Offer a **new alternative to patients** who have enterocutaneous fistulas, even after standard treatments have been tried.

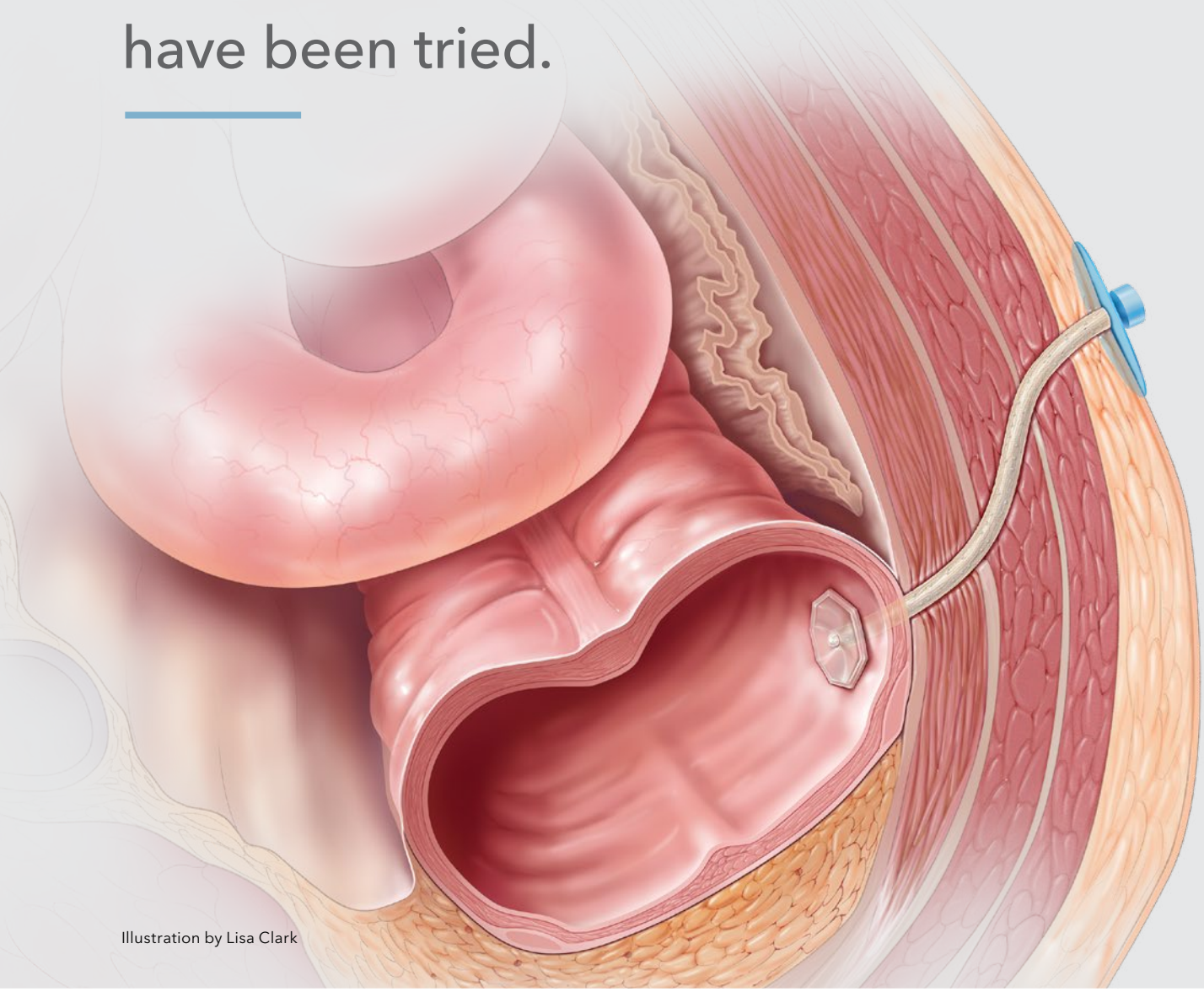


Illustration by Lisa Clark

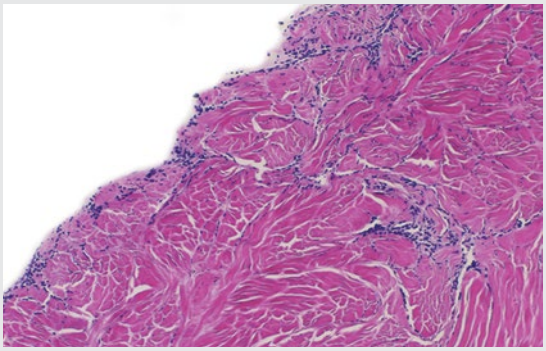
Biodesign®
ENTEROCUTANEOUS FISTULA PLUG

COOK® MEDICAL

BIODESIGN®
ADVANCED TISSUE REPAIR

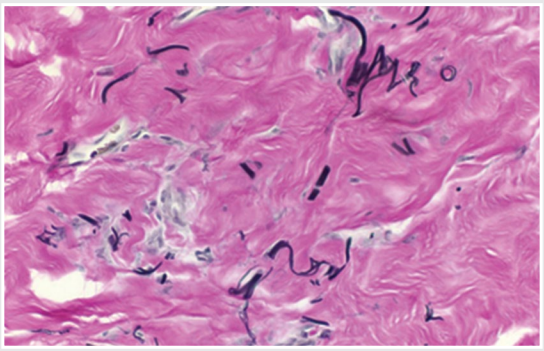
How is Biodesign **different?**

Other biologic grafts



Cross-linked biologic grafts

Cross-linked biologic grafts inhibit remodeling and vascular ingrowth, and have been associated with chronic inflammation and encapsulation.[1]



