

BIODESIGN[®]
ADVANCED TISSUE REPAIR

**PROVEN
TECHNOLOGY**

**REDUCED
RECURRENCE**

**COST
EFFECTIVE**

COOK[®]
MEDICAL



MOVE BEYOND
to the next generation



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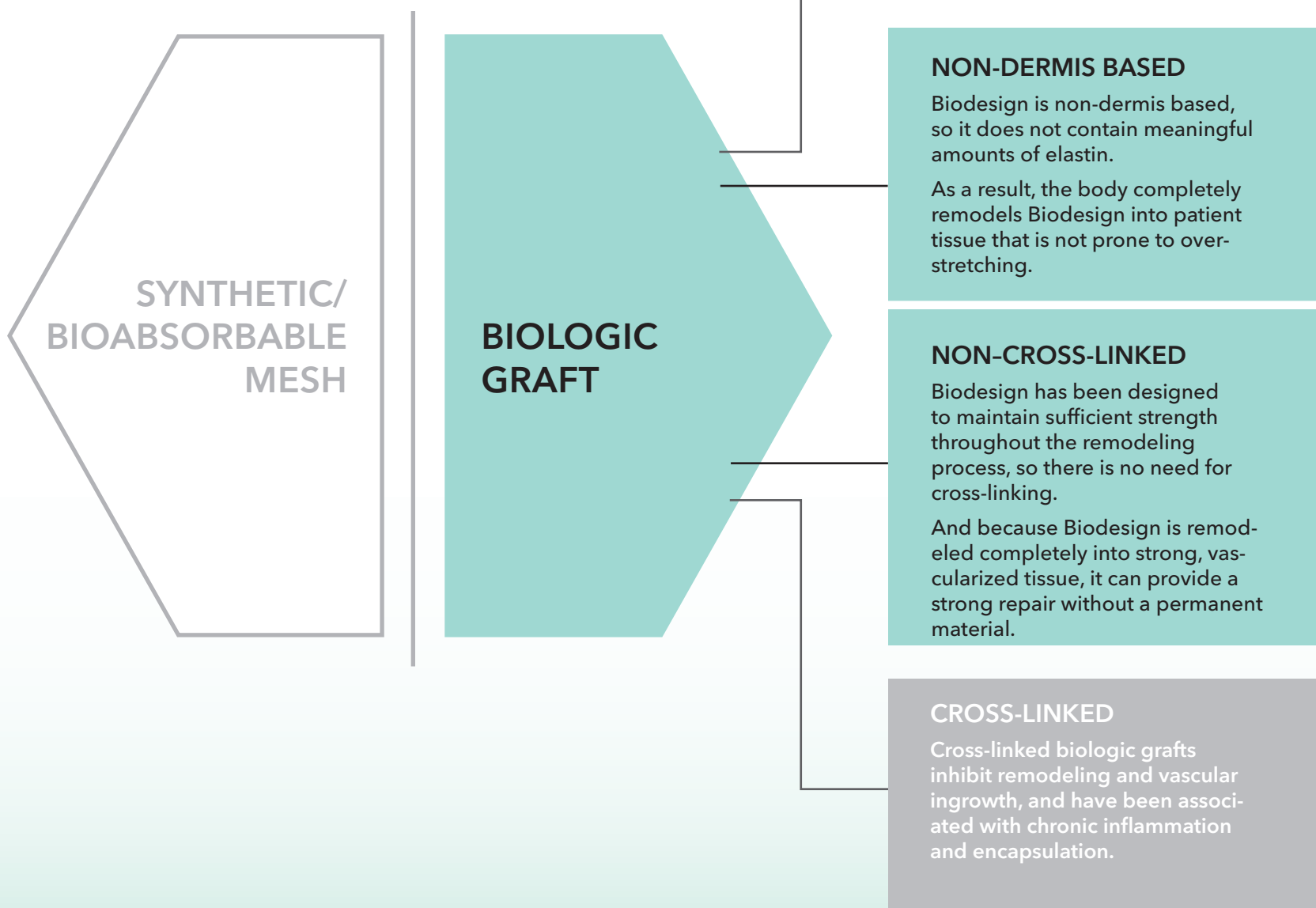
Move beyond to advanced tissue repair

