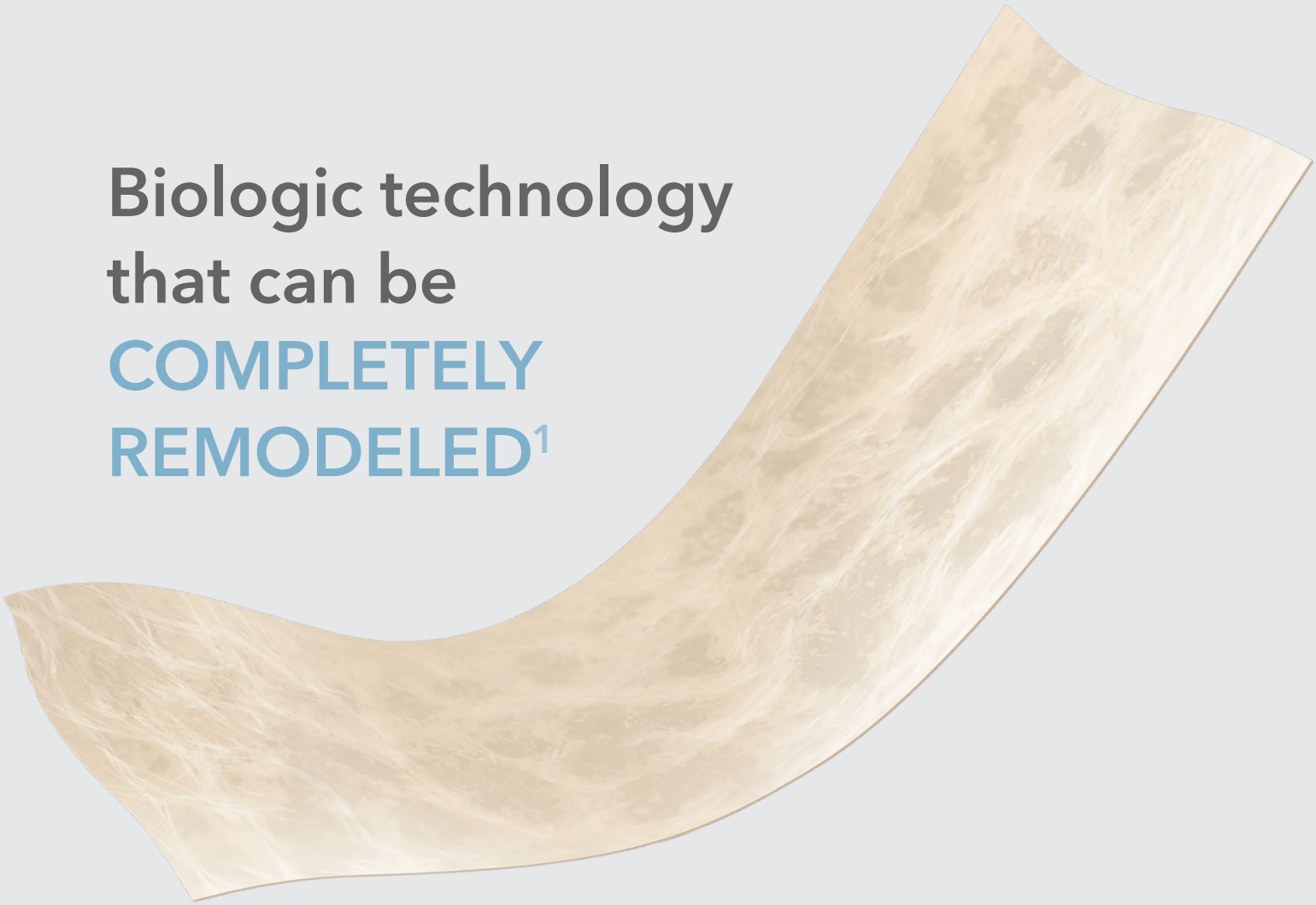
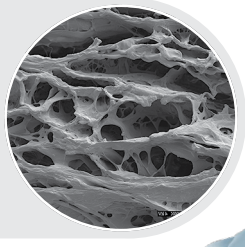
Biologic technology that can be COMPLETELY REMODELED[1]



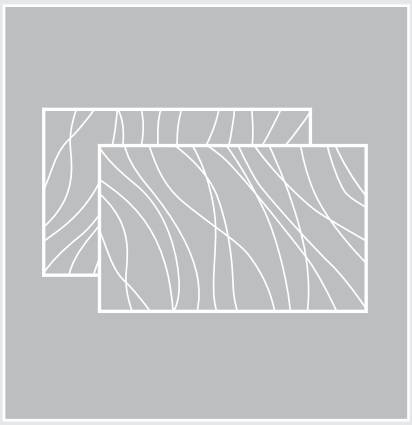
Biodesign®
ADVANCED TISSUE REPAIR

A surgeon saw a need. We listened. The Biodesign 4-Layer Tissue Graft is made from a biologic technology that provides support as it is completely remodeled into patient tissue.[1]