Dermis-based biologic grafts

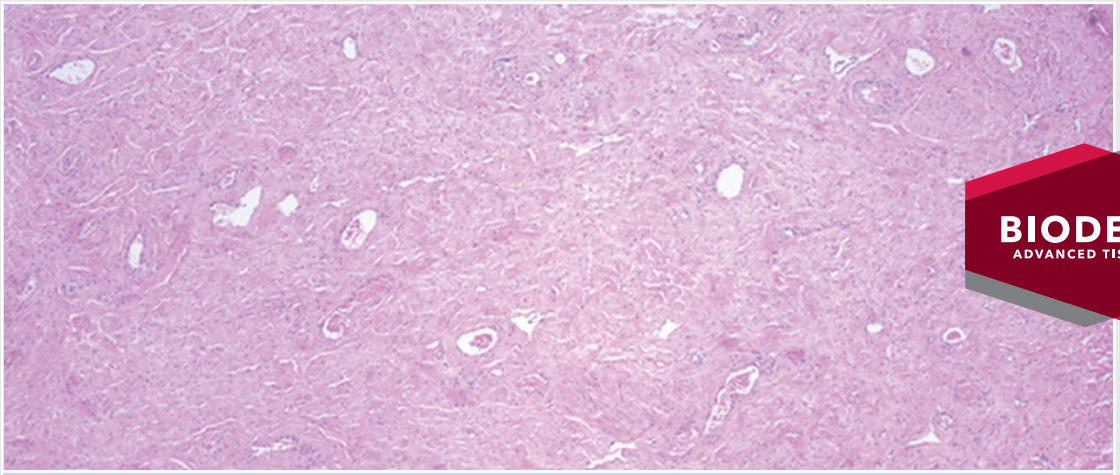
Dermis-based biologic grafts contain high amounts of elastin. Over time, this elastin remains in the patient's body. The elastin can stretch and possibly lead to failure.[2]

1. Novitsky YW, Rosen MJ. The biology of biologics: basic science and clinical concepts. *Plast Reconstr Surg.* 2012;130(5 Suppl 2):9S-17S.

2. 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.

Remodel patient tissue.