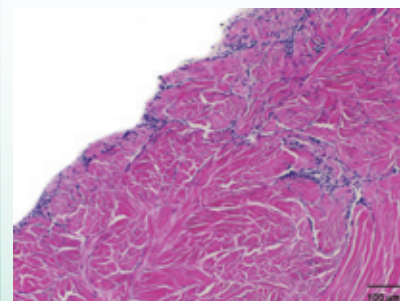
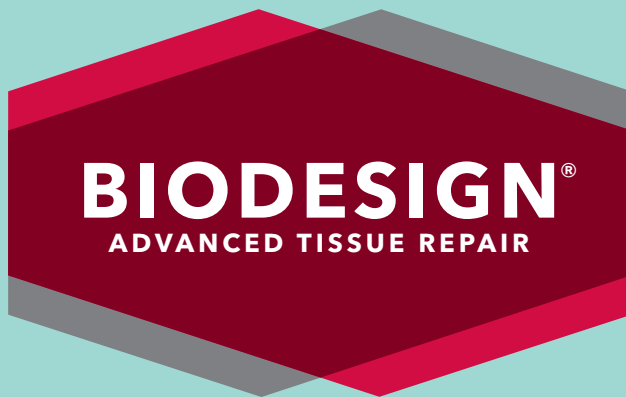
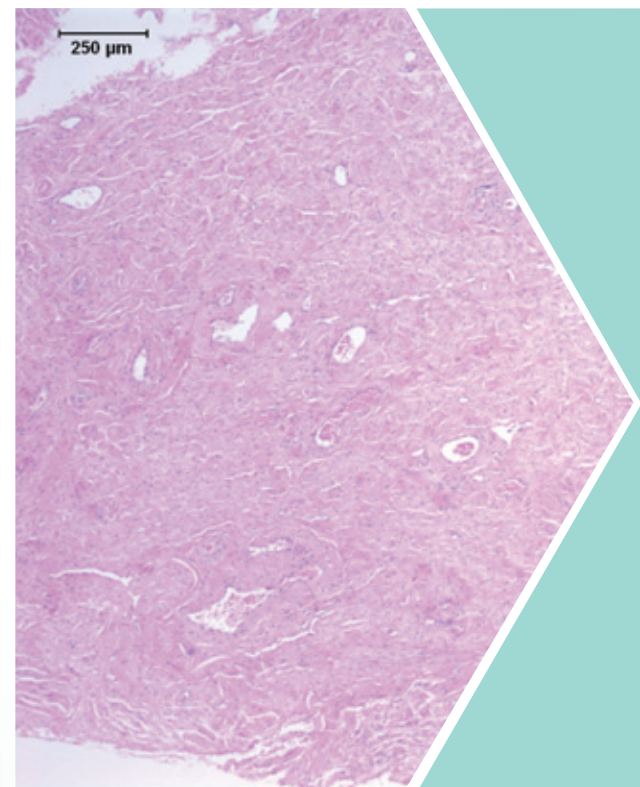
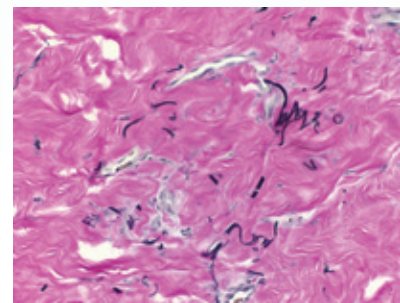
Biodesign is a non-dermis, non-cross-linked biologic graft technology that moves beyond:

