

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 forks of the stapling device. Select the SEAMGUARD® sleeve with the larger diameter and slide it over the cartridge fork of the stapling device. Select the SEAMGUARD® sleeve with the smaller diameter and slide it over the anvil fork of the stapling device. When using the MultiFire GIA® stapler from US Surgical Corporation, the SEAMGUARD® sleeve may tend to bunch when sliding over the plastic alignment tab (Figure 1).

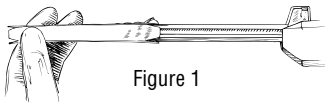


Figure 1

To facilitate placement of the sleeve on the anvil fork, grasp the sleeve on both sides (Figure 2) and pull the sleeve over the alignment tab as shown in Figure 3.

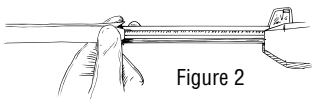


Figure 2

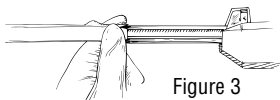


Figure 3

Two SEAMGUARD® sleeves will be used per each load and fire. Position the forks of the stapling device on either side of the tissue to be stapled. Close and lock the stapling device. Fire stapling device. DO NOT UNLOCK THE STAPLING DEVICE UNTIL EXCESS SEAMGUARD® STAPLE LINE REINFORCEMENT MATERIAL IS REMOVED.

AFTER FIRING THE STAPLING DEVICE, GRASP THE SIDE WALL OF THE SEAMGUARD® SLEEVES AT EITHER END OF THE STAPLING DEVICE (FIGURE 4) AND GENTLY PULL UNTIL THE MATERIAL BEGINS TO TEAR ALONG THE PREDEFINED TEAR LINE (FIGURE 5).

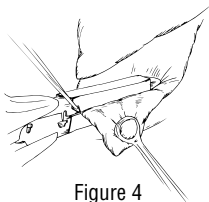


Figure 4

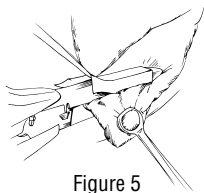


Figure 5

Remove the SEAMGUARD® sleeves from both sides and top of both the anvil and cartridge forks of the stapling device. Unlock the stapling device. Carefully remove any excised material (Figure 6).

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.

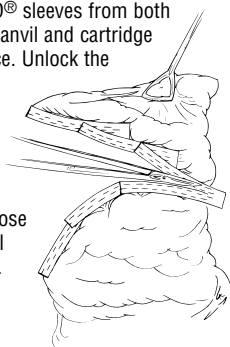


Figure 6

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



AD0613-ML1



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