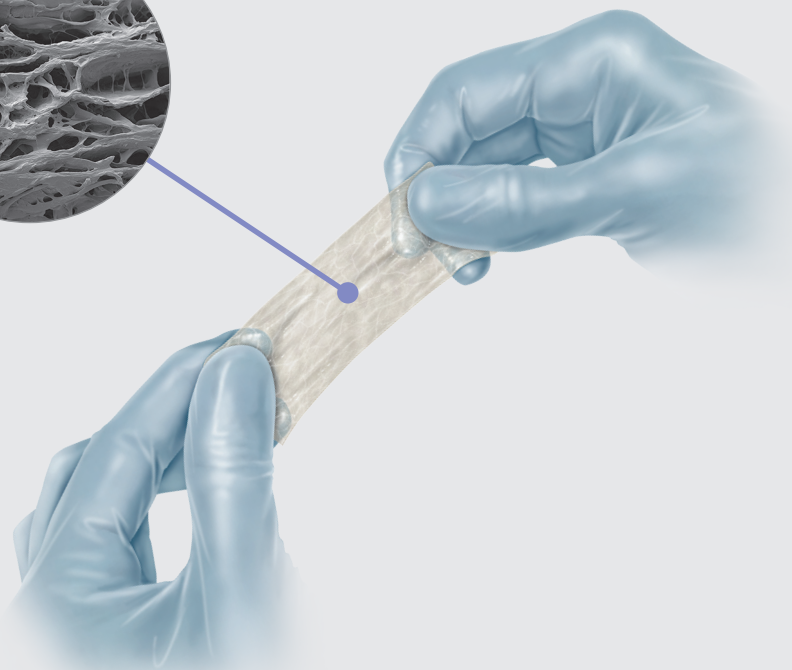
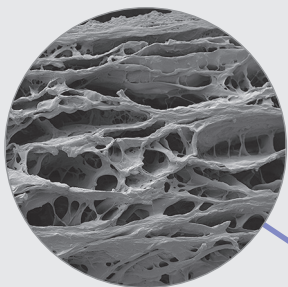


# Biodesign<sup>®</sup>

## Your biologic choice



Biodesign<sup>®</sup>  
BIOLOGIC GRAFT PORTFOLIO



[cookbiotech.com](http://cookbiotech.com)

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## Our history

More than 30 years ago, a Purdue University biomedical engineering team discovered the regenerative properties of porcine small intestinal submucosa (SIS).

In 1995, based on research supporting the versatility and effectiveness of SIS, Cook Biotech Incorporated was founded to develop and manufacture the promising new material.

Since then, Cook Biotech has globally distributed more than 6 million SIS products.<sup>1</sup>