Beyond to completely remodeled tissue

Beyond to a strong repair

Beyond to alternative treatment options



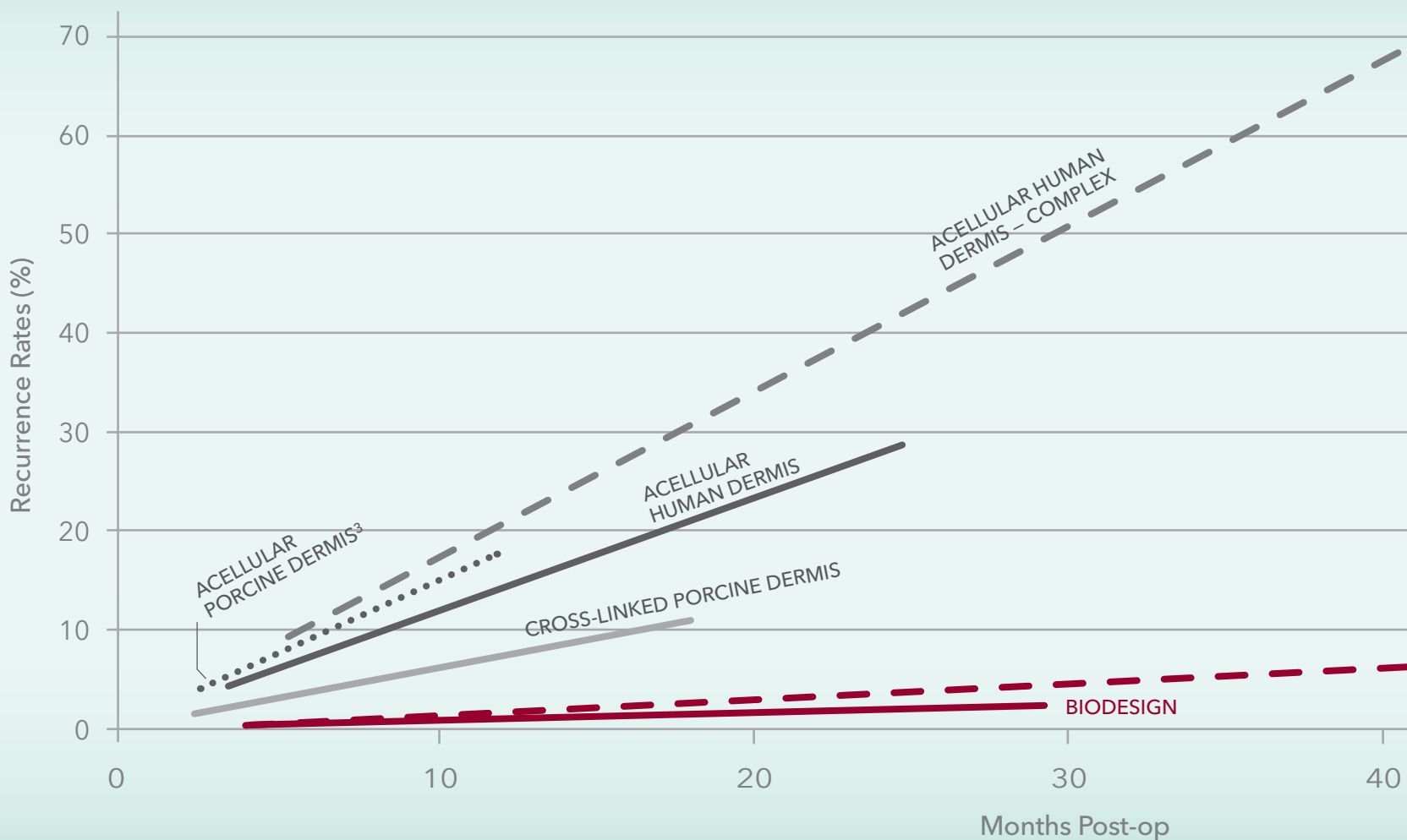


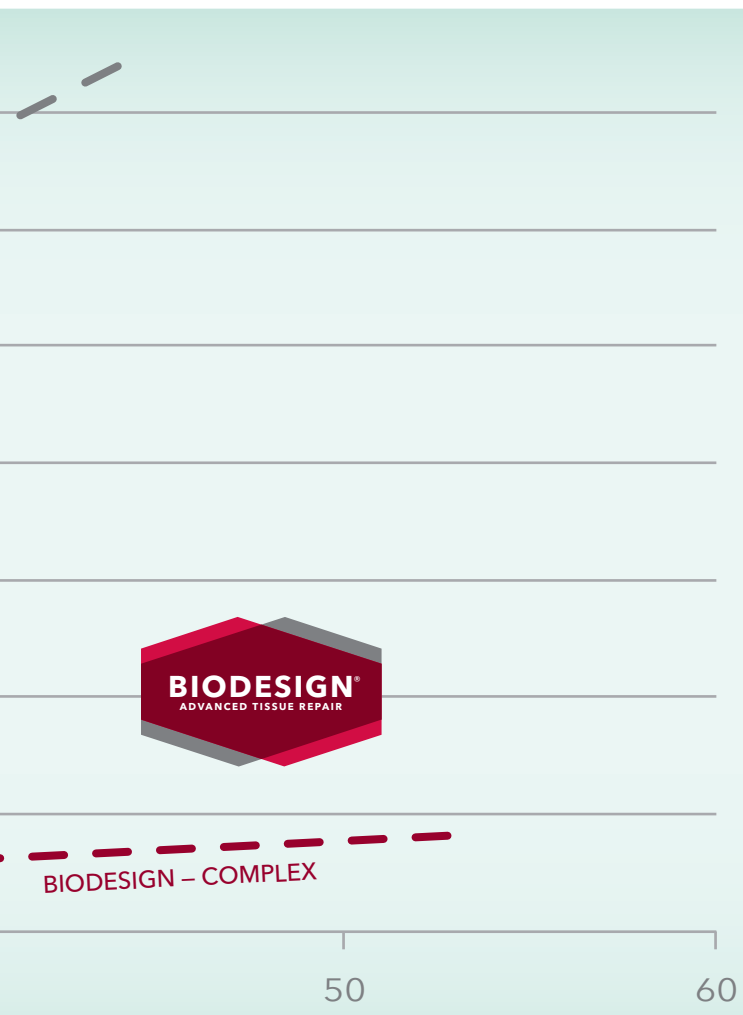
Move beyond to reduced recurrence

Biodesign has been developed with one goal in mind: to give surgeons the graft they need to **achieve optimal patient outcomes**.

But achieving optimal outcomes means looking beyond short-term results. **An ideal biologic graft repair should not allow recurrence**, and should **not leave residual materials** that cause problems down the road.