Biodesign is a **non-cross-linked**, **non-dermis-based** biologic graft technology that is completely remodeled into strong, well-vascularized tissue.[3]



Non-cross-linked biologic grafts

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.[3]

Non-dermis-based biologic grafts

Biodesign material is non-dermis-based, so it does not contain meaningful amounts of elastin.[4] As a result, the body completely remodels Biodesign material into patient tissue that has an organized deposition of collagen.[3]

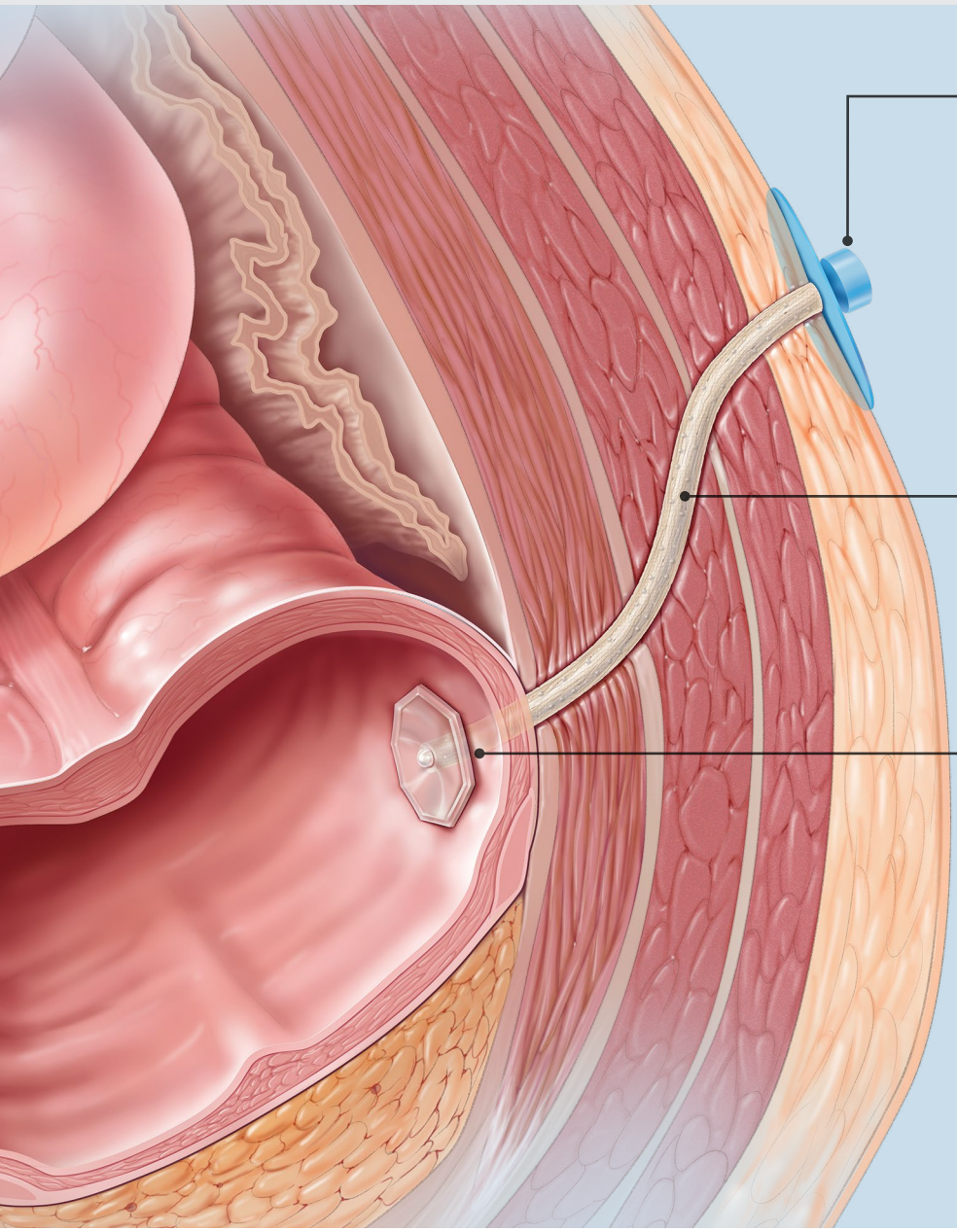
3. Franklin ME Jr, Treviño JM, Portillo G, et al. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up. *Surg Endosc.* 2008;22(9):1941-1946.
NOTE: The name Surgisis has changed to Biodesign since the printing of this article.