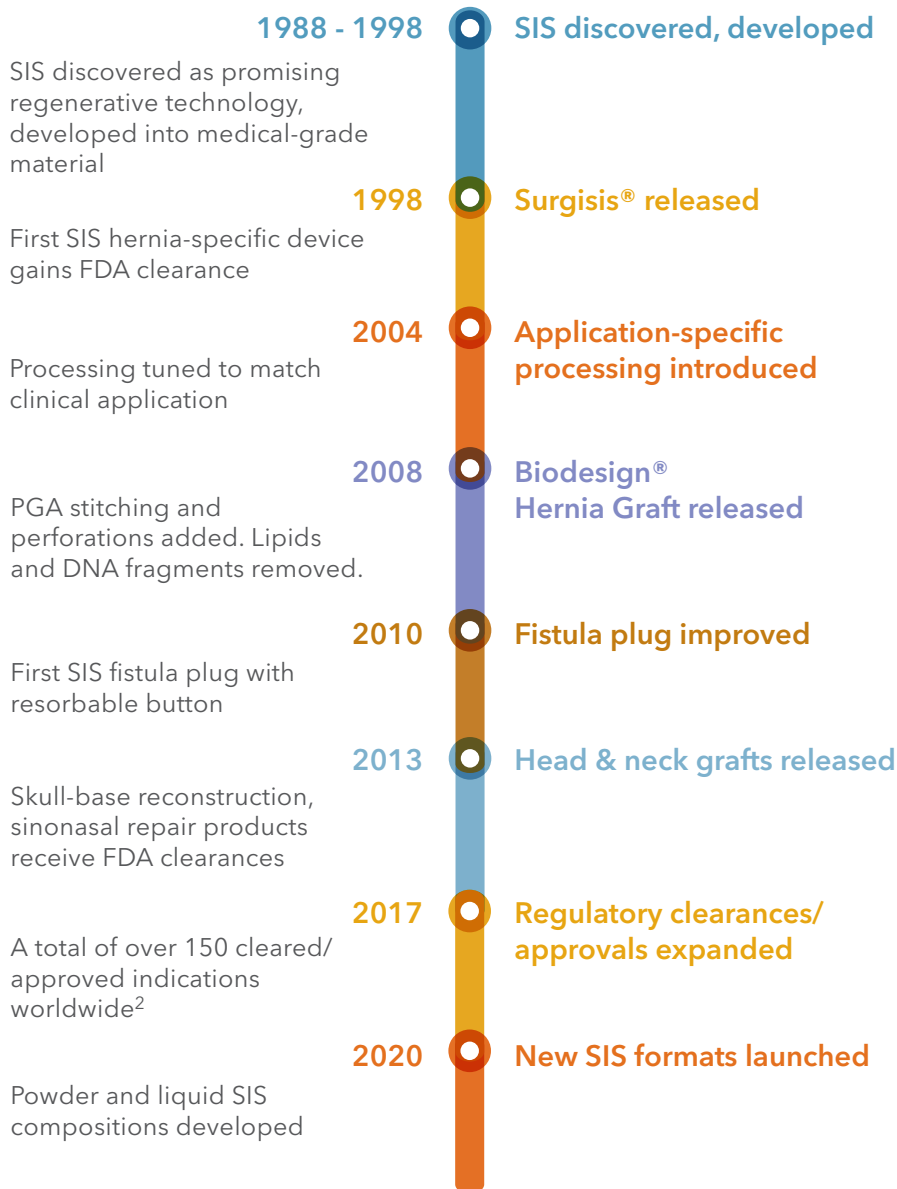


**Cook Biotech was founded in 1995 to develop and commercialize advanced tissue-repair products derived from SIS.**



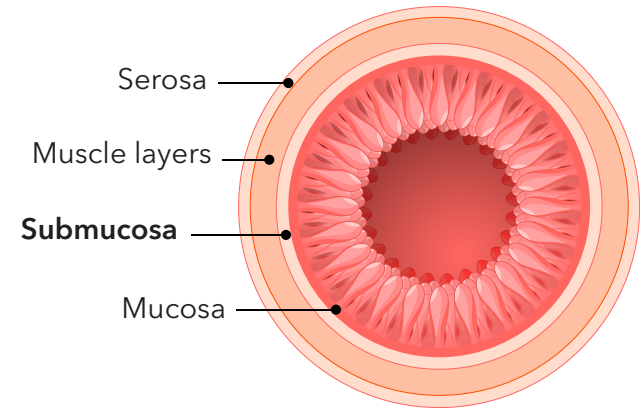
**Cook Biotech, Purdue Research Park, West Lafayette, Indiana.**

## A foundation of continuous improvement



## SIS technology

SIS is derived from porcine small intestinal submucosa, a naturally occurring extracellular matrix (ECM) located between the mucosal and muscular layers of the small intestine.

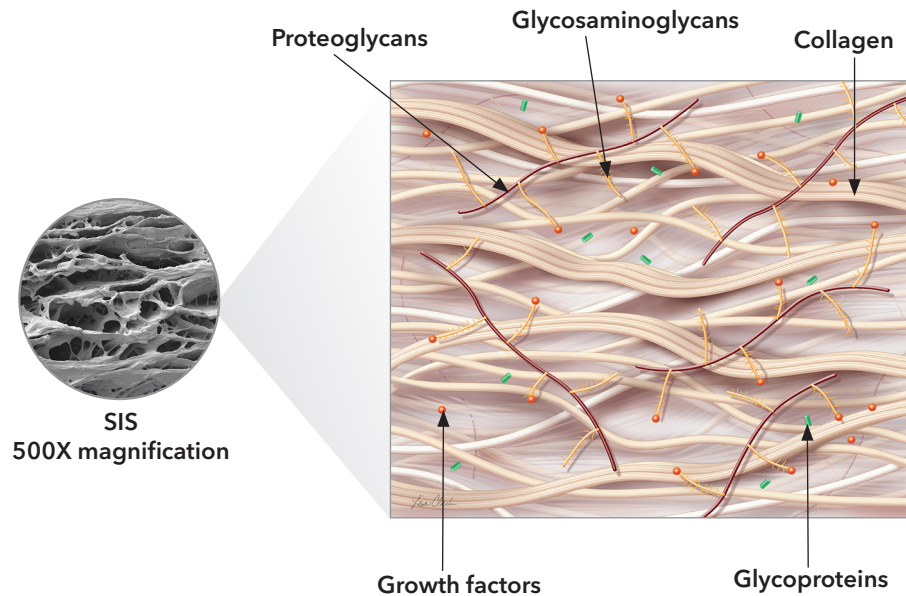


ECM is the structural and functional material that supports cells in nearly all body tissue. It serves as the structure upon which cells orient and move in response to other cells and signals and provides a healthy environment necessary for tissue maintenance and repair.<sup>3</sup>

Tissue-repair processes occur through the coordinated activity of cells that reside within the ECM. Because the ECM is necessary for tissue maintenance, it also plays a major role in tissue repair.<sup>3</sup> Without a functional ECM, the body can no longer support normal cellular processes, and tissue repair fails to progress.<sup>4</sup>

## Complex composition

SIS is a naturally occurring ECM that contains collagen, glycosaminoglycans, proteoglycans, growth factors, and glycoproteins.<sup>5</sup>



These components create an environment that allows cells in the body to secrete growth factors and replicate.<sup>6,7</sup>

## The Biotech Process

Cook Biotech designs and continuously improves proprietary processing methods to adapt SIS for specific clinical applications.