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





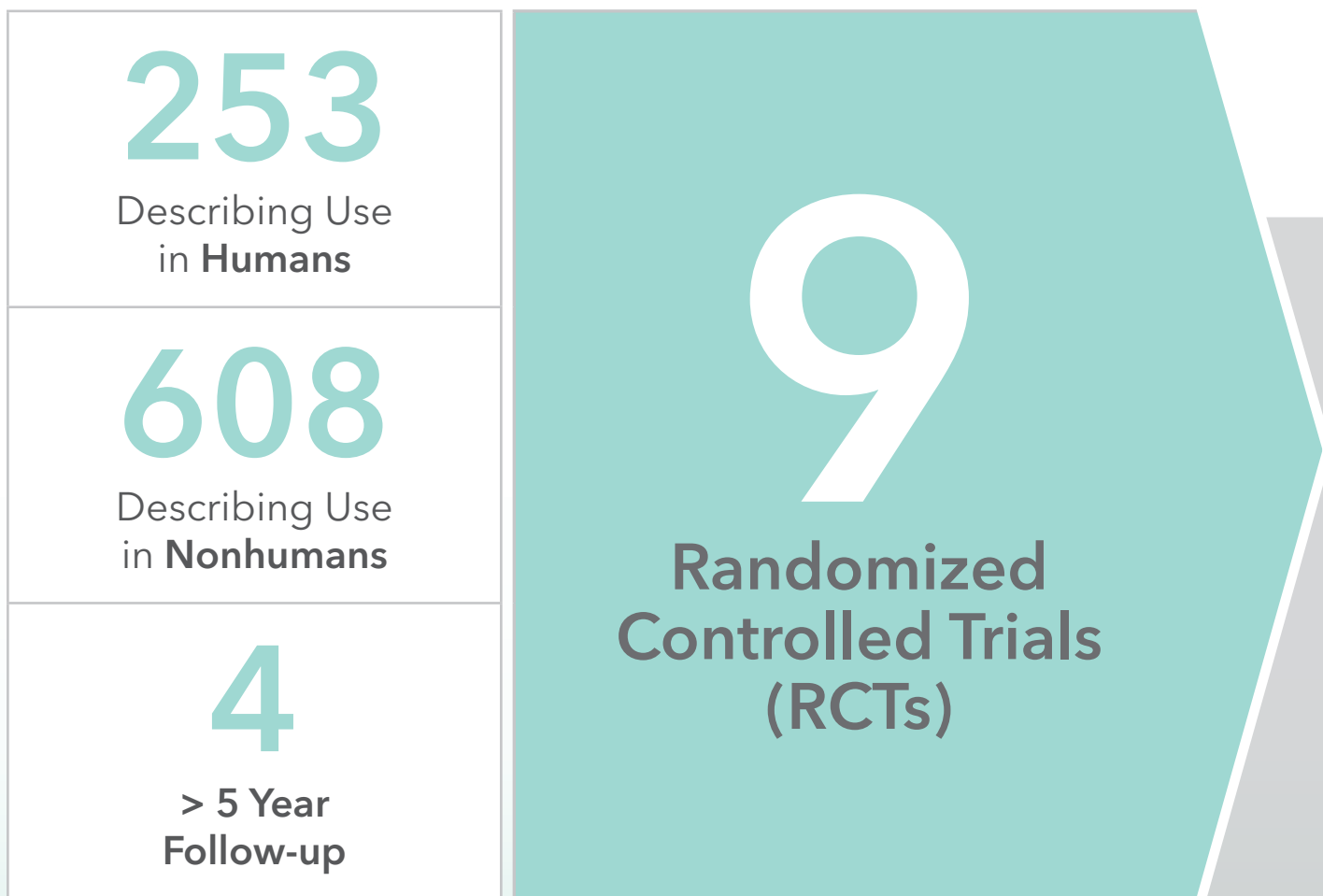
Long-term strength: A meta-analysis

The graph to the left 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.^{1,2}

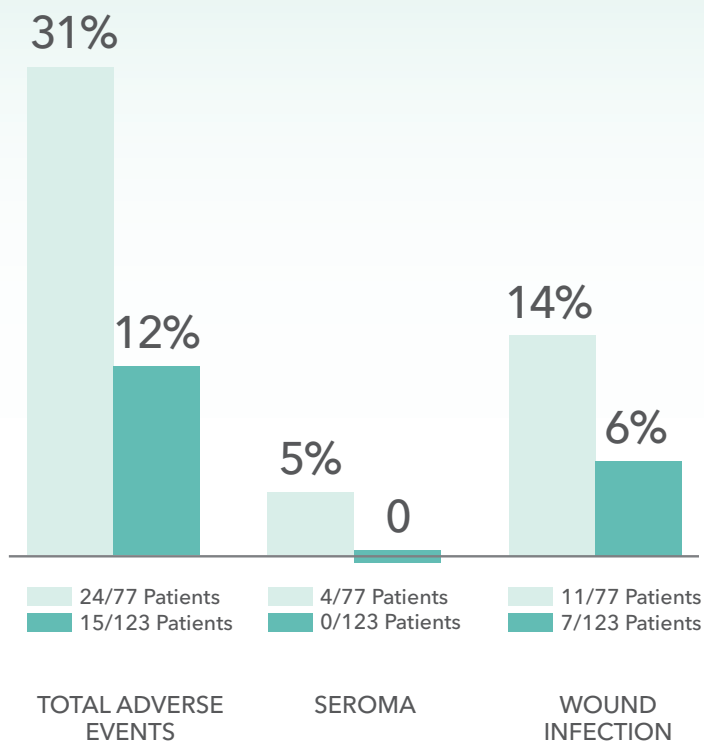
Move beyond to a proven technology

Data describing Biodesign's use isn't just available—it's abundant. With more than **861** total peer-reviewed articles published to date, and with several procedure-specific high-level studies regarding its use, Biodesign is the evolution of one of the most thoroughly studied biologic graft technologies available.

Total studies conducted



Explore the data for yourself. Visit the online resource library at www.cookbiodesign.com



Reduced Complication Rates⁴

Biodesign is the result of more than a decade of scientific advancement and user-based refinement. Recent 6 month data from a randomized controlled trial by Sarr, et al., show that Biodesign is associated with **significantly reduced rates of complication** when compared to earlier submucosa-based products.

