A biologic graft supported by data
Biodesign® Hernia Graft

The Biodesign Hernia Graft is a non-cross-linked, non-dermis biologic graft that is completely remodeled into strong, vascularized tissue.¹⁻³
Studied and proven

The technology behind Biodesign® tissue-repair products is supported by more than 1,400 published articles. More than 500 of those describe use in humans. And 10 of those have more than five years of follow-up data.
Are all biologic grafts the same?

No. Some biologic grafts are associated with higher rates of failure.⁴

Dermis-based biologic grafts

Studies attribute higher rates of failure to higher elastin levels.⁵ ⁶
Dermis-based biologic grafts contain high amounts of elastin. Elastin remains in the patient’s body and can stretch over time, possibly leading to failure.⁵

Biodesign® non–dermis-based grafts

Biodesign grafts are non–dermis-based, so they do not contain meaningful amounts of elastin.⁴
Strength

Studies have shown long-term strength as the Biodesign® Hernia Graft remodels.\(^3\)

Two years after implantation, the Biodesign Hernia Graft showed more than four times the strength of the normal canine body wall.
Are all biologic grafts the same?

No. Over time, the Biodesign® source material remodels completely into new patient tissue—letting the body’s own defense mechanisms fight infection naturally.

The Biodesign Hernia Graft is sourced from porcine small intestinal submucosa (SIS). The material acts as a scaffold that, once implanted, allows host cells to infiltrate and remodel into vascularized tissue.\(^1,2\)

Small intestinal submucosa supports one of the harshest environments in the body and supports rapid cell turnover.\(^7\)
Tissue remodeling

Once it’s implanted in the body, the Biodesign® source material helps the patient’s own cells infiltrate the scaffold and remodel the material into natural host tissue.

Biodesign becomes remodeled by the body over a period of several weeks.

Day 0 - Implanted

Day 7 - Caramelization

The body begins to send cells into the material.

8 weeks - Granulation

tissue begins to form.

Images used with permission from Prof. Mohammed Ballal, MD.


Biodesign® Hernia Graft

Used for implantation to reinforce soft tissue where weakness exists. Indications for use include repair of a hernia or body wall defect.

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

More information:
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cs@progressivemedinc.com | www.progressivemedinc.com

Biodesign® Hernia Graft

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

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. 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 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 healing and tissue remodeling. - Suturing, stapling, or tacking more than one graft together may decrease graft performance. - No studies have been conducted to evaluate the reproducibility 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 drying.

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.