This biologic graft, an extracellular matrix, doesn't contain a meaningful amount of elastin.[2] Plus, new blood vessels can grow into the open, three-dimensional structure of the matrix.[3]



COOK® MEDICAL



BIODESIGN 4-LAYER TISSUE GRAFT

Used for implantation to reinforce soft tissue

- Small intestinal submucosa (SIS), the biomaterial used in the Biodesign 4-Layer Tissue Graft, provides support as it is completely remodeled into patient tissue.[1]
- SIS is an extracellular matrix that doesn't contain a meaningful amount of elastin.[2]
- New blood vessels can grow into the open structure of the matrix.[3]
- SIS is processed in a way that retains its natural three-dimensional structure and components.[4]
- SIS has been studied in more than 1,400 published articles. 10 of those articles have more than five years of follow-up.

Order Number	Reference Part Number	Size cm
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

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

1. Franklin ME Jr, Treviño JM, Portillo G, et al. 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.
2. Heise RL, Ivanova J, Parekh A, et al. Generating elastin-rich small intestinal submucosa-based smooth muscle constructs utilizing exogenous growth factors and cyclic mechanical stimulation. *Tissue Eng Part A*. 2009;15(12):3951-3960.
3. Nihsen ES, Johnson CE, Hiles MC. Bioactivity of small intestinal submucosa and oxidized regenerated cellulose/collagen. *Adv Skin Wound Care*. 2008;21(10):479-486.
4. Hodde J, Janis A, Ernst D, et al. Effects of sterilization on an extracellular matrix scaffold: part I. Composition and matrix architecture. *J Mater Sci Mater Med*. 2007;18(4):537-543.

INTENDED USE: The Cook® Biodesign® Tissue Graft is intended for implantation to reinforce soft tissue. The graft is supplied sterile in peel-open packages and is intended for one-time use. Rx ONLY This symbol means the following: **CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.** 1-LAYER TISSUE GRAFT This symbol means the following: 1-Layer Tissue Graft. 4-LAYER TISSUE GRAFT This symbol means the following: 4-Layer Tissue Graft. This product is intended for use by trained medical professionals.

CONTRAINDICATIONS: This graft is derived from a porcine source and should not be used for patients with known sensitivity to porcine materials.

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. • Graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard the graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date. • Single-layer graft should not be used in applications requiring high strength. • The graft may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs. • Ensure that the graft is rehydrated prior to suturing or stapling. • Patients undergoing radiation therapy may not experience normal wound healing. • **Graft performance has not been evaluated with suture spacing greater than 2 mm. • Ensure that all layers of the graft are secured when suturing or stapling.**

POTENTIAL COMPLICATIONS: Complications that can occur with the use of any surgical graft material may include, but are not limited to: • Inflammation • Induration • Migration • Allergic reaction • Erosion • Extrusion • Seroma formation • Infection • Fever • Abscess • Tissue trauma • Pain • Adhesion • Recurrence of tissue defect • Bleeding • Fistula formation • Delayed or failed incorporation. If any of the following conditions occur and cannot be resolved, device removal should be considered: • Infection • Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation) • Allergic reaction • Seroma formation

See instructions for use for full product information.

AB_FP0005-04_REV0

Customer Service

EU Website: cookmedical.eu
EDI: cookmedical.eu/edi
Distributors: +353 61239240, ssc.distributors@cookmedical.com
Austria: +43 179567121, oe.orders@cookmedical.com
Belgium: +32 27001702, be.orders@cookmedical.com
Denmark: +45 38487607, da.orders@cookmedical.com
Finland: +358 972519996, fi.orders@cookmedical.com
France: +33 171230269, fr.orders@cookmedical.com
Germany: +49 6950072804, de.orders@cookmedical.com
Hungary: +36 17779199, hu.orders@cookmedical.com
Iceland: +354 800 7615, IS.orders@cookmedical.com
Ireland: +353 61239252, ie.orders@cookmedical.com
Italy: +39 0269682853, it.orders@cookmedical.com
Netherlands: +31 202013367, nl.orders@cookmedical.com
Norway: +47 23162968, no.orders@cookmedical.com
Spain: +34 912702691, es.orders@cookmedical.com
Sweden: +46 858769468, se.orders@cookmedical.com
Switzerland – French: +41 448009609, fr.orders@cookmedical.com
Switzerland – Italian: +41 448009609, it.orders@cookmedical.com
Switzerland – German: +41 448009609, de.orders@cookmedical.com
United Kingdom: +44 2073654183, uk.orders@cookmedical.com

USA Website: cookmedical.com
EDI: cookmedical.com/edi.do
Americas:
Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335
E-mail: orders@cookmedical.com
Australia:
Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283
E-mail: cau.custserv@cookmedical.com

AI-ESC-IR-OHNS-PI-RH-SUR-A4