The result of the Biotech Process is variations of SIS that are optimized for application-specific requirements, such as strength and biochemical specifications.

Cook Biotech obtains SIS material from the intestine in a manner that removes all viable cells but leaves the naturally fibrous and porous nature of the matrix behind.<sup>5</sup>



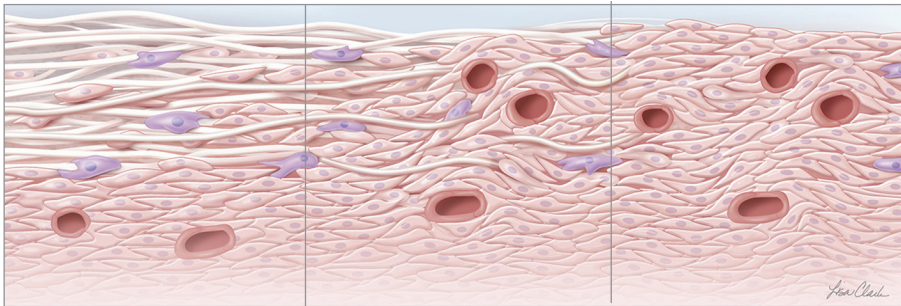
SIS is carefully processed and meticulously crafted into Biodesign® tissue-repair products designed for specific clinical applications.

The complex architecture and composition of the ECM are retained, providing not only the structural collagen framework but also the natural non-collagenous ECM components that are essential for cell interaction, function, and growth.<sup>5,6</sup>

Each product is then meticulously crafted to meet global quality standards with SIS material that was processed specifically for the product's clinical application.

## Tissue remodeling

SIS provides a natural scaffold that allows the body to restore itself through the complex natural process of tissue remodeling. Tissue remodeling involves the **recruitment** of cells, the **renewal** of tissue composition, and the **reinforcement** of structural tissue architecture.<sup>8</sup> As the body heals, SIS is gradually remodeled and integrated into the body, leaving behind organized tissue that provides long-term strength.<sup>9-11</sup>



### Recruit

Immediately after implantation, the remodeling process starts when the body's inflammatory and progenitor cells populate the matrix and release cytokines and growth factors that recruit collagen-secreting fibroblasts.<sup>12,13</sup> In this phase, SIS acts as a scaffold material to support the population of the ECM with patient-derived cells.

### Renew

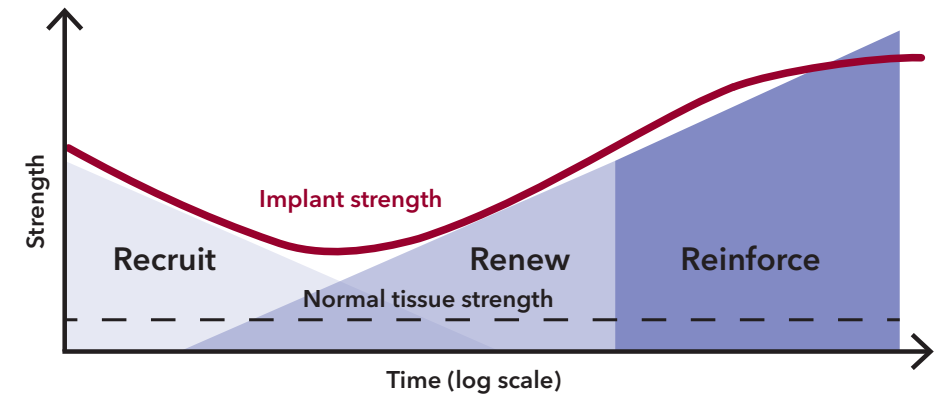
As remodeling progresses, host macrophages and fibroblasts in the newly populated matrix work together to renew the tissue through the complementary processes of phagocytosis, collagen deposition, and angiogenesis (blood vessel formation).<sup>14</sup> In this phase, SIS is gradually replaced by the patient's own tissue and cells.

