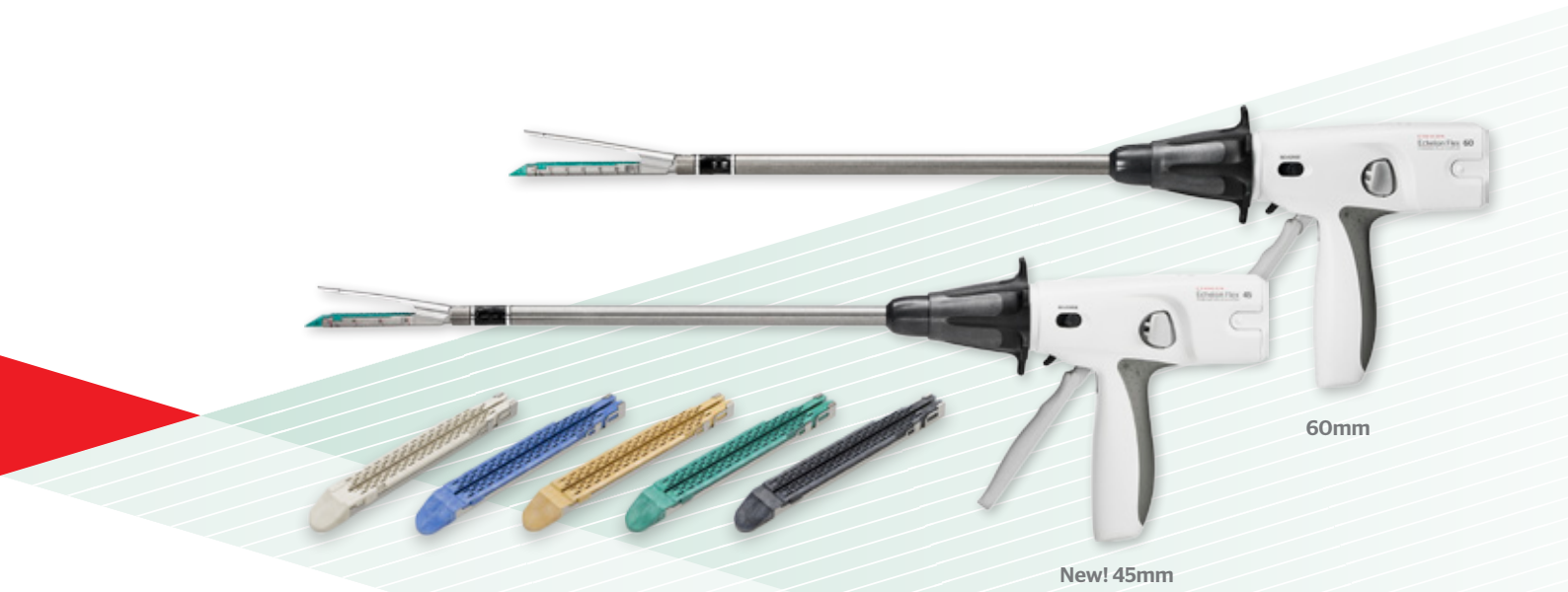
Echelon Flex™

Mastering movement.
To transect as you intend.



ECHELON FLEX™ GST System

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

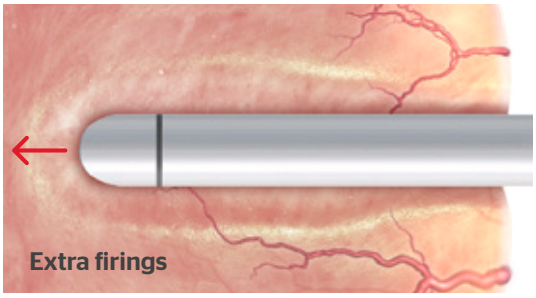
Shaping
the future
of surgery

Precise performance. Even in challenging tissue.[2,3,4,5]

