



# MOVE BEYOND DERMIS-BASED BIOLOGIC GRAFTS

HERNIA REPAIR





**MOVE BEYOND**  
to the next generation

# BIODESIGN®

## ADVANCED TISSUE REPAIR

PROVEN  
TECHNOLOGY

COST  
EFFECTIVE

REDUCED  
RECURRENCE

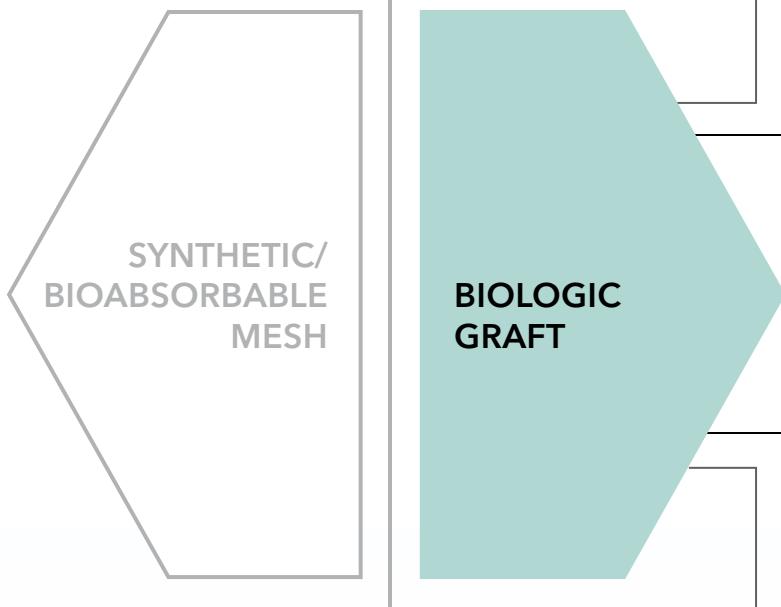
Biodesign evolved from one of the **most thoroughly studied** biologic graft technologies available.

Biodesign is designed to reduce recurrence by giving the body a way to **remodel strong, vascularized patient tissue**, without long-term complications.

Biodesign can provide an advanced tissue repair solution that **minimizes overall cost** while helping provide better patient outcomes.

# Move beyond to advanced tissue repair

Biodesign is a non-dermis, non-cross-linked biologic graft technology that is completely remodeled into strong, well-vascularized tissue.



## DERMIS BASED

Dermis-based grafts contain high amounts of elastin. Over time, this elastin remains in the patient's body and can stretch, possibly leading to recurrence.

## NON-DERMIS BASED

Biodesign is non-dermis based, so it does not contain meaningful amounts of elastin.

As a result, the body completely remodels Biodesign into patient tissue that is not prone to overstretching.

