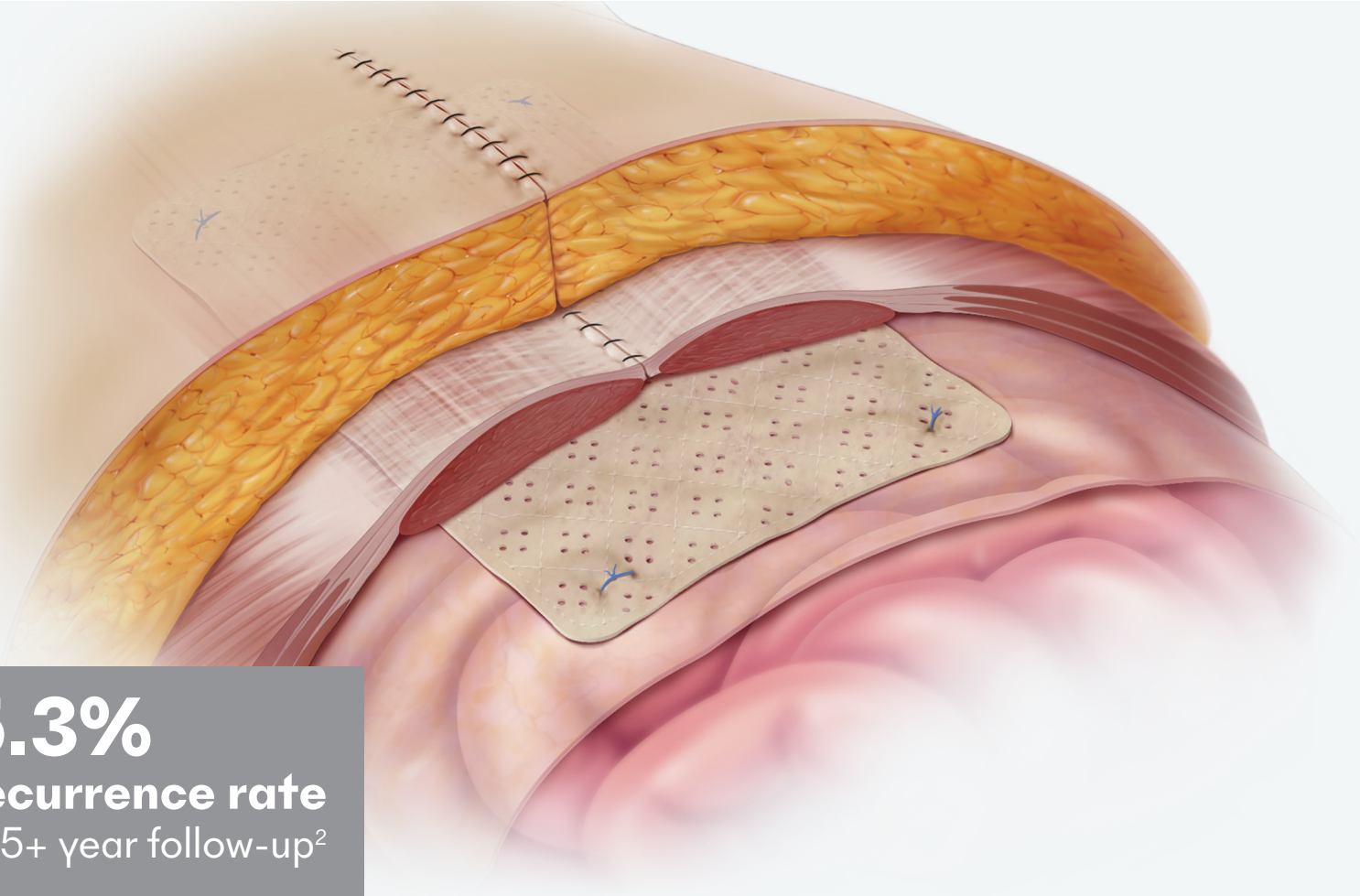


Biodesign® Hernia Graft

Long-term strength from a biologic graft^{1,2}



5.3%
recurrence rate
in 5+ year follow-up²

The Biodesign Hernia Graft fully remodels into strong, vascularized patient tissue, providing a strong repair without a permanent material.^{1,2}

Evergen™

Graft information

Biodesign Hernia Graft

For implantation to reinforce soft tissues where weakness exists.

Indications for use include the repair of a hernia or body wall defect.

Order number	Reference part number	Size
G55267	C-BIG-8X30	8 x 30cm
G55266	C-BIG-8X20	8 x 20cm
G55265	C-BIG-8X10	8 x 10cm
G48216	C-SLH-8H-20X30	20 x 30cm
G36033	C-SLH-8H-20X20	20 x 20cm
G46600	C-SLH-8H-13X22	13 x 22cm
G36032	C-SLH-8H-13X15	13 x 15cm
G23764	C-SLH-8H-10X10	10 x 10cm

Graft features

- Manufactured in the U.S.
- Biologic xenograft made from porcine SIS
- Non-cross-linked, non-dermis
- Easily hydrated in the operating room
- No special orientation or sidedness
- Suitable for use in open or laparoscopic procedures³
- Off-the-shelf graft that does not require special storage
- Does not require AATB tissue tracking
- MRI safe

RISK INFORMATION: BIODESIGN HERNIA GRAFT

INTENDED USE

The Biodesign® Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect. The graft is supplied sterile and is intended for one-time use.

This graft is intended for use by trained medical professionals.

CONTRAINDICATIONS

This graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

PRECAUTIONS

- The graft is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to graft failure and/or transmission of disease. • **Do not resterilize.** • Ensure that the graft is hydrated prior to cutting, suturing, stapling, tacking or loading the graft laparoscopically. • Ensure that all layers of the graft are secured when suturing, stapling, or tacking. •

Place the graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling. • Suturing, stapling, or tacking more than one graft together may decrease graft performance. • If wound is left open, keep graft moist to prevent dryness.

POTENTIAL COMPLICATIONS

Possible adverse reactions with the use of any prosthesis may include, but are not limited to: • adhesion • bowel erosion • fistula formation • hematoma • infection • inflammation • premature degradation • recurrence of tissue defect • seroma formation

Complications, such as delayed wound infection, premature degradation, hernia recurrence, bowel erosion, and the need for re-operation, should be reasonably expected in patients who are critically ill or who have severely contaminated abdomens.

ERI_FP0036-02P

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2. Franklin ME Jr, Treviño JM, Portillo G, Vela I, Glass JL, González JJ. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated field: Long-term follow-up. *Surg Endosc.* 2008;22(9):1941-1946.
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Biodesign grafts are manufactured by Cook Biotech Incorporated.

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