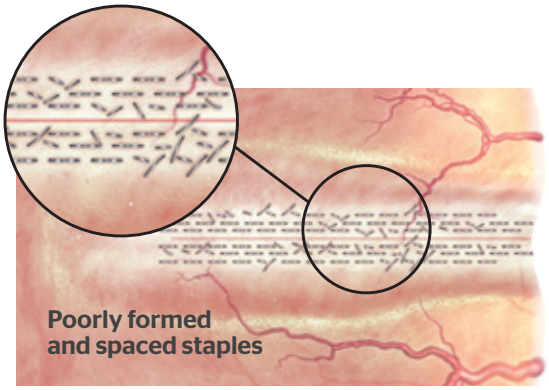
Increasingly complex patient variables leave very little margin for error when stapling laparoscopically. Unfortunately, challenging tissue—diseased, thick, thin, fragile and varying—can lead to tissue movement between the jaws of the endocutter affecting the results of an intended transection.

This tissue movement or slippage during firing can have consequences which may call into question the integrity of the staple line. Tissue movement can result in exposed tissue layers, poorly formed and spaced staples, and extra firings.

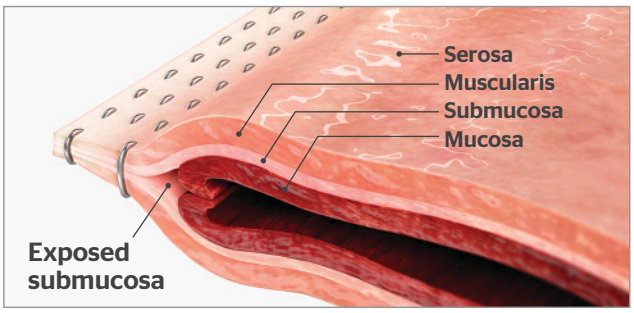
Tissue movement can result in:



Extra firings may be required to complete the intended tissue transection as tissue is pushed or "milked" out of the end of the stapler.



Tissue movement or slippage during firing can result in poorly formed and spaced staples.



Greater tissue movement when stapling creates exposed submucosal layers more often.

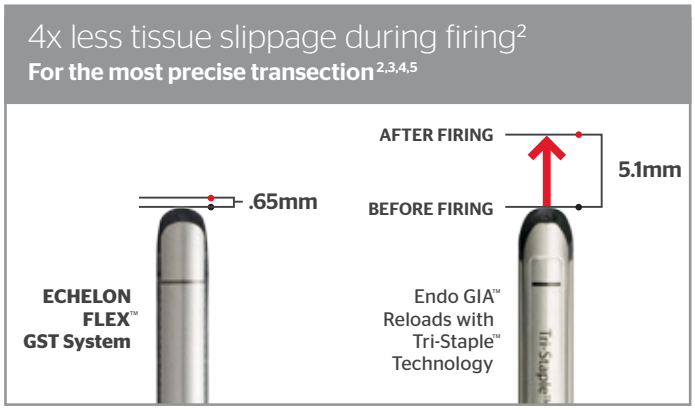
Surgical stapling intentions

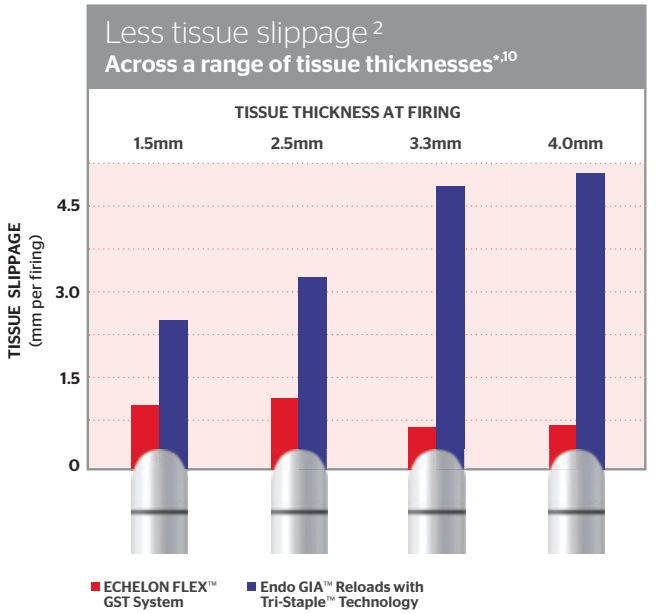
- **Colorectal:** Staple line integrity with minimal firings across varying tissue thickness in colon and rectum
- **Thoracic:** Staple line integrity on highly variable lung parenchyma thickness and diseased tissue, which ranges from fragile and friable to dense and fibrotic
- **Bariatric:** Staple line integrity on thick gastric tissue while minimizing variables that may lead to leaks

