Biologic technology that can be COMPLETELY REMODELED¹

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
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.

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


INTENDED USE:
- This Cook® Biodesign® Tissue Graft is intended for implantation to reinforce soft tissue. The graft is supplied sterile in a peel-open package and is intended for one-time use.
- This symbol means the following: CAUTION (Federal (U.S.A.) law restricts this device to sale by or on the order of a physician).
- 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, or reseal 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 the package outside breaks. Discard this graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration data. Single-layer graft should not be used in applications requiring high strength. This graft may not have sufficient strength to support masses encountered in some ventral hernia orlarge, bowelwallrepairs. Ensure that this graft is secured prior to suturing or stapling. Patients undergoing radiation therapy may not experience normal wound healing. Graft performance has not been evaluated with subcutaneous spacing greater than 2 mm. Ensure that all layers of the graft are secured when suturing or stapling.

POSSIBLE COMPLICATIONS: Complications that can occur with the use of any surgical graft materials may include, but are not limited to: Inflammation, Induration, Migration, Allergic reaction, Dehiscence, Extrusion, Seroma formation, Infection, Fever, Abscess, Tissue trauma, Pain, Adhesion, Reurrence of tissue defect, Bleeding, Fibrosis formation, Delayed or failed incorporation. If any of the following conditions occur and cannot be rectified, device removal should be considered: Infection, Acute or chronic inflammation, Abscess formation, Degranulation of surgical graft materials may be associated with transfection, mild localized inflammation. Allergic reaction - Seroma formation. See instructions for use for full product information.

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