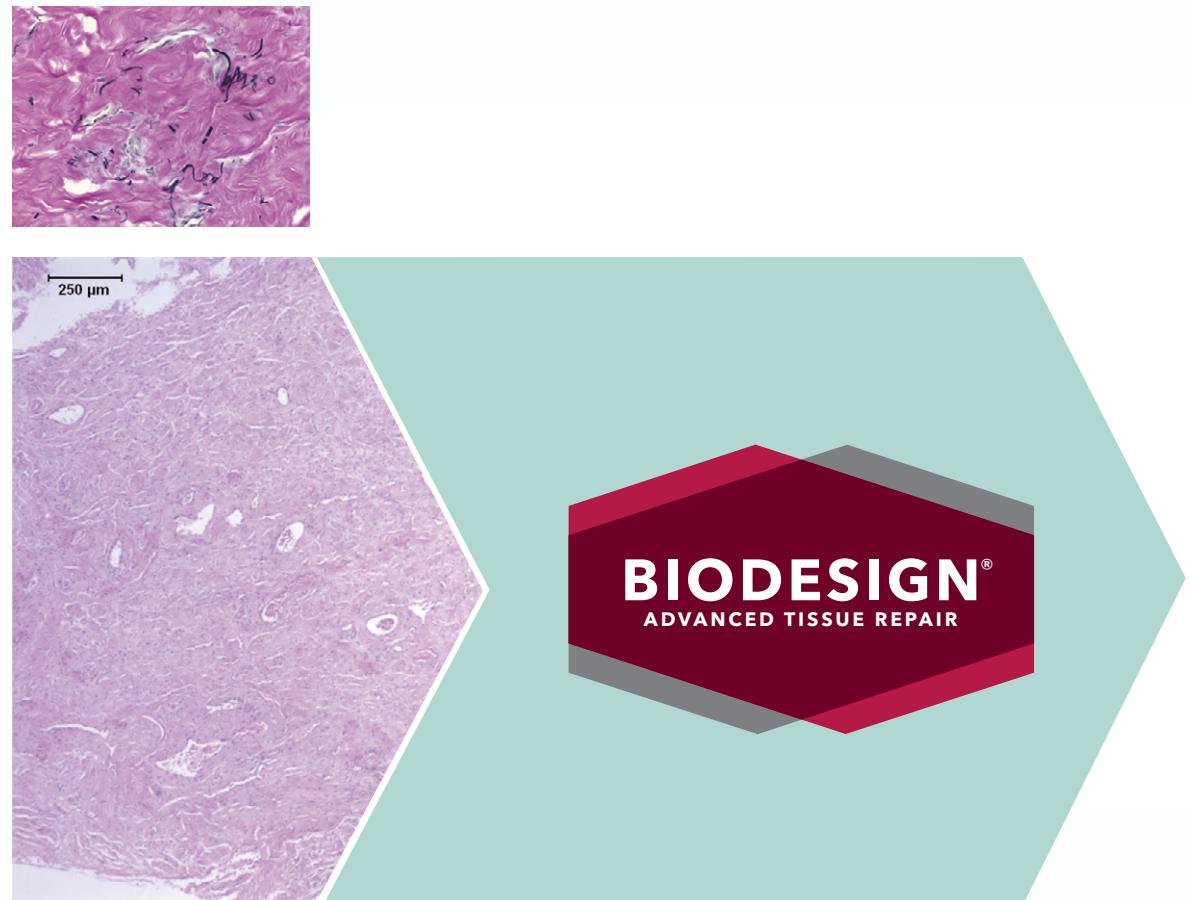
## NON-CROSS-LINKED

Biodesign has been designed to maintain strength throughout the remodeling process, so there is no need for cross-linking.

And because Biodesign is remodeled completely into strong, vascularized tissue, it can provide a strong repair without a permanent material.

## CROSS-LINKED

Cross-linked biologic grafts inhibit remodeling and vascular ingrowth, and have been associated with chronic inflammation and encapsulation.



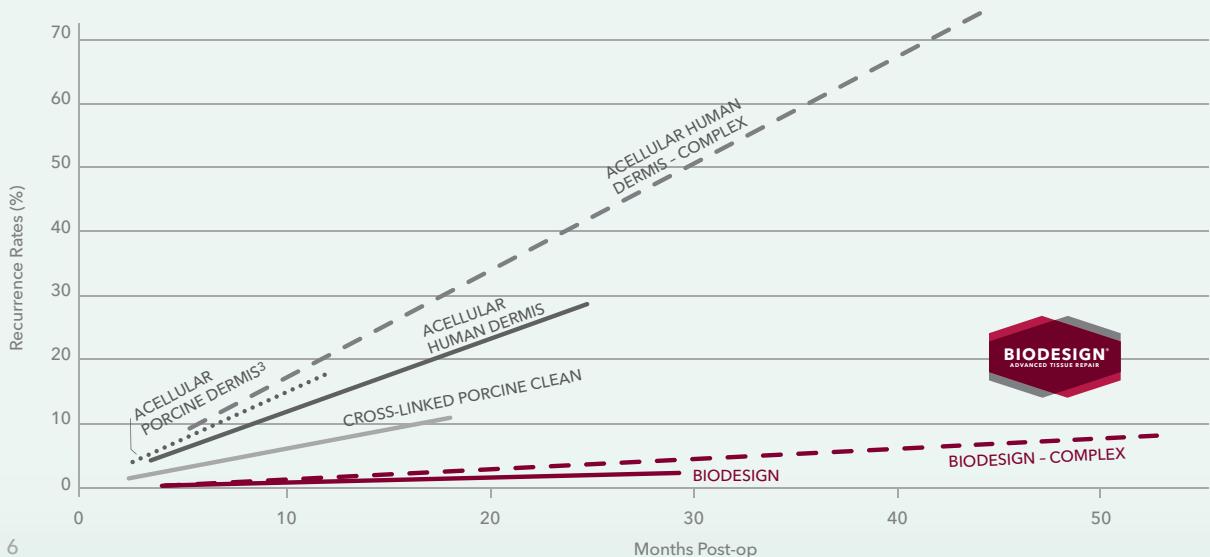
# Move beyond dermis-based biologic grafts

Specifically designed for hernia repair and abdominal wall reconstruction, the Biodesign hernia graft offers reduced recurrence rates in comparison to dermis-based and cross-linked biologic grafts. Biodesign has been extensively used in hernia repair and has been the subject of several long-term studies.

## REDUCED RECURRENCE

Long-term strength: A meta-analysis

The graph below shows recurrence over time for Biodesign, acellular human dermis, and cross-linked porcine dermis in both clean and complex fields, according to a 2009 meta-analysis by Hiles et al. Updated through June 2011.<sup>1,2</sup>



## HERNIA-SPECIFIC DATA

Biodesign has been the subject of numerous high-level hernia repair studies, some with follow-up as far out as 5 years.