■ Biodesign
■ Surgisis


Procedure-Specific Data

Procedure	# of Patients	Study Type	Years of Follow-up
Ventral Hernia ¹	200	Retrospective review	5
Incision Reinforcement ⁴	400	RCT	2
Hiatal Hernia ⁵	108	RCT	5
Inguinal Hernia ⁶	70	RCT	3

Move beyond to cost-effective tissue repair

In comparing approaches to tissue repair, some may have low material costs, but there are more factors to consider. Theatre time, secondary surgeries, follow-up visits and more can dramatically increase the overall cost of the repair.

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

								
BIODESIGN £8,103	Success 88%	£7,541	NON-CROSS-LINKED PORCINE DERMIS £12,939	Success 81%	£12,049	CROSS-LINKED PORCINE DERMIS £10,069	Success 92%	£9,695
	Failure 12%	£12,221		Failure 19%	£16,729		Failure 8%	£14,375
			RESORBABLE MESH £8,699	Success 0%	£4,019			
				Failure 100%	£8,699			

Despite low material costs, staged repairs with synthetic mesh require additional theatre time and hospital stays.

Biodesign's moderate material cost and availability in large sizes make ventral hernia repair procedures less costly than those using other biologic grafts.

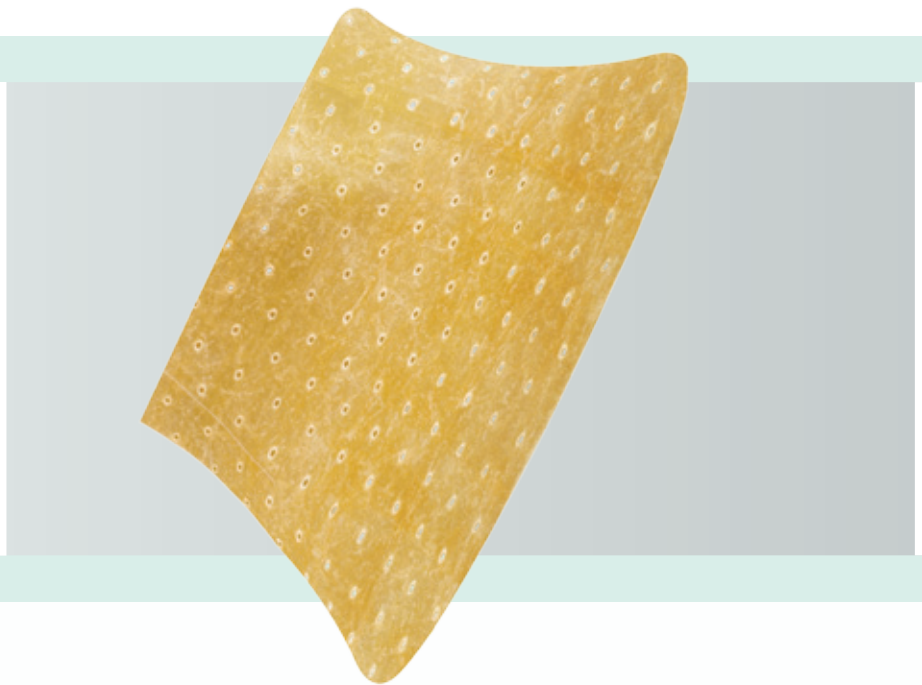
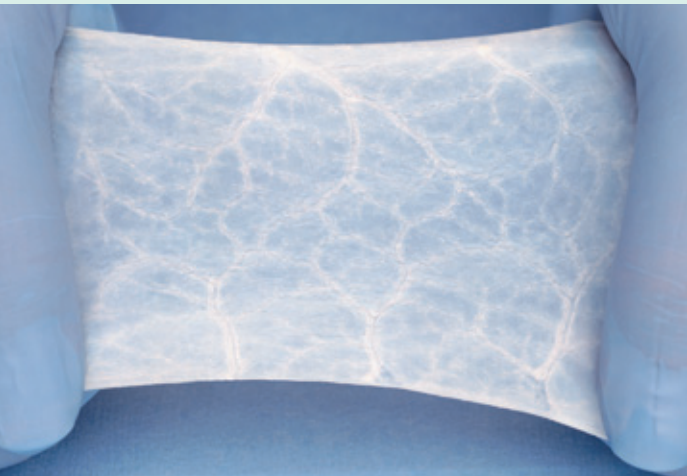
Ventral Hernia Repair⁷

A recent cost analysis performed by Hiles, et al., showed that at one year, ventral hernia repair with Biodesign was the most cost-effective option when compared to human and porcine dermis, and to staged repairs with synthetic mesh.