### Reinforce

Over time, the resident fibroblasts secrete cytokines and growth factors to signal reinforcement of the deposited tissue through the processes of additional collagen deposition and maturation, resulting in a strong, repaired tissue.<sup>6,9-11</sup> In this phase, SIS is no longer needed as the patient's own collagen has gradually matured into a stable structure that has long-term strength but is entirely the patient's own.<sup>9-11</sup>

Recruitment of cells, renewal of tissue composition, and reinforcement of structural tissue architecture result in mature, organized, strong tissue that can withstand the natural physiological forces it encounters.<sup>15</sup>

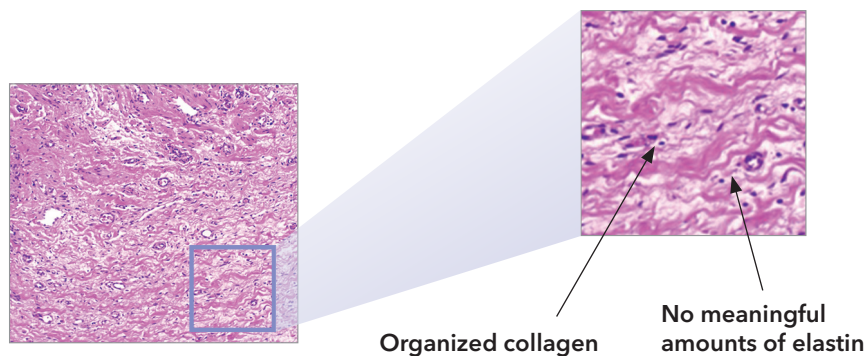
### Biodesign® graft remodeling



## Non-dermis, non-cross-linked

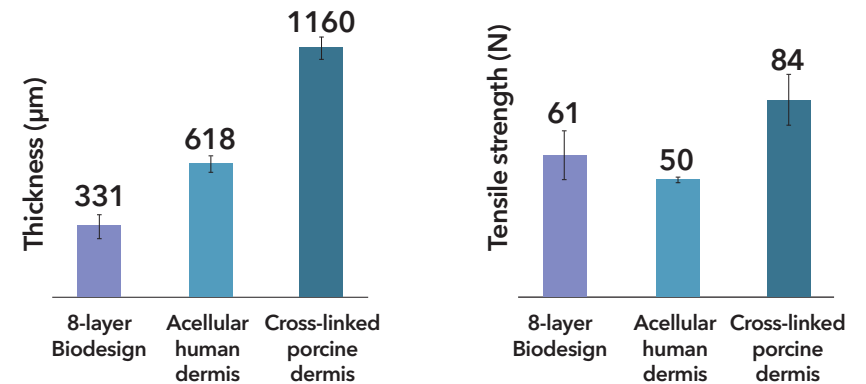
Because Biodesign® products are not manufactured from dermis, they contain no meaningful amount of elastin.<sup>16</sup> Dermis-based biologic grafts contain high amounts of elastin. Studies attribute higher rates of failure to higher elastin levels.<sup>17,18</sup>

Biodesign grafts are designed to maintain strength throughout the remodeling process, so there is no need for chemical cross-linking.<sup>11</sup> Cross-linked grafts have been associated with chronic inflammation and encapsulation.<sup>19</sup>



## Thin but strong

Even though Biodesign® grafts are typically thinner than dermis-based grafts, the average tensile strength of Biodesign is comparable to the average strength of either an acellular human dermal graft or a cross-linked porcine dermal graft.<sup>20,21</sup>



Because Biodesign grafts are thin yet strong, they offer significant advantages to grafts made from thicker materials.

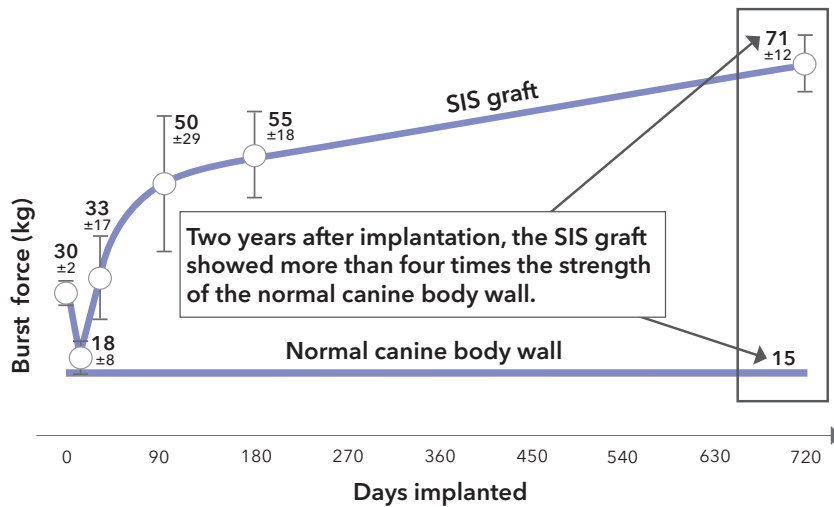
- They can be quickly hydrated, in a minute or less, using sterile saline or lactated Ringer's solution.
- They can easily be secured to the adjacent tissues using a suture, tack, or staple, as described in the Instructions for Use (IFU).
- They can easily be placed through a laparoscopic port during a laparoscopic operation.

