

Important Customer Notification: ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads in Sleeve Gastrectomy Procedures

Insert Date

Dear Chief of Surgery, Surgeon, and/or OR Manager,

The purpose of this communication is to reinforce the importance of following proper reload selection during surgical procedures, particularly laparoscopic sleeve gastrectomy, that involve the cutting and sealing of thicker tissue. Ethicon Endo-Surgery, LLC (“Ethicon”) recognizes the criticality of surgeon expertise in pairing tissue type with the appropriate reload to deliver optimal surgical outcomes. As part of our continued commitment to surgeons and patient safety, we want to share some important information about reload selection for Ethicon’s ENDOPATH™ Endoscopic Linear Cutter Reloads as it relates to laparoscopic sleeve gastrectomy procedures.

Laparoscopic sleeve gastrectomy continues to be a fast-growing bariatric procedure and, as cited by the recently published data by Rawlins (outlined below)ⁱ, may require cutting and sealing tissue that is thicker than some surgeons anticipate.

Recently published data (Rawlins) demonstrates that in some patients, particularly male and at higher BMIs, have gastric tissue whose thicknesses in the antrum may be greater than surgeon experience would anticipate. Rawlins concludes that “Surgeons should consider using a thicker staple load, such as black, when these factors are present. Also, significant changes in tissue thickness at the fourth and fifth staple fires suggest stepwise alteration in staple cartridge color selection.”ⁱ

Ethicon’s ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads, from Gray to Black, have closed staple heights per the table below:

Reload Code	Reload Color	Closed Staple Height
ECR60M	Gray	0.75mm
ECR60W	White	1.0mm
ECR60B	Blue	1.5mm
ECR60D	Gold	1.8mm
ECR60G	Green	2.0mm
ECR60T	Black	2.3mm

We would like to reinforce the following from the Instructions for Use (IFU) of Ethicon’s ECHELON ENDOPATH™ and ECHELON FLEX™ Family of Staplers:

Tissue thickness should be carefully evaluated before firing any stapler. If tissue cannot comfortably compress to the closed staple height listed in the table, or easily compresses to less than the closed staple height listed in the table, the tissue is contraindicated as it may be too thick or too thin for the selected staple size. Selection of the appropriate staple cartridge should be based upon the combined thicknesses of both the tissue and the staple-line reinforcement material.

Because any given stapler reload performance may be stressed at tissue thicknesses that cannot comfortably compress to a reload's closed staple height, moving towards larger staple reloads may improve performance in these thicker gastric tissues. Echelon Black reload was specifically designed to meet the clinical needs for a thicker tissue application.

Ethicon wanted to provide this information to you as part of our commitment to the safety of your patients. Please share this information with any of your staff involved in laparoscopic sleeve gastrectomy procedures. Like you, Ethicon remains dedicated to advancing the standard of care in bariatric surgical procedures. Thank you for your cooperation.

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Rawlins L., Rawlins M., D. Teel II, et al. Human tissue thickness measurements from excised sleeve gastrectomy specimens. Surg Endosc (2014) 28:811-814