smith MD, Campbell RM.

Use of a biodegradable patch for reconstruction of large thoracic cage defects in growing children. J Pediatr Surg. 2006;41(1):46-49.



### Long-Term Strength

#### Badylak S, Kokini K, Tullius B, et al.

Strength over time of a resorbable bioscaffold for body wall repair in a dog model. J Surg Res. 2001;99(2):282-287.

### Rutner AB, Levine SR, Schmaelzle JF.

Processed porcine small intestine submucosa as a graft material for pubovaginal slings: durability and results. *Urology*. 2003;62(5):805-809.

#### Fine AP.

Laparoscopic repair of inguinal hernia using Surgisis mesh and fibrin sealant. JSLS. 2006;10(4):461-465. Edelman DS, Hodde JP. Bioactive prosthetic material for treatment of hernias. *Surg Technol Int.* 2006;15:104-108.

### Grynberg M, Dedecker F, Staerman F.

Laparoscopic sacral colpopexy: comparison of nonresorbable prosthetic tape (Mersuture) and a SIS collagen matrix (Surgisis ES). *Prog Urol.* 2005;15(4):751-755. To learn more about Biodesign, visit cookbiodesign.com, contact your Cook Medical representative or call customer service at 800.457.4500.



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N CARDIOLOGY CRITICAL ENDOSCOPY

INTERVENTIONAL PERIPHERAL RADIOLOGY INTERVENTION SURGERY UROLOGY

WOMEN'S HEALTH