## Long-term strength

Preclinical data have shown long-term strength as SIS remodels.<sup>11</sup>

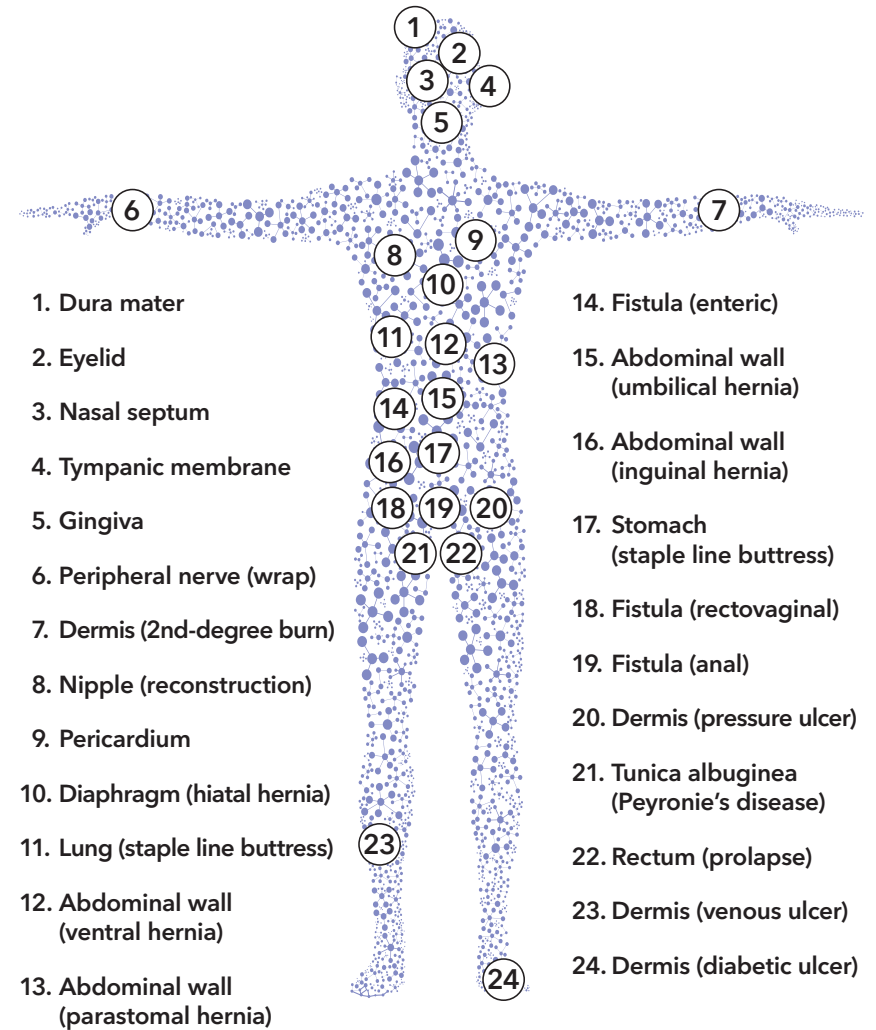
Not only is the material strong at the time of implant, it is designed to exceed the strength of the recipient's tissue during the time it is being remodeled into vascularized tissue.

When tissue repair and remodeling are complete, the resulting tissue is stronger than that which was implanted. No permanent material is left in the patient's body.<sup>9,11</sup>



## Versatile platform

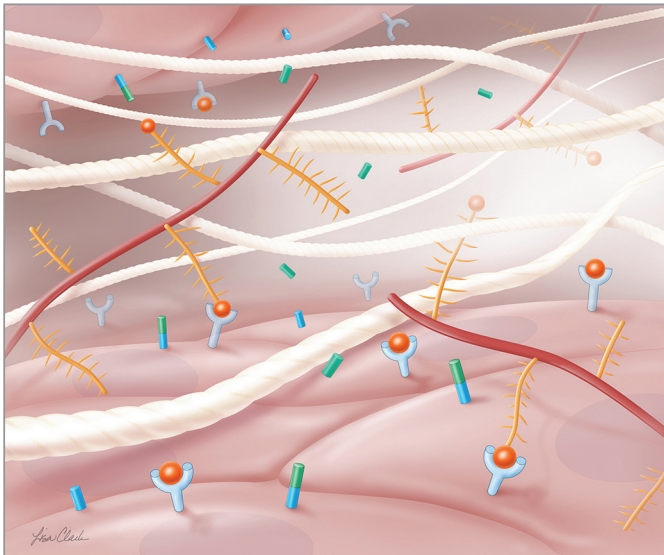
SIS has been used globally in more than 6 million tissue repairs.<sup>1</sup>



This is a summary of historic global uses for Cook Biotech products. Not all products or indications are approved in all regulatory jurisdictions. Products should be used for on-label, approved indications only.