4. Heise RL, Ivanova 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.

Biodesign®

ENTEROCUTANEOUS FISTULA PLUG

Enterocutaneous fistulas can significantly affect patient health and quality of life. Cook's Biodesign Entercutaneous Fistula Plug is specifically designed to correct this notoriously difficult and often debilitating condition where closure cannot be achieved by using conservative therapies.



The **molnar disk** ensures that the Biodesign material and the plug remain positioned throughout the tract.

Biodesign material is designed to be remodeled by the body when suitable conditions are established.*

4 or 7 mm diameter and 18 cm length fit most fistula tracts.

The **radiopaque flange** provides a method of visualization during placement and creates a seal to restrict fluids from entering the tract.

*When the device is placed appropriately and the seal is established to keep bowel contents out of the fistula tract, Biodesign material can be remodeled by the patient's body to assist in closing the fistula tract.

Constructed from Biodesign material, and engineered for placement, the enterocutaneous fistula plug is designed to assist the patient's body in closing the tract on its own.

Biodesign® Enterocutaneous Fistula Plug

INTENDED USE: The Biodesign® Enterocutaneous Fistula Plug is for implantation to reinforce soft tissue for repair of enterocutaneous fistulas. The device is supplied sterile and is intended for one time use. 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 product is intended for use by medical professionals trained in the use of this device technology.

CONTRAINDICATIONS: This device is derived from a porcine source and should not be used for patients sensitive to porcine materials. • **Not for vascular use.**

PRECAUTIONS: • IMPORTANT: Users should counsel patients on the following: – The typical clinical outcomes, risks and benefits associated with the use of the Biodesign Enterocutaneous Fistula Plug – MRI safety (See section on MRI information in the complete INSTRUCTIONS FOR USE) – No strenuous physical activity beyond a gentle walk for at least 6 weeks after procedure – No lifting of items over 10 pounds for at least 6 weeks after procedure – The use of stool softeners after the procedure – Dietary restrictions after the procedure to include a liquid diet for the first 48 hours, followed by a high fiber diet – Expectation of some drainage for up to 16 weeks after the procedure – Use of over-the-counter pain medicine after the procedure – Use of an abdominal binder after the procedure to reduce tissue approximation. Failure to counsel patients on the information above may result in additional patient exposure to potential risks. These may include but are not limited to early release of the flange, plug migration out of the fistula, fluid accumulation, infection, abscess, and failure of the fistula to heal. • This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. • **Do not resterilize.** Discard all unused portions of this product following the implant procedure. • 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. • Do not implant the device in a grossly infected, abscessed or inflamed fistula tract. • Do not implant the device in a bowel fistula that exceeds 7 mm in diameter. • Do not implant the device in a bowel fistula that is less than 2 cm in length. • Use caution if implanting the device in a recently irradiated field. • Use caution if neoplasm exists in the field. • Use caution if implanting the device into a bowel that is currently diverted (e.g. with ileostomy, colostomy) as bowel motility may be compromised. • Ensure that the gastrointestinal tract is free of obstruction distal to the fistula prior to placement of the enterocutaneous fistula plug. (**See BOWEL PREPARATION in the complete INSTRUCTIONS FOR USE**) • **Do not flush the device or delivery sheath with fluids before deploying the self-expanding flange into the bowel. The plug must be advanced through the delivery system dry, and rehydrated after the self-expanding flange is confirmed to be fully expanded in the bowel. • Use caution when advancing the delivery sheath and dilator into diseased bowel.** • Once the plug is loaded into the transfer tube, do not separate the plug from the transfer tube until the device is transferred into the delivery sheath. • Use fluoroscopic confirmation to ensure that the flange of the plug is flush against the bowel wall to restrict ingress of intestinal contents back into the fistula. • Use fluoroscopic confirmation to ensure that all bowel communications within the fistula tract are sealed. • Ensure that the device is rehydrated before cutting or suturing. • Users should be familiar with surgical technique for enterocutaneous fistula repair. • Users should exercise good surgical practice for the management of clean-contaminated, contaminated or infected fields. • The potential for infection of the graft material following implantation may be reduced by the use of prophylactic antibiotics and cleaning of the fistula tract. • The fistula opening at the dermal surface should maintain an open pathway for drainage to occur. • Ensure that the patient is provided with the Patient Pamphlet to guide them through the post-operative care period. • If the flange is retained in the patient beyond an eight week period, the patient should be monitored for bowel obstruction, erosion, perforation or flange migration. **NOTE: Device incorporation into surrounding tissue may be inhibited if granulation tissue lines the fistula tract. Abrading the tract gently may improve device incorporation and lead to a better healing response.**

