



SYMPHASIS™
SMART REMODELING MATRIX

**The Natural
Choice for
Pelvic
Restoration™**

COOK®

Symphasis™

The Natural Choice for Pelvic Restoration™

The challenge of any pelvic reconstruction is to provide support while returning the surrounding structures to the natural anatomical state. While there are many materials that can provide support, few have the properties necessary to restore the qualities of live tissue.¹

Symphasis is an acellular biomaterial that supports tissue repair with a scaffold-like matrix having an all natural structure and composition. Unlike other “biomaterials” currently available, Symphasis does not encapsulate when surgically implanted, but is gradually remodeled, leaving behind organized tissue.

When Symphasis is implanted in close contact with living tissue and a good blood supply, it provides a scaffold for connective and epithelial tissue growth and differentiation. The result is site-specific tissue remodeling – a phenomenon that is called “smart tissue remodeling.” Remodeling takes place as the implant and host become indistinguishable. During the remodeling process, Symphasis provides sufficient mechanical strength for tissue support while it acts as a scaffold for rapid, guided tissue incorporation.

Unlike synthetic or cross-linked implants that eventually encapsulate and form a barrier to the body’s natural defenses, Symphasis is rapidly infiltrated by host cells, tissues and blood vessels.

Symphasis is configured in four convenient sizes suitable for most urogynecologic repairs such as cystoceles, rectoceles, enteroceles, and intraoperative sling placement. It is designed for easy handling and suturing. Symphasis can be trimmed to any desired shape or size.

Mechanical Properties

Burst Values (Modified ASTM D 3797-87)

Nominal burst values:

Symphasis 485.7 +/- 101.6 N 109.15 lb

Upper limit of physiologic pressures:

Bladder @ 65 mmHg 0.60 lb

Aorta @ 220 mmHg 0.90 lb

Colon @ 130 mmHg 1.40 lb

Body Wall @ 200 mmHg 6.00 lb

Suture Retention Strength (ANSI/AAMI VP20)

Nominal suture retention strength:

	Longitudinal	Transverse
Symphasis	1397 +/- 325 gF	1397 +/- 325 gF

Ranges of physiologic forces:

Bladder: 15.6 to 37.2 g

Aorta: 36.0 to 59.9 g

Colon: 22.8 to 71.2 g

Body Wall: 32.4 to 120.0 g

What is Symphasis?

Symphasis is a natural biomaterial harvested from the porcine small intestine and made into a sterile, biocompatible medical product using a patented process. The final product is a three-dimensional, extracellular matrix (ECM) comprised of collagen, non-collagenous proteins and other biomolecules including glycosaminoglycans, proteoglycans, and glycoproteins.²⁻³ Symphasis is dried, packaged and sterilized, permitting long-term storage at room temperature. Symphasis is fabricated into a variety of shapes and thicknesses, and is easily rehydrated and handled during surgery.

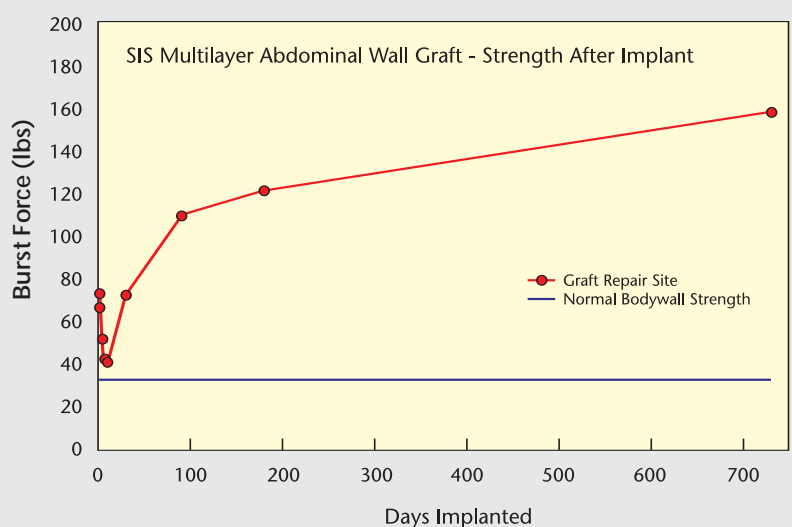
How Symphasis Implants Work

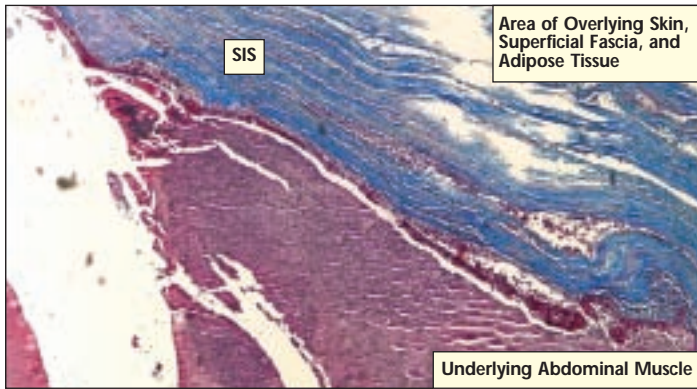
When Symphasis is implanted in close contact with living tissue and a good blood supply, host cells gradually remodel the three-dimensional structure, providing long-term biomechanical strength without encapsulation. Symphasis provides a scaffold or matrix for connective and epithelial tissue growth and differentiation, as well as deposition, organization, and maturation of host extracellular matrix (ECM) components. The result is site-specific tissue remodeling – a phenomenon that is called “smart tissue remodeling.”^{4,6}