Move beyond to continual improvement

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

Unlike other biologic grafts, the technology behind Biodesign has been continually researched and improved based on surgeon feedback and scientific advancement. Today's Biodesign is a substantial improvement over earlier submucosa-based products.



1989

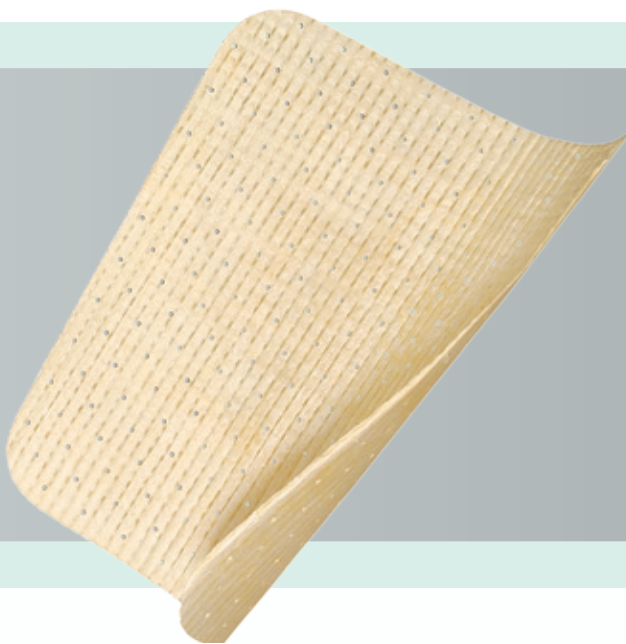
Discovery of SIS

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

1998

Surgisis® is released

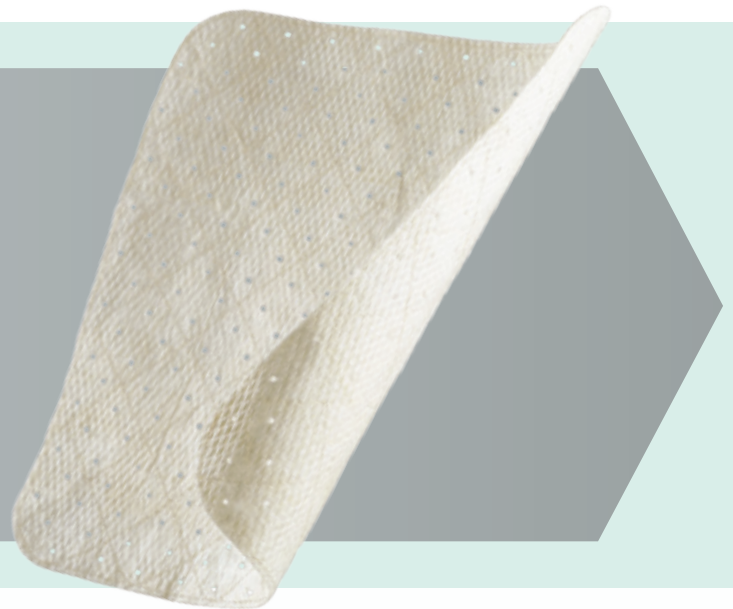
After rigorous research and development, Cook receives FDA clearance for release of Surgisis, the first medical-grade hernia device made from SIS-based technology.



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. New generation of grafts are renamed Biodesign.

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 showing 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.
- ✓ Has been developed into 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 based on surgeon feedback and scientific research.

References

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2. Data on file at Cook Biotech.
3. Awad S, Baumann D, Bellows C, et al. Prospective multicenter clinical study of single-stage repair of infected or contaminated abdominal incisional hernias using Strattice™ Reconstructive Tissue Matrix. Poster presented at: American College of Surgeons Clinical Congress; October 3-7, 2010; Washington DC.
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7. Hiles M, Briggs CM. The overall cost of complex ventral hernia repair with biologic grafts. *Gen Surg News.* 2010;37(12):24-25.

4" POCKET



Slits for business card

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