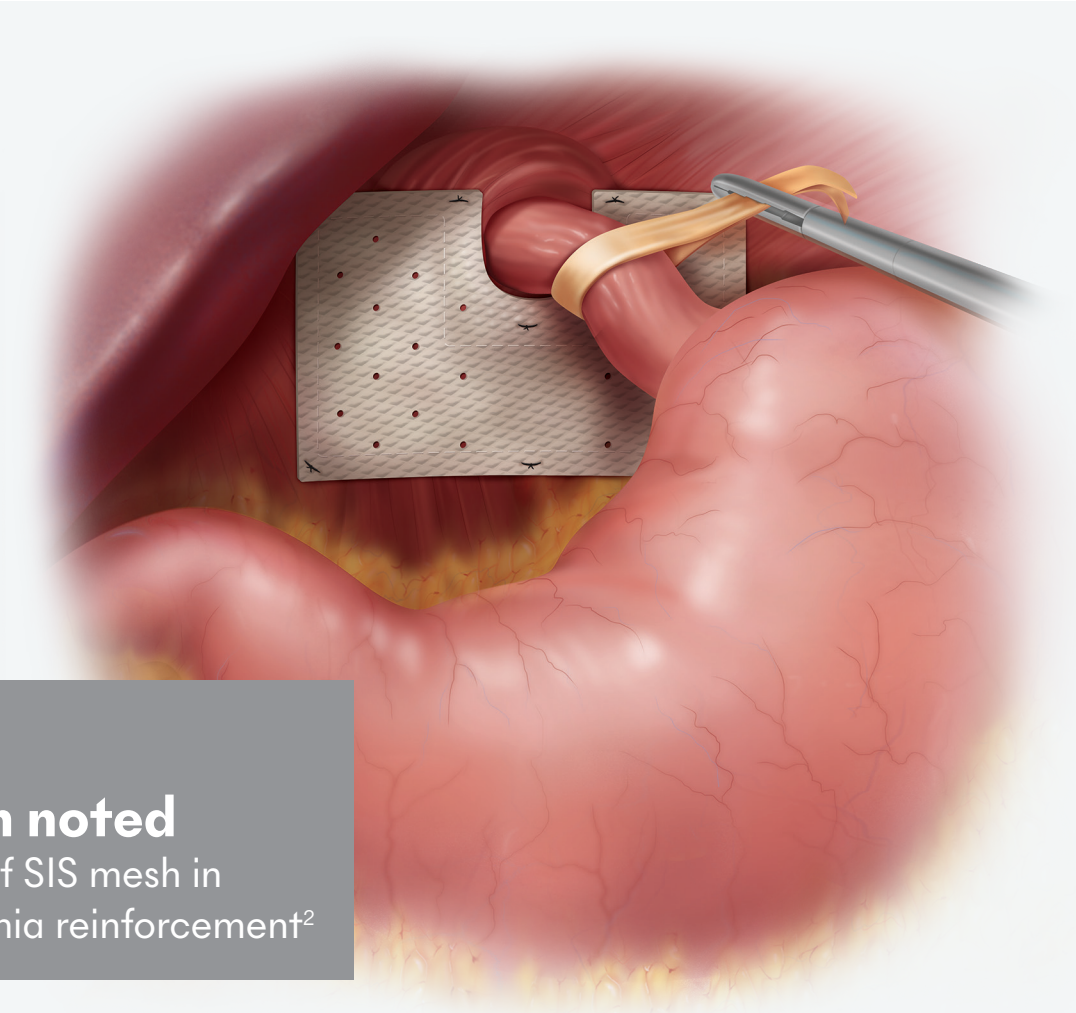


Biodesign® Hiatal Hernia Graft

Fully remodels into vascularized tissue¹



NO
erosion noted
with use of SIS mesh in
hiatal hernia reinforcement²

The Biodesign Hiatal Hernia Graft is derived from small intestinal submucosa (SIS), a natural biologic material that provides support as it is fully remodeled into native tissue.¹

Evergen™

Clinical cases are unique and individual results may vary.

Graft information

Biodesign Hiatal Hernia Graft

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

Order number	Reference part number	Size
G51578	C-PHR-7X10	7 x 10cm
G31455	C-PHR-7X10-U	7 x 10cm

Graft features

- Manufactured in the U.S.
- Biologic xenograft made from porcine SIS
- Non-crosslinked, non-dermis
- Easily hydrated in the operating room
- Suitable for use in open³ or laparoscopic⁴ procedures
- Off-the-shelf graft that does not require special storage
- Does not require AATB tissue tracking
- MRI safe

RISK INFORMATION: BIODESIGN HIATAL HERNIA GRAFT

INTENDED USE

The Biodesign Hiatal Hernia Graft is used for implantation to reinforce soft tissue where weakness exists, including repair of hiatal hernias. This graft is supplied sterile in peel-open packages and is intended for one-time use.

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

The graft is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.

PRECAUTIONS

• The graft is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to graft failure and/or transmission of disease. • **Do not resterilize.** • Ensure that the graft is hydrated prior to cutting or suturing. Insufficient hydration may cause device damage during laparoscopic delivery. • Ensure

that all layers of the graft are secured when suturing. • Ensure that the graft does not touch the esophagus.

NOTE: Clinical literature suggests the use of tacks or staples at the diaphragm may be associated with cardiovascular complications

POTENTIAL COMPLICATIONS

The following complications are possible with the use of surgical graft materials. • Adhesion • Allergic reaction • Fistula formation • Graft detachment/migration • Hematoma • Infection • Inflammation • Recurrence of tissue defect • Seroma formation

The following complications are associated with use of graft materials in hiatal hernia repair. • Dysphagia • Esophageal erosion • Perforation • Stricture formation

ERI_FP0032-03N

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Biodesign grafts are manufactured by Cook Biotech Incorporated.

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