

INSTRUCTIONS FOR USE FOR SEAMGUARD® STAPLE LINE REINFORCEMENT MATERIAL

INTENDED USE

For use as a prosthesis for surgical repair of soft tissue deficiencies using linear surgical staplers.

INDICATIONS

The SEAMGUARD® Staple Line Reinforcement Material can be used for reinforcement of staple lines during lung resection and for reinforcement of gastric staple lines during bariatric surgical procedures of gastric bypass and gastric banding.

CONTRAINDICATIONS

Not for the reconstruction of cardiovascular defects such as cardiac, great vessel, and peripheral vascular arteries or veins. Not for reinforcement of bronchial closure staple lines.

STERILITY

SEAMGUARD® Staple Line Reinforcement Material is supplied STERILE. Provided that the integrity of the package is not compromised in any way, the package will serve as an effective barrier for a minimum of five years from the date of sterilization. There is no expiration date for product function or characteristics. The device is for **single-use** only and may not be resterilized.

RECOMMENDED TECHNIQUES

SEAMGUARD® sleeves are sized to fit snugly onto the jaws of the stapling device. The ePTFE threads are attached to facilitate removal of the excess SEAMGUARD® material after the stapler has been fired. Select the SEAMGUARD® sleeve with the larger diameter and slide it over the cartridge jaw of the stapling device such that the ePTFE thread attachment point is on the outside surface of the distal end of the cartridge (Figure 1). Select the SEAMGUARD® sleeve with the smaller diameter and slide it over the anvil jaw of the stapling device such that the ePTFE thread attachment point is on the outside surface of the distal end of the anvil (Figure 1).



Figure 1

Close and lock the stapler jaws. Keep the stapler jaws locked while passing the stapler through the thoracoscopic port or chest incision. Excess force due to friction applied to the SEAMGUARD® sleeve during introduction into the abdominal or thoracic cavity may result in tearing of the excess material from the stapler jaws. Trocars sized to fit the stapler should be employed (see stapler Instructions for Use). If a trocar is not used, an incision of sufficient size to prevent excess force on the stapler should be used.

Unlock the stapler allowing it to return to its fully opened position. Place the stapler over tissue to be resected. Make sure that the ePTFE thread material is not inside the jaws of the stapler. Close and lock the stapler jaws. Fire the stapler. **DO NOT UNLOCK THE STAPLER UNTIL EXCESS SEAMGUARD® MATERIAL IS REMOVED.**

Remove excess SEAMGUARD® material by grasping the end of one of the two ePTFE threads on the outside of the trocar port (Figure 2) and pulling it along the axis of the stapler. It will tear along predefined tear lines located along the edge of the SEAMGUARD® material next to the firing surface of the stapler jaws (Figure 3). Continue pulling until the ePTFE thread and excess SEAMGUARD® material is removed from the body. Grasp the second ePTFE thread and pull the excess SEAMGUARD® material from the other arm of the stapler. Discard excess SEAMGUARD® material and attached ePTFE thread. Carefully remove any excised material (Figure 4).

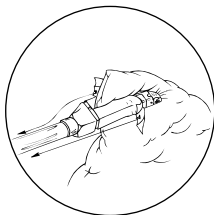


Figure 2

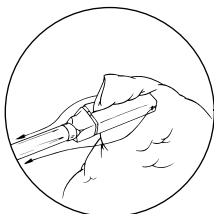


Figure 3



Figure 4

WARNINGS

Use of this product in applications other than those indicated has the potential for serious complications. Potential complications include: inadequate reinforcement strength, staple pullout, infection and abrasion.

The use of SEAMGUARD® material will increase the thickness of the area to be stapled by approximately 0.7 mm. Selection of staple size should reflect the thickness of SEAMGUARD® material such that the total thickness of material to be stapled falls within the recommended range for the stapler (see stapler Instructions for Use). Use of staples with insufficient length for the procedure performed may lead to disruption of the staple line due to inadequate staple closure.

PRECAUTIONS


To avoid damage or contamination, always use clean gloves and atraumatic instruments when handling the SEAMGUARD® sleeves. Always protect the SEAMGUARD® sleeves from damage by heavy or sharp objects.

Ensure that the properly sized SEAMGUARD® sleeves are placed onto the forks of the stapling device. Attempting to place the smaller diameter SEAMGUARD® sleeve onto the larger cartridge fork may tear the SEAMGUARD® sleeve, resulting in an inadequate repair. Placing the larger diameter SEAMGUARD® sleeve onto the smaller anvil fork may cause SEAMGUARD® sleeve rotation and/or slippage during use, resulting in an inadequate repair.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to: infection, inflammation, adhesions, hematoma.

DEFINITIONS

 Expiration Date

 See Instructions for Use

 Single Use Only

REF Item Number

LOT Manuf. Lot

EU REP European Authorized Representative

STERILE

Contents sterile unless package has been opened or damaged.

STERILE 

Contents sterile unless enclosed package has been opened or damaged. Sterilized by steam.

CONFIGURED FOR: Configured For

LENGTH Length



AD0612-ML1



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MADE IN USA.

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