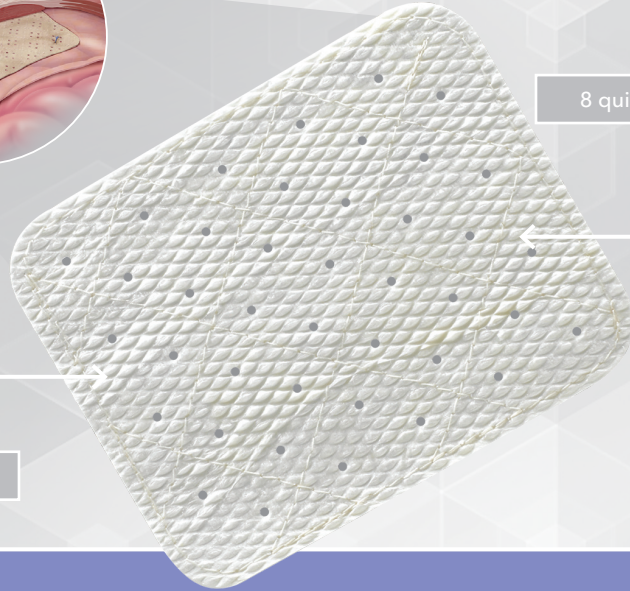
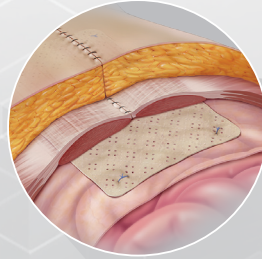


A biologic graft with **STRENGTH**¹

BIODESIGN HERNIA GRAFT



8 quilted layers

perforations

Biodesign[®]
ADVANCED TISSUE REPAIR



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BIODESIGN HERNIA GRAFT

Hernias and abdominal wall defects can benefit from the immediate and long-term strength provided by Biodesign material.¹

This advanced tissue-repair technology provides support as it is completely remodeled into patient tissue.²

¹ 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.

² 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.

Order Number	Reference Part Number	Size cm
G23764	C-SLH-8H-10X10	10 x 10
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
G55265	C-BIG-8X10	8 x 10
G55266	C-BIG-8X20	8 x 20
G55267	C-BIG-8X30	8 x 30

Some products or part numbers may not be available in all markets.



BIODESIGN® HERNIA GRAFT

INTENDED USE

The Cook® 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.

[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.

[HERNIA GRAFT] This symbol means the following: Hernia Graft

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: • 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 open and unused portions of the graft. • The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard graft if

mishandling has caused possible damage or contamination, or if the graft is past its expiration date. • Ensure that graft is rehydrated prior to cutting, suturing, stapling, tacking or loading of the graft laparoscopically. • Ensure that all layers of the graft are secured when suturing, stapling, or tacking. • Place 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. • No studies have been conducted to evaluate the reproductive impact of the clinical use of the graft. • Extended rehydration or excessive handling could lead to partial delamination of superficial layers of the graft. • Care should be taken to avoid damage to the graft when loading laparoscopically. It is recommended to load through a 10 mm or larger port. • 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: • infection • inflammation • adhesion • fistula formation • seroma formation • hematoma • bowel erosion • recurrence of tissue defect • premature degradation. 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.

See package insert for full product information.

ELP_FP0036-020