ADD REINFORCEMENT
without using glue or strings.

A surgeon saw a need. We listened. Biodesign Staple Line Reinforcement strips are designed to add strength without increasing the difficulty of the procedure. Coated with fructose self-adhesive, the strips are easy to load into the stapler.

These biologic strips are made from an extracellular matrix that remodels into patient tissue. New blood vessels can grow into the open, three-dimensional structure of the matrix.  

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2. Based on internal Cook benchtop testing; CBI Internal Report #D00205174.
BIODESIGN STAPLE LINE REINFORCEMENT

Used for the reinforcement of the gastric staple line during bariatric surgical procedures. Staple line reinforcement strips are coated with fructose self-adhesive. No strings or glue are needed.

- The strips are designed to offer consistent thickness, even in overlapping strips.
- Small intestinal submucosa (SIS), the biomaterial used in Biodesign Staple Line Reinforcement, becomes remodeled into patient tissue.¹

<table>
<thead>
<tr>
<th>Reinforcement material</th>
<th>Amount of increased tissue thickness after application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodesign Staple Line Reinforcement</td>
<td>0.3 mm</td>
</tr>
<tr>
<td>Bovine pericardium</td>
<td>0.4 – 1.2 mm</td>
</tr>
<tr>
<td>Synthetic polymer A²</td>
<td>&lt;0.4 mm</td>
</tr>
<tr>
<td>Synthetic polymer B²</td>
<td>0.4 mm</td>
</tr>
</tbody>
</table>

¹Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.

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Customer Service

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BIODESIGN® STAPLE LINE REINFORCEMENT

INTENDED USE: The Biodesign® Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The Staple Line Reinforcement may be used for buttressing and reinforcing staple lines during long resections (e.g., wedge resections, bilobectomy, lobectomy, bullaectomy, bronchial resection, segmentectomy, pneumonectomy/pulmonary resection, pneumonectomy) and other invasions and excisions of the lung and bronchus. The Staple Line Reinforcement can be used for the reinforcement of the gastric staple lines during bariatric surgical procedures of gastric bypass, and for reinforcement of staple lines during small bowel, mesenteric, colon and colorectal procedures. The Staple Line Reinforcement may be used with anastomotic staples or with non-anastomotic staples. This symbol means the following: The surgical stapler for which this device is intended for use. This symbol means the following: This symbol means the following: Staple Line Reinforcement. This symbol means the following: Staple Line Reinforcement. This product is intended for use by trained medical professionals. This device is supplied sterile and is intended for one-use use.

CONTRAINDICATIONS: This Staple Line Reinforcement is derived from a porcine source and should not be used in patients with known sensitivity to porcine materials. This Staple Line Reinforcement contains fructose and should not be used in patients with known sensitivity to fructose.

PRECAUTIONS: This device is designed for single use only. Attempts to repurpose, resterilize, and/or reuse may lead to device failure and/or transmission of disease. Do not resterilize. Discard open and unused portions. Staple Line Reinforcement is sterile if the package is dry, unopened, and undamaged. Do not use if package seal is broken. Discard Staple Line Reinforcement if mishandling has caused possible damage or contamination or if Staple Line Reinforcement is past its expiration date. NOTE: Staple Line Reinforcement may get damaged if foam applicator is folded. - Follow the manufacturer’s instructions regarding the use of the stapler, including precautions regarding use with staple reinforcement materials. NOTE: When firing across thick tissue, holding the jaws in place for 15 seconds after closing and prior to firing may result in better compression and staple formation. - Use stapler loads that allow for combined thickness of tissue and the Staple Line Reinforcement*, use only specified staples with appropriate sized Staple Line Reinforcement*. - This device is designed for use with flat surface reloads. - Use of uneven surface reloads could lead to insufficient device advancement. - If an uneven surface reload is used, advancement may be improved by use of the warming tray method of device preparation (see instruction for use option A in the COMPLETE INSTRUCTIONS FOR USE). - Ensure that prior to firing the surgical stapler the entire active portion of staple jaws are covered by the reinforcement device. - Fire the staple within 10 minutes after applying the Staple Line Reinforcement. Otherwise, the device may be difficult to disengage from the staple jaws after firing. - Avoid dropping the tray-device assembly from the edge onto the sterile field. - Avoid using the tip to remove the Staple Line Reinforcement from the tip as this could lead to premature detachment from the foam applicator. - Avoid trying to reassemble the Staple Line Reinforcement to the stapler it comes off. - Avoid excessive manipulation of tissue with a stapler loaded with the Staple Line Reinforcement.

- To prevent loss of adhesive, avoid dipping the Staple Line Reinforcement in water. — Dip the staple jaws instead.
- The average total nominal thickness (dev. cartridge side including adhesive) of the Staple Line Reinforcement is indicated on the sterilization label at 0.08 mm.

POSSIBLE COMPLICATIONS: Infection - Acute or chronic inflammation (Initial application of graft materials may be associated with transient, mild, localized inflammation - Allergic Reactions

See Instructions for use for full product information.

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