## Site-specific remodeling

Biologic grafts made from natural tissues, when processed correctly for clinical use, have unique properties that are not found in synthetic materials, bioabsorbable materials, or highly processed and cross-linked graft materials.



The natural ECM, when retained in its complex arrangement of matrix proteins and associated factors, can provide the key components needed to restore damaged tissues to their natural state.<sup>7,22</sup>

These unique properties allow the naturally occurring biologic graft to completely integrate with the recipient's tissues and cells to ultimately form a vascularized, highly organized tissue structure that resembles the native tissue structure and architecture.<sup>9,11</sup>

As a result of this site-specific remodeling process, **no permanent material is left behind.**<sup>9,11</sup>

A key concern when implanting any material into the body is how it will react and what may go wrong. Because no Biodesign® material is left behind after site-specific remodeling is complete, complications that may be common when synthetic materials are implanted, such as **erosion, encapsulation, and prolonged inflammation, are minimized.**<sup>13</sup>

### Immune response

SIS-derived biologic grafts have been shown to be accepted by the body's immune system and do not lead to a rejection response.<sup>23</sup> They do not cause the activation of the complement cascade, nor are they acutely rejected following implant.<sup>23</sup> They are associated with a Th2-dominant lymphocyte response (a response associated with transplant acceptance<sup>24</sup>) that does not adversely affect the patient's ability to overcome viral or bacterial infections,<sup>25,26</sup> and have also been associated with an M2 macrophage phenotype response<sup>27</sup> – a macrophage phenotype that promotes immunoregulation, tissue repair, and constructive tissue remodeling.<sup>28</sup>

### Pain or discomfort

Two clinical studies have shown that SIS-derived biologic grafts are associated with **lower incidence of pain or discomfort** when compared to polypropylene mesh in inguinal hernia repair.<sup>29,30</sup>

### Erosion, encapsulation, inflammation

Additionally, because Biodesign is designed to fully integrate with the patient's surrounding tissues, numerous studies in a variety of clinical applications have shown a reduced risk of erosion, encapsulation, and prolonged inflammation as compared to synthetic materials.<sup>9, 31-33</sup>



## Studied and proven

The technology behind Biodesign® tissue-repair products is supported by more than 1,850 total publications. More than 750 publications describe clinical use. Eight publications have more than five years of follow-up data.

**36**  
Clinical RCTs

**>1,850**  
Published articles

**>750**  
Clinical publications

**8**  
Articles with more than  
five years of follow-up

Publications focused on SIS and its applications continue to grow. These numbers are accurate as of April 2023.

## Key clinical evidence

### Porcine small intestinal submucosa mesh to treat inguinal hernia in young adults using laparoscopic inguinal hernia repair: a retrospective controlled study

Liu Y, Cao Z, Yang H, Shen Y, Chen J. Porcine small intestinal submucosa mesh to treat inguinal hernia in young adults using laparoscopic inguinal hernia repair: A retrospective controlled study. *Surg Laparosc Endosc Percutan Tech.* 2020;30(4):367-370.

### 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.

Franklin ME Jr, Treviño JM, Portillo G, Vela I, Glass JL, González JJ. 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.

### Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial

Oelschläger BK, Pellegrini CA, Hunter JG, et al. Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial. *J Am Coll Surg.* 2011;213(4):461-468.

### Porcine small intestinal submucosa (SIS) myringoplasty in children: a randomized controlled study

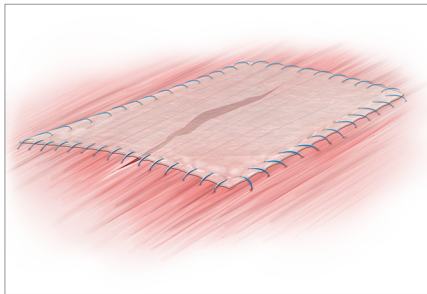
D'Eredita RD. Porcine small intestinal submucosa (SIS) myringoplasty in children: a randomized controlled study. *Int J Pediatr Otorhinolaryngol.* 2015;79(7):1085-1089.

### Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm

Gupta A, Zahriya K, Mullens PL, Salmassi S, Keshishian A. Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm. *Hernia.* 2006;10(5): 419-425.

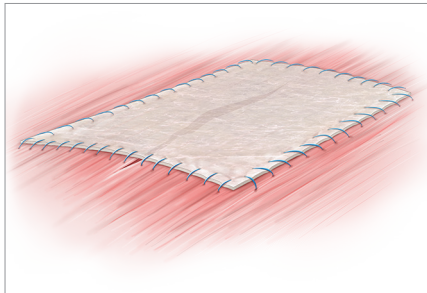
### Porcine small intestine submucosal graft for endoscopic skull base reconstruction

Illing E, Chaaban MR, Riley KO, Woodworth BA. Porcine small intestine submucosal graft for endoscopic skull base reconstruction. *Int Forum Allergy Rhinol.* 2013;3(11):928-932.