Procedure	# of Patients	Years of Follow-up
Ventral Hernia <sup>1</sup>	113	Retrospective review
Incision Reinforcement <sup>4</sup>	379	RCT
Hiatal Hernia <sup>5,6</sup>	108	RCT
Inguinal Hernia <sup>7</sup>	70	RCT

# Move beyond to continual improvement

Biodesign is the evolution of a technology that started the biologic graft soft tissue repair revolution.



**1988**

## **Discovery of SIS**

Small intestinal submucosa (SIS) is used as an aortic replacement in a canine model. Remarkably, the SIS is fully remodeled into vascular tissue.

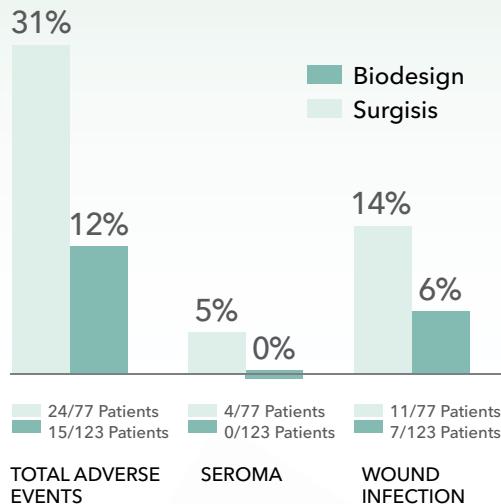
**1998**

## **Surgisis® is released**

After rigorous research and development, Cook receives FDA clearance for release of Surgisis, the first medical-grade hernia device made from SIS-based technology.

## REDUCED COMPLICATION RATES

Recent 6 month data from a randomized controlled trial by Sarr et al. shows that Biodesign is associated with **significantly reduced rates of complication** in comparison to earlier submucosa-based products.<sup>4</sup>



2006

### Processing improvements

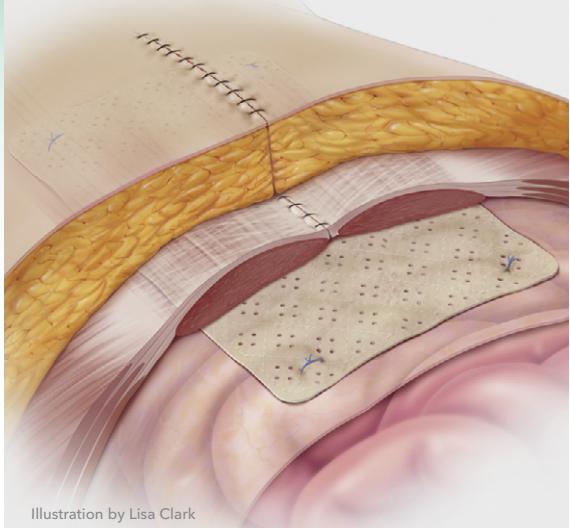
In response to surgeon feedback, substantial improvements in the processing are made, opening the structure to allow the body to more easily infiltrate and remodel the graft.

2008



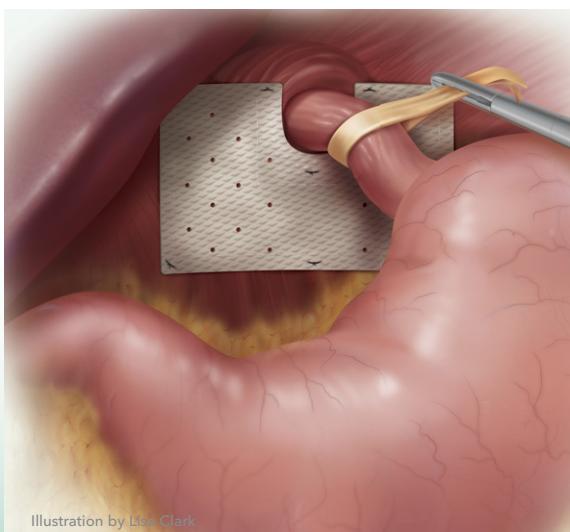
### Biodesign is released

Additional improvements are made to the base technology, speeding rehydration and mitigating perioperative issues. The new generation of grafts is renamed Biodesign.