POTENTIAL COMPLICATIONS: Complications that can occur with this device include, but are not limited to: inflammation, induration, migration, extrusion, bowel obstruction, bowel perforation, erosion, seroma formation, infection, abscess, fistula recurrence, and delayed or failed incorporation of the device. If any of the following conditions occur and cannot be resolved, surgical intervention should be considered: • Infection • Abscess • Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation) • Allergic reaction • Bowel perforation • Bowel obstruction or impaction • Device erosion through bowel tissue • Flange migration into the abdominal cavity • Abnormal bleeding

See instructions for use for full product information.

AB_FP0069-01_REV1

Two technologies converge to create a **unique treatment option.**

The Biodesign Enterocutaneous Fistula Plug combines Cook's proven percutaneous access technology with an advanced biologic graft technology, Biodesign.

A comprehensive set

The enterocutaneous fistula plug set includes the components that are necessary for a successful percutaneous placement.

- Biodesign Enterocutaneous Fistula Plug (4 or 7 mm in diameter and 18 cm long)
- Transfer tube
- Flexor® delivery sheath (16 or 22 Fr)
- Dilator
- Pusher
- Molnar disk

Important considerations for **patient selection**

If you have a patient with an enterocutaneous fistula that you would like to refer for a consultation about the Biodesign Enterocutaneous Fistula Plug, please consider these important topics for discussion with the interventional radiologist:

- The length and width of the tract are important. The ideal size is 2-6 mm wide and less than 18 cm long.
- Width sizing is crucial. If the internal opening of the fistula tract is too wide, the plug could disintegrate due to the leaking of GI fluids into the tract and could expose patients to potential risk.
- Some conditions can cause adverse reactions and reduce the efficacy of the plug. Examples include a distal obstruction, diverted bowel, abscess, infection, neoplasia, and radiation.
- If the patient has drainage, then a low output is preferred (less than 200 mL per day).
- The cause, duration, and location of the fistula are important.

If you are interested in bringing a new procedure to your practice and learning an innovative treatment option for enterocutaneous fistula repair, please **contact** your local **Cook representative**.

To learn more about Biodesign technology, visit **cookbiotech.com**

BIODESIGN®
ADVANCED TISSUE REPAIR

Reasons to choose Biodesign products

- An intact extracellular matrix, Biodesign material is processed in a way that preserves its natural structure and supports tissue remodeling.[5]
- With proper placement, Biodesign material is remodeled into strong, vascularized patient tissue and provides **long-term strength** without a permanent material.[3]
- Biodesign is a non-cross-linked biologic material, so no residual cross-linked material is left behind to cause inflammation or encapsulation.[1]
- Biodesign material has specific data showing efficacy across a wide variety of procedures.
- Biodesign material has undergone more than **18 years of improvement** based on surgeon feedback and scientific research, including 6 studies with more than 5 years of follow up.
- Biodesign material is based on a technology that has been the subject of more than **1,269 published studies**, including 437 describing use in humans and 19 randomized controlled trials.

5. Hodde J, Janis A, Ernst D. Effects of sterilization on an extracellular matrix scaffold: part I. Composition and matrix architecture. *J Mater Sci Mater Med.* 2007;18(4):537-543.

Customer Service

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