**Biodesign® 1-Layer Tissue Graft**  
Used for implantation to reinforce soft tissue

Order Number	Reference Part Number	Size cm
G13221	C-SLH-1S-2X3	2 x 3
G12581	C-SLH-1S-7X10	7 x 10



**Biodesign® 4-Layer Tissue Graft**  
Used for implantation to reinforce soft tissue

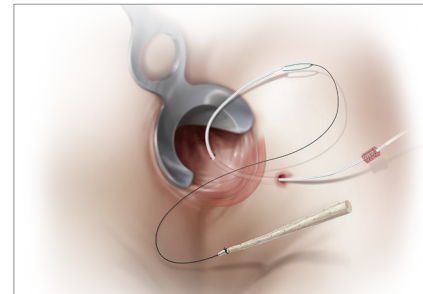
Order Number	Reference Part Number	Size cm
G13544	C-SLH-4S-1X10	1 x 10
G31320	C-SLH-4S-2X3	2 x 3
G13181	C-SLH-4S-4X7	4 x 7
G12580	C-SLH-4S-7X10	7 x 10
G12579	C-SLH-4S-7X20	7 x 20

Illustrations by Lisa Clark

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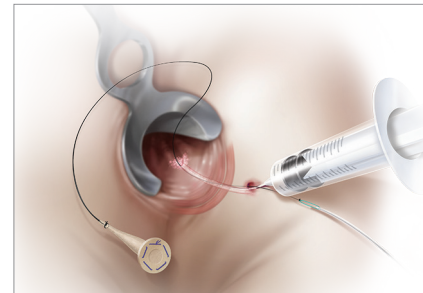
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**Biodesign® Anal Fistula Plug Set**  
Used for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anorectal fistulas

Order Number	Reference Part Number	Size cm
G53614	C-AFPS-0.6X9.5	0.6 x 9.5



**Biodesign® Fistula Plug Set**  
Used for implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas

Order Number	Reference Part Number	Size cm
G54612	C-FPS-0.2	0.2
G54613	C-FPS-0.4	0.4
G54614	C-FPS-0.7	0.7

Illustrations by Lisa Clark



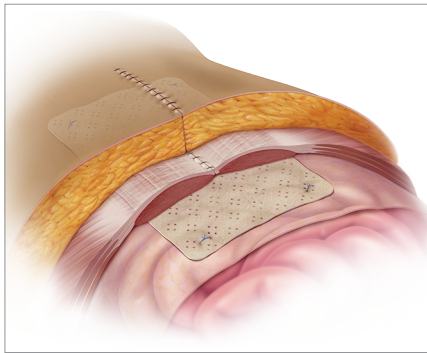
**Cook® Fistula Brush**  
Used to identify, clean, or debride a rectal fistula tract, and facilitate placement of the Biodesign fistula plugs.

Order Number	Reference Part Number	Length cm
G48527	J-FB-100	46

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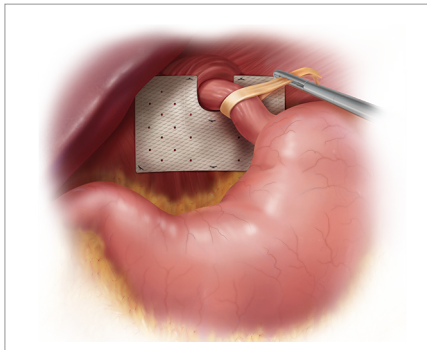
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**Biodesign® Hernia Graft**

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

Order Number	Reference Part Number	Size cm
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
G55265	C-BIG-8X10	8 x 10
G55266	C-BIG-8X20	8 x 20
G55267	C-BIG-8X30	8 x 30



**Biodesign® Hiatal Hernia Graft**

Used for implantation to reinforce soft tissue where weakness exists, including repair of hiatal hernias

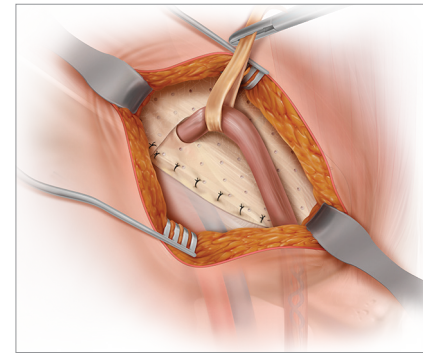
Order Number	Reference Part Number	Size cm
<b>Preshaped</b>		
G31455	C-PHR-7X10-U	7 x 10
<b>Standard</b>		
G51578	C-PHR-7X10	7 x 10

