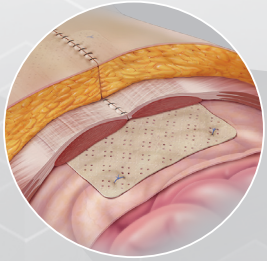
A biologic graft with STRENGTH[1]



Biodesign®
ADVANCED TISSUE REPAIR

BIODESIGN® HERNIA GRAFT

Ventral hernias benefit from the immediate and long-term strength provided by Biodesign material.[1]

This advanced tissue-repair technology provides support as it completely remodels into vascularised patient tissue.[2,3]

Order Number	Reference Part Number	Size cm
G57513	C-SLH-8H-10X10-2	10 x 10
G57514	C-SLH-8H-13X15-2	13 x 15
G57515	C-SLH-8H-13X22-2	13 x 22
G57516	C-SLH-8H-20X20-2	20 x 20
G57517	C-SLH-8H-20X30-2	20 x 30

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

[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.
[3] Nihsen ES, Johnson CE, Hiles MC. Bioactivity of small intestinal submucosa and oxidized regenerated cellulose/collagen. *Adv Skin Wound Care*. 2008;21(10):479-486.

COOK® BIOTECH

BIODESIGN® HERNIA GRAFT

INTENDED USE: The Cook® Biodesign® Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists during ventral hernia repair. 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.** MR This symbol means the following: Magnetic Resonance Safe. 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 when device is placed in infected wounds. • 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 biologic hernia prostheses may include: • adhesion • allergic reaction • bowel erosion • bowel obstruction • discharge • fever • fistula formation • hematoma • hernia recurrence • infection/abscess formation • inflammation • pain • premature degradation • seroma formation • wound dehiscence

See package insert for full product information.

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For European distribution only