

LOADING BIODESIGN[®] STAPLE LINE REINFORCEMENT ON ETHICON[®] ECHELON STAPLER

Step 1



Remove the pouch containing the device from the box. Using aseptic technique, open the pouch and pass the device onto the sterile field. **Note:** A humidity control packet is included in the packaging and should be discarded if encountered.

Step 2



Grasp the printed release liner tabs and slowly peel away the liner from the entire device, making sure not to dislodge the device from the foam applicator. Do not open the tray or remove the device from the tray. **Note:** Avoid touching the adhesive surface after the liner has been removed.

Step 3



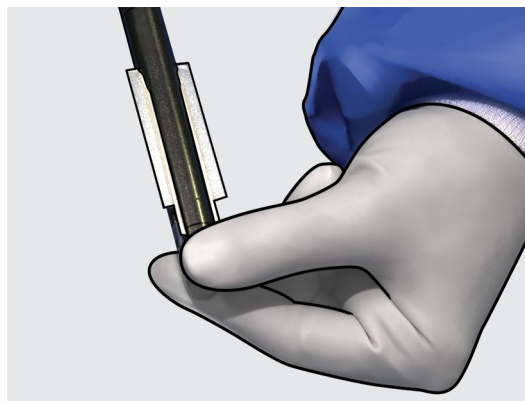
Completely insert the stapler jaws into the tray alignment channel, avoiding contact with the adhesive surface. Notches in the applicator provide a stopping point to indicate how far the applicator should be inserted into the stapler jaws. Close the stapler on the applicator.

Step 4



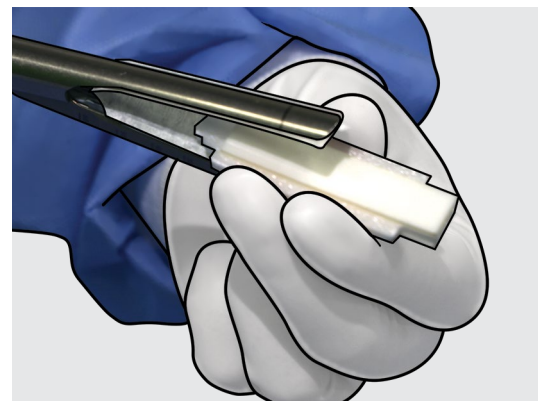
Holding the tray in one hand and securing the stapler closed with the other, firmly remove the tray to detach the foam applicator.

Step 5



Use your fingers to provide compression at the end of the stapler jaws.

Step 6



Open the stapler jaws and remove the remaining portion of the foam applicator. Inspect for alignment and ensure that the stapler jaws are completely covered with the device. Use caution to avoid displacing the staple line reinforcement from the stapler jaws. **Note:** If material becomes displaced from the stapler, **do not** attempt to re-adhere it. Use a new device. Follow the manufacturer's instructions for using the stapler, and deploy the stapler within 20 minutes after applying the staple line reinforcement material.

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 lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The Staple Line Reinforcement can be used for the reinforcement of the gastric staple line during bariatric surgical procedures, and for reinforcement of staple lines during small bowel, mesentery, colon and colorectal procedures. The Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers.

Caution: This symbol means the following: Quantity of devices per box. **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.** **STAPLE LINE REINFORCEMENT** This symbol means the following: Staple Line Reinforcement. This product is intended for use by medical professionals trained in the use of surgical staplers. This device is supplied sterile and is intended for one-time use.

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

known sensitivity to sorbitol or maltitol.

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 open and unused portions. • This device is sterile if the package is dry, unopened, and undamaged. Do not use if the package seal is broken. • Discard the Staple Line Reinforcement if mishandling has caused possible damage or contamination or if it is past its expiration date.

• Allow for the combined thickness of patient tissue and the Staple Line Reinforcement when selecting a stapler cartridge.*** • Use appropriate size of Staple Line Reinforcement for 45 mm or 60 mm staplers. • Avoid dropping the tray-device assembly from the pouch onto the sterile field. • To prevent loss of adhesive, **do not** dip the Staple Line Reinforcement in sterile water or saline. • Avoid excessive manipulation of tissue with a stapler loaded with the Staple Line Reinforcement. *The average total nominal thickness (anvil+cartridge side including adhesive) of the Staple Line Reinforcement is indicated on the label as Dimension "C". **The average nominal thickness of the adhesive is 0.09 mm.

POTENTIAL COMPLICATIONS: Allergic reaction • Infection • Inflammation

See Instructions for Use for full product information.

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AI, ESC, IR, OHNS, PI, RH, SUR-8.5X11