Tissue Remodeling

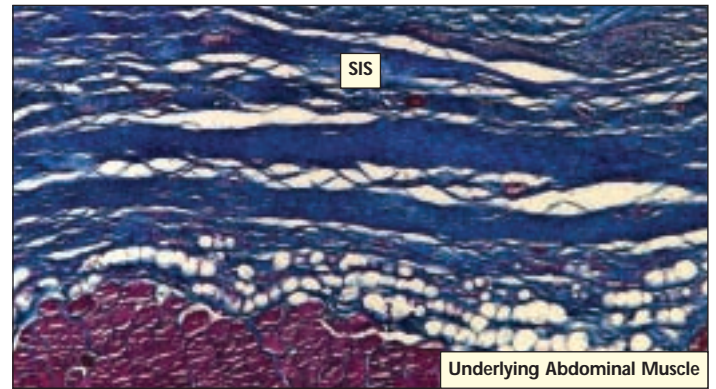
Remodeling takes place as the implant and host become indistinguishable. During the remodeling process, Symphasis provides sufficient mechanical strength for tissue support while it acts as a scaffold for rapid, guided tissue incorporation. Unlike synthetic or cross-linked implants that eventually encapsulate and form a barrier to the body’s natural defenses, Symphasis is rapidly infiltrated by host cells, tissues and blood vessels.⁵⁻¹¹

Strength Over Time⁵

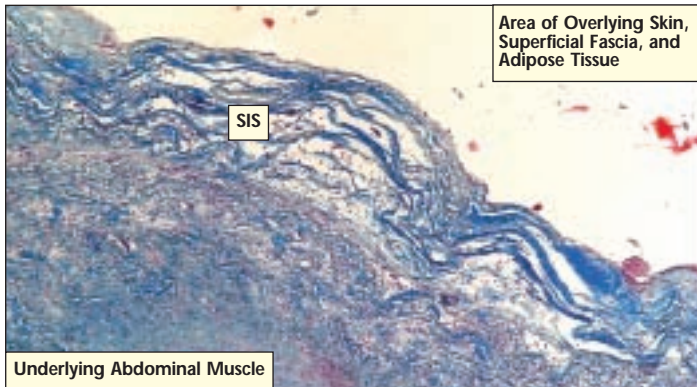




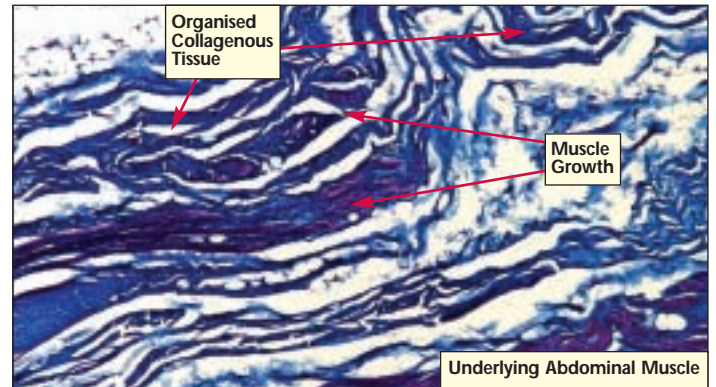
Symphysis After Seven Days – The SIS is already being invaded by host cells. A mild inflammatory response is initiating the remodeling response and matrix deposition by the cells has begun. The SIS remains largely intact at this time point.



