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
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

---

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

---


   NOTE: The name Surgisis has changed to Biodesign since the printing of this article.

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.
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
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.

---