Control and capture tissue

Control tissue slippage

The ECHELON FLEX™ GST System is uniquely designed for better grip[7] to provide the least tissue slippage of any leading endocutter[8] for the most precise transection. On each reload, the proprietary Gripping Surface Technology provides a superior tissue grip[7] without additional trauma during firing.[6] This means you can transect more of the tissue[9] you intended—even in very thick tissue—with each firing.

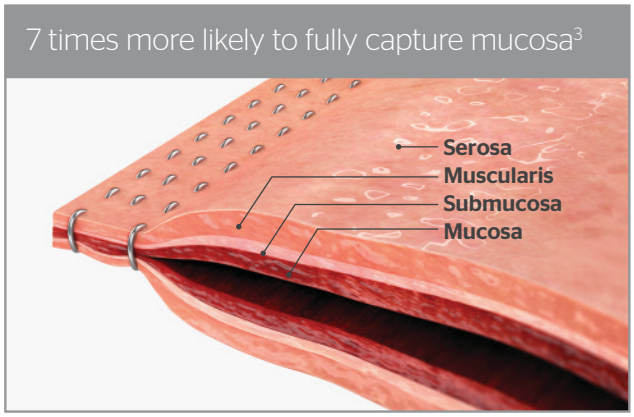




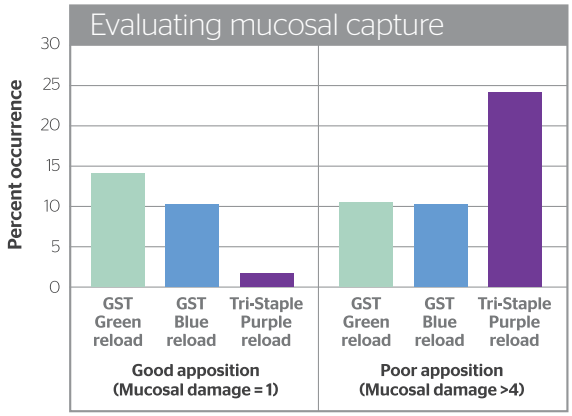
* Uncompressed tissue measured at 8g/mm² prior to firing. Tissue comfortably compressed to closed staple height during firing per IFU.

Better mucosal capture improves leak resistance

By providing better mucosal capture, staple line integrity is improved, leak resistance is increased and optimal conditions for tissue healing are established. The ECHELON FLEX™ GST System is 7 times more likely to fully capture mucosa in the staple line.[3] By controlling tissue movement, the ECHELON FLEX™ GST System more consistently captures both layers of mucosa in the staple line.



Both layers of the mucosa captured in the staple line.
Both sides of mucosa captured.