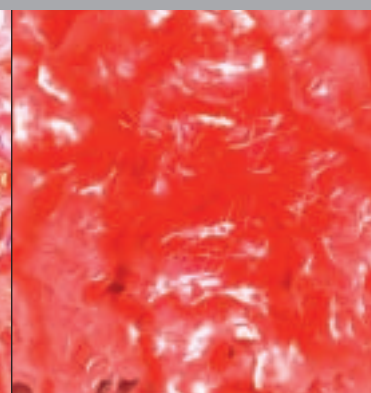
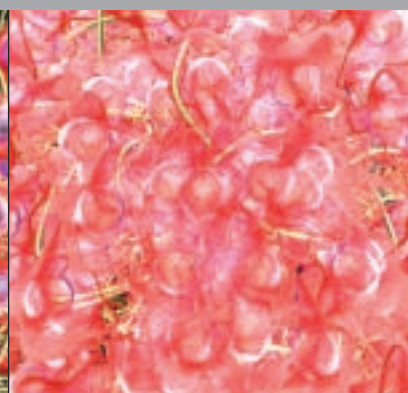
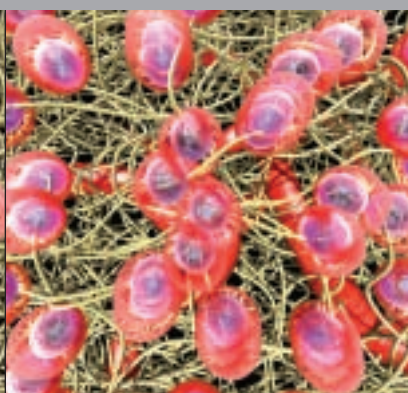
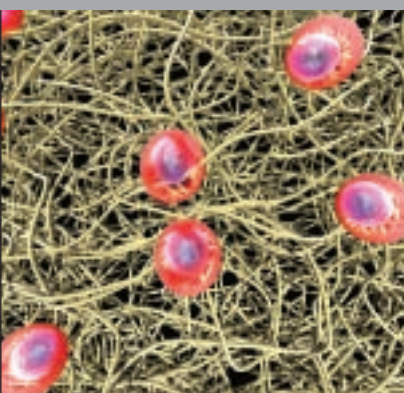
Symphysis After Three Months – The delineation between SIS and the surrounding abdominal wall becomes difficult to distinguish as the SIS gradually takes on the appearance of the surrounding tissue.



Symphysis After One Month – The SIS is continuing to be invaded by host cells. A mild inflammatory response is continuing as the matrix is gradually remodeled into host tissue. The SIS layers gradually separate as the host cells populate the graft site and secrete their own matrix.



Symphysis After One Year – The SIS can no longer be seen, though the area of implant can still be determined from the surrounding tissue because the organised collagenous tissue remains in the area. The area remains normally vascularized, and focal areas of muscle ingrowth are common. The inflammation has completely resolved and the abdominal wall appears histologically normal.



Following implantation, tissues adjacent to the SIS matrix begin to deliver cells and nutrients.

Cells rapidly invade the SIS matrix. Capillary growth follows allowing more nutrients and cells to enter the matrix.

SIS is gradually replaced as the host system reinforces and rebuilds the weakened site.

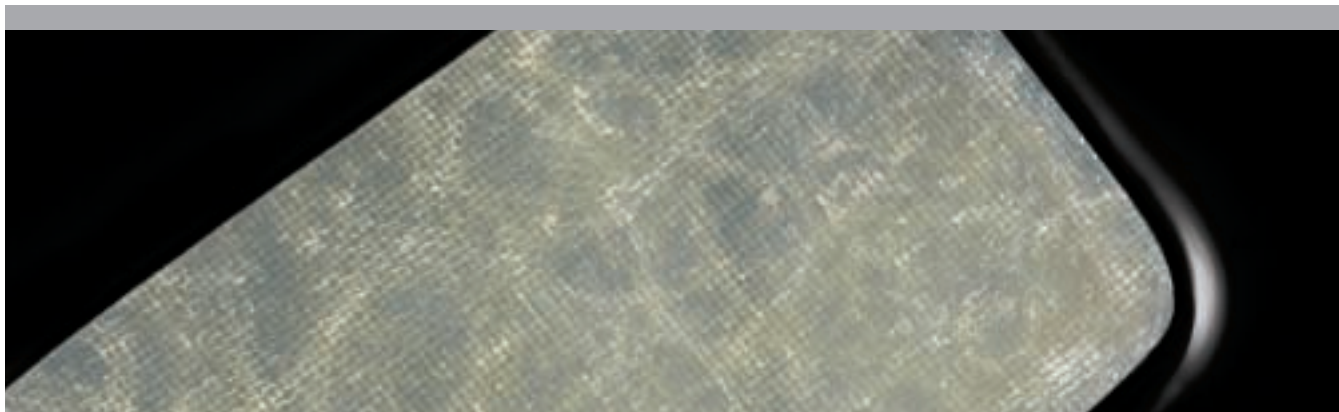
The body's tissue grows completely into the surgical site while SIS maintains the needed tissue support.

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Symphasis™ - Smart Remodeling Matrix: *The Natural Choice for Pelvic Restoration™*

Symphasis is used for soft tissue repair of pelvic floor defects such as: cystocele, rectocele, enterocele, sacrocolpopexy, and/or intraoperative bladder neck suspension. Symphasis is available in the following sizes: 2 cm x 20 cm, 4 cm x 7 cm, 6 cm x 22 cm and 8 cm x 13 cm. Supplied sterile in peel-open packages. Intended for one-time use.



SYMPHASIS®

ORDER NUMBER	Dimension	Remarks
PFG-2X20	2 cm x 20 cm	Eight-Layer, Dry Sheet
PFG-4X7	4 cm x 7 cm	
PFG-6X22	6 cm x 22 cm	
PFG-8X13	8 cm x 13 cm	

COOK®

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