Illustrations by Lisa Clark

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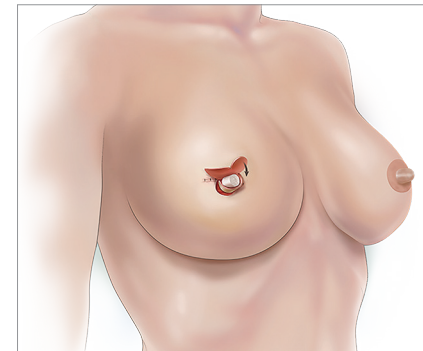
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**Biodesign® Inguinal Hernia Graft**

Used for reinforcing soft tissues where weakness exists, including the repair of inguinal hernias

Order Number	Reference Part Number	Size cm
G44777	C-IHM-10X15-B	10 x 15
G44778	C-IHM-6X13-P-B	6 x 13
G44779	C-IHM-8X15-P-B	8 x 15



**Biodesign® Nipple Reconstruction Cylinder**

Used for implantation to reinforce soft tissue, where weakness exists, in plastic and reconstructive surgery of the nipple

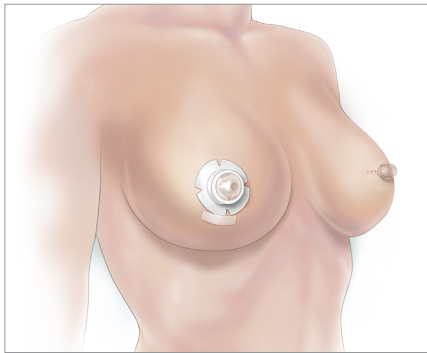
Order Number	Reference Part Number	Size cm
G49127	C-NRC-0.7X1.0	0.7 x 1.0
G49126	C-NRC-1.0X1.0	1.0 x 1.0
G52549	C-NRC-1.0X1.5	1.0 x 1.5

Illustrations by Lisa Clark

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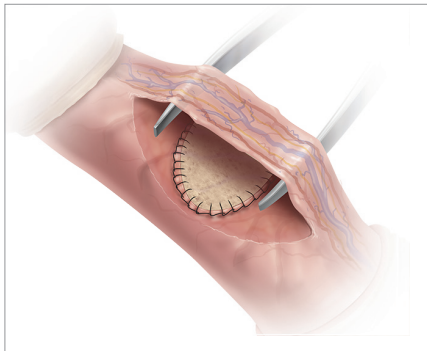
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**HaloShield® Nipple Protector**

Used as a wound cover protector for the areola and nipple in breast reconstruction or surgery

Order Number	Reference Part Number	Projection clearance (mm)
G46289	C-SHIELD-1.0	10
G46290	C-SHIELD-2.0	20



**Biodesign® Peyronie's Repair Graft**

Used for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to repair of tunica albuginea defects and reinforcement in the repair of Peyronie's disease

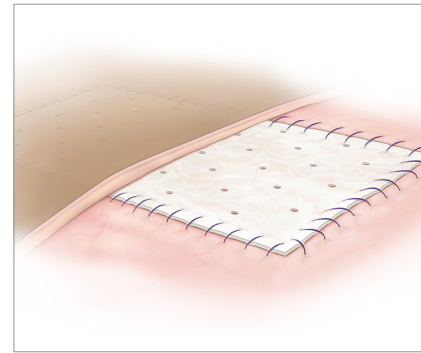
Order Number	Reference Part Number	Size cm
G47654	SLH-4-PR1	4 x 10
G47655	SLH-4-PR2	7 x 10

Illustrations by Lisa Clark

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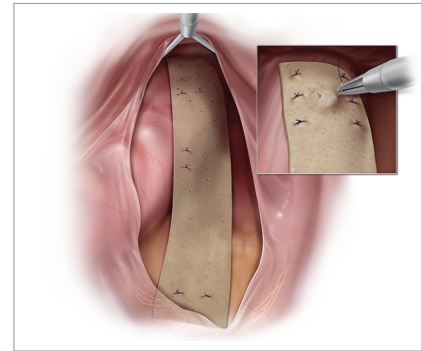
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**Biodesign® Plastic Surgery Matrix**

Used for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery

Order Number	Reference Part Number	Size cm
G52865	C-SLH-6H-7X10	7 x 10
G52866	C-SLH-6H-7X20	7 x 20
G52867	C-SLH-6H-4X7	4 x 7



**Biodesign® Rectopexy Graft**

Used to reinforce soft tissue where weakness exists in the gastroenterological anatomy including transabdominal repair of colon and rectal prolapse

Order Number	Reference Part Number	Size cm
G35247	C-BRG-7X20-US	7 x 20

Illustrations by Lisa Clark

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1. Internal Cook Biotech document: D00278582.
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