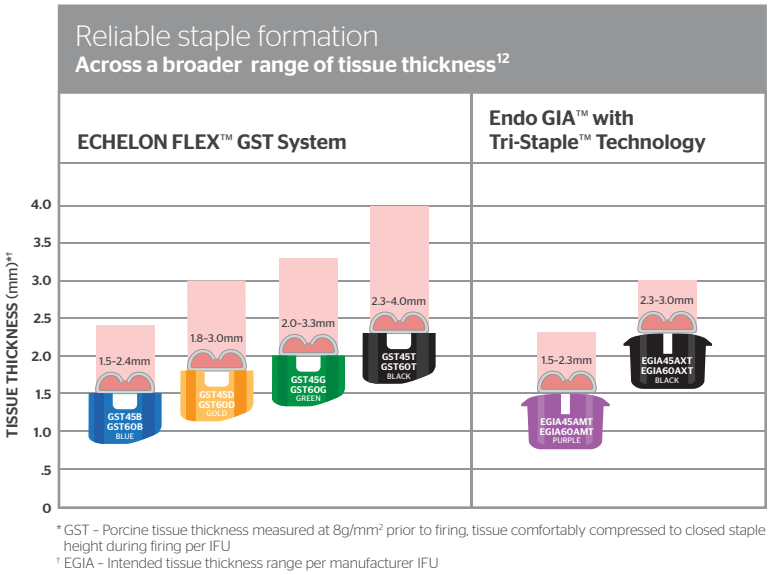


Preclinical animal study comparing compression damage, mucosal injury and mucosal "capture" on varying thicknesses of porcine gastrointestinal tissues utilizing a 5-point Likert scale.[11]

Unsurpassed staple performance[12]

Exceptional staple formation

Experience exceptional staple line integrity across a broader range of tissue thicknesses.[12] This surgeon-controlled stapling system accomplishes this with a proprietary combination of multi-stage compression, powered firing and Gripping Surface Technology, including re-engineered stronger internal reload components and staple geometry designed to mitigate the amount and effect of tissue slippage during firing.



* GST – Porcine tissue thickness measured at 8g/mm² prior to firing, tissue comfortably compressed to closed staple height during firing per IFU

† EGIA – Intended tissue thickness range per manufacturer IFU

Transect as you intend

The ECHELON FLEX™ GST System[1] controls tissue movement to enable you to transect as you intend.[2]

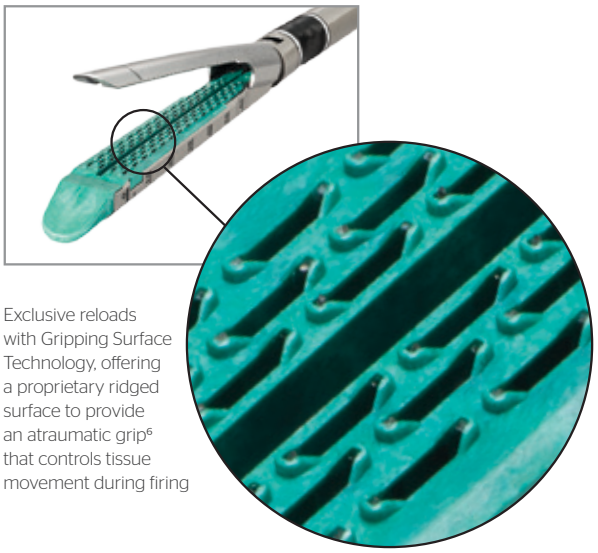
Control and capture tissue

- **4x less tissue slippage** during firing[2] compared to Endo GIA™ Reloads with Tri-Staple™ Technology, for a precise transection.
- **7x more likely to fully capture mucosa** in the staple line[3] compared to Endo GIA™ Reloads with Tri-Staple™ Technology

Transect as intended

- **Exceptional staple line integrity across a broader range** of tissue thicknesses[12]
- **In thick tissue testing, zero percent occurrence of compromised staple line integrity** compared to 43% with EndoWrist® Stapler due to 3x fewer malformed staples[5]

The ECHELON FLEX™ GST System stabilizes tissue through the entire surgical transection with multi-stage compression, Gripping Surface Technology and powered firing.



Exclusive reloads with Gripping Surface Technology, offering a proprietary ridged surface to provide an atraumatic grip[6] that controls tissue movement during firing

ECHELON FLEX™ GST System

New! 45mm

60mm

ECHELON FLEX™ GST System

- ECHELON FLEX™ Powered Plus Stapler and ECHELON ENDOPATH™ Reloads with GST; now in both 45mm and 60mm
- The reloads can be used across the entire platform of ECHELON ENDOPATH™ Staplers

CODE	DESCRIPTION	JAW LENGTH	QUANTITY PER SALES UNIT
PCEE45A	Compact Articulating Endoscopic Linear Cutter,* 280mm	45mm	3
PSEE45A PSEE60A	Standard Articulating Endoscopic Linear Cutter,* 340mm	45mm 60mm	3
PLEE45A PLEE60A	Long Articulating Endoscopic Linear Cutter,* 440mm	45mm 60mm	3

*Instrument does not contain a reload.

