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 1,500 total publications. More than 500 of those describe clinical use. And 10 of those have more than five years of follow-up data.
Studies attribute higher rates of failure to higher elastin levels.\textsuperscript{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.\textsuperscript{5}

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

The Biodesign® Hernia Graft is specifically designed to provide strength during the repair and remodeling of a hernia or body wall defect. It is sourced from porcine small intestinal submucosa (SIS), a naturally occurring biomaterial.

Preclinical data have shown long-term strength as SIS remolds.³

Not only is the graft strong at the time of implant, it is designed to exceed the strength of the normal abdominal wall during the time it is being remodeled into vascularized tissue. When tissue repair and remodeling are complete, the resulting tissue is stronger than that which was implanted. No permanent material is left in the subject’s body.³
Are all biologic grafts the same?

No. Over time, the Biodesign® source material remolds completely into new patient tissue—letting the body’s own defense mechanisms fight infection naturally.\textsuperscript{7}

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.\textsuperscript{1-3}

Small intestinal submucosa supports one of the harshest environments in the body and supports rapid cell turnover.\textsuperscript{8}
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 patient tissue.¹⁻³

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

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.

**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.

**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.
- Extended rehydration or excessive handling could lead to partial delamination of superficial layers of the graft.
- 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.
- The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- 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.

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**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.