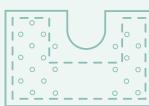
### AWR and Ventral/Incisional Hernia Repair

Order Number	Reference Part Number	Size cm
<b>Hernia Graft</b>		
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

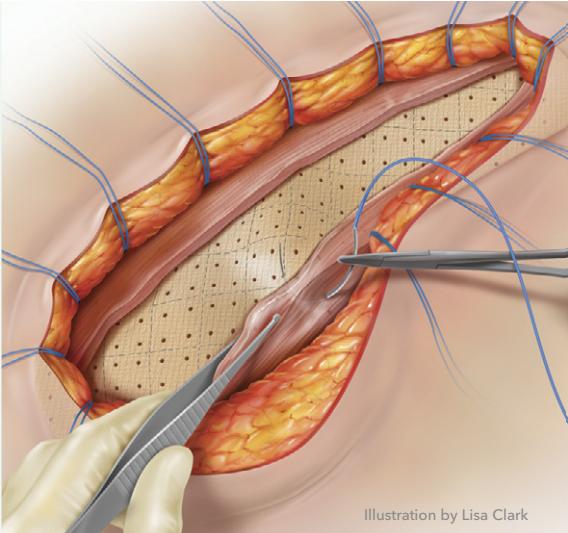


### Hiatal Hernia Repair

Order Number	Reference Part Number	Size cm	Comments
<b>Hiatal Hernia Graft</b>			
G31455	C-PHR-7X10-U	7 x 10	preshaped
G51578	C-PHR-7X10	7 x 10	standard
<b>4-Layer Tissue Graft</b>			
G12580	C-SLH-4S-7X10	7 x 10	

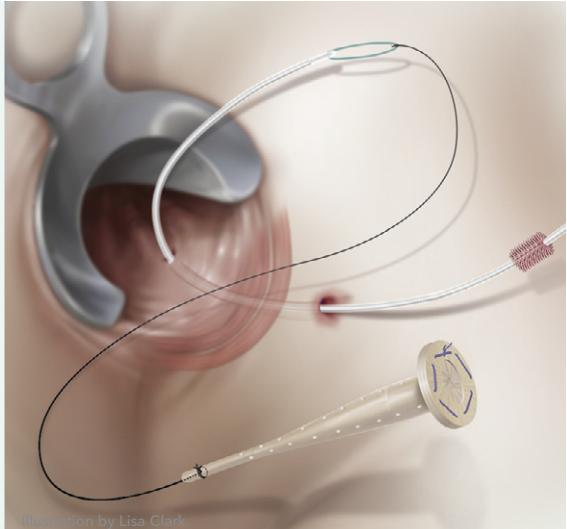


Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.



## Incision Reinforcement

Order Number	Reference Part Number	Size cm
<b>Incision Graft</b>		
G55265	C-BIG-8X10	8 x 10
G55266	C-BIG-8X20	8 x 20
G55267	C-BIG-8X30	8 x 30
G23946	C-BIG-10X40	10 x 40



## Fistula Repair

Order Number	Reference Part Number	Size cm	Comments
<b>Fistula Plug</b>			
G53614	C-AFPS-0.6X9.5	.6 x 9.5	set
G54612	C-FPS-0.2	.2	Biodesign button set
G54613	C-FPS-0.4	.4	Biodesign button set
G54614	C-FPS-0.7	.7	Biodesign button set



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# Move beyond to Biodesign

## 10 reasons to choose Biodesign over other biologic grafts.

- ✓ Non-dermis based, so unwanted elastin stretch is not an issue.
- ✓ Non-cross-linked, so no residual cross-linked material is left behind to encapsulate, erode, or become infected.
- ✓ Completely remodeled into strong, vascularized patient tissue, providing long-term strength without a permanent material.
- ✓ An intact extracellular matrix, Biodesign is processed in a way that preserves its natural structure, supporting tissue remodeling.
- ✓ Derived from proven technology—demonstrated effective in more than 1,000,000 patient treatments.
- ✓ Based on a technology that has been the subject of more than 861 peer-reviewed journal articles, including 9 randomized controlled trials.
- ✓ Has specific data that shows efficacy across a wide variety of procedures, including ventral hernia repair, fistula repair, wound treatment, and pelvic floor restoration.
- ✓ Can provide cost-effective tissue repair, improving outcomes without increasing spend.
- ✓ Available in specific shapes and sizes to fit common soft tissue repairs, such as hiatal hernia and anal fistula repair.
- ✓ Has undergone more than 12 years of evolution on the basis of surgeon feedback and scientific research.

## References

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2. Data on file at Cook Biotech.
3. Itani KM, Awad SS, Baumann D, et al. Single stage repair of large contaminated hernia defects with Stratitice™ Reconstructive Tissue Matrix reinforcement of component separation, *Hernia.* 2010;14(suppl 1):S32-S33.
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7. Ansaloni L, Catena F, Coccolini F, et al. Inguinal hernia repair with porcine small intestine submucosa: 3-year follow-up results of a randomized controlled trial of Lichtenstein's repair with polypropylene mesh versus Surgisis Inguinal Hernia Matrix. *Am J Surg.* 2009;198(3):303-312.

## Randomized Controlled Trials

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