CODE	COLOR	DESCRIPTION	OPEN STAPLE HEIGHT	CLOSED STAPLE HEIGHT	QUANTITY PER SALES UNIT
GST45W GST60W	White	White reload intended for use in vascular/thin tissue	2.6mm	1.0mm	12
GST45B GST60B	Blue	Blue reload intended for use in regular tissue	3.6mm	1.5mm	12
GST45D GST60D	Gold	Gold reload intended for use in regular/thick tissue	3.8mm	1.8mm	12
GST45G GST60G	Green	Green reload intended for use in thick tissue	4.1mm	2.0mm	12
GST45T GST60T	Black	Black reload intended for use in very thick tissue	4.2mm	2.3mm	12

Expanded offering! Black 45mm reload

References: 1. System components include ECHELON FLEX™ Powered Plus Stapler and ECHELON™ ENDOPATH Reloads with Gripping Surface Technology. **2.** Benchtop testing in porcine stomach tissue. Mean tissue movement from after clamping on tissue to after firing ECHELON FLEX™ Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and EndoGIA™ Reload with Tri-Staple™ Technology at 3.3 and 4.0mm tissue thicknesses (3.3mm: GST60T 0.642mm vs EGIA60AMT 4.806mm p<0.001; 4.0mm: GST60T 0.654mm vs EGIA60AXT 5.116mm p<0.001). PRC067394 Tissue flow and functional performance of ENDOPATH ECHELON Reloads (GST) and Covidien's reloads with Tri-Staple™ Technology, July 2014, Ethicon Data on File (018980-140728) **3.** ECHELON FLEX™ GST System Blue and Green Reloads compared to Endo GIA™ with Tri-Staple™ Technology Purple Reloads evaluated via gross observations of firings in 1.5mm to 3.0mm thick animate porcine ileum. Mucosal capture was rated via a 5-point Likert scale with the highest rating representing fully captured mucosa. PSB004500 - Compare compression damage and mucosal injury created during the firing of endoscopic stapling devices, August 2016, Ethicon Data on File (057890-160810) **4.** ECHELON FLEX™ GST System designed and tested to accommodate a tissue thickness range of 1.0mm to 4.0mm (measured at 8g/mm2) vs the Medtronic Tri-Staple™ portfolio intended for a thickness range of 0.75mm to 3.0mm (per IFU & materials downloaded from Medtronic website on Nov 16, 2016), E877 Outstanding performance across a broader range of tissues and applications, November 2016, Ethicon Data on File (063471-161117) **5.** Benchtop testing of GST (PCEE60A & GST60G) vs. EndoWrist™ (410298 & 41445G) on excised porcine stomach that measured overall non-B staple form quality at 3.3mm tissue thickness. Compromised staple line integrity defined as groups of malformed staples that could potentially allow fluid to pass to the cut line. Lower occurrence of compromised staple line integrity (p=0.006), fewer malformed staples (p<0.001). PRC076256B ECHELON FLEX vs Endo Wrist Competitive Testing Completion Report, November 2016, Ethicon Data on File (063896-161130, 063894-161130) **6.** Based on acute and long term evaluations in animate porcine stomach, bowel, lung and vasculature. Visual comparisons of 10-20 second clamp and release and full firing staple lines immediately following, 1hr after clamping, 14 days post op and at necropsy, as well as histological evaluation at 14 days post op, revealed no additional clinically relevant trauma to the tissues. E775 ECHELON ENDOPATH™ Reloads with Gripping Surface Technology Pocket Extensions – Clinical relevance of tissue trauma. November 2015. Ethicon Data on File (018992-161026) **7.** Benchtop testing in porcine stomach tissue. Mean peak load required to pull tissue from the clamped jaws of ECHELON FLEX™ Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and Endo GIA™ Reload with Tri-Staple™ Technology (GST60B 6.496lbf & GST60T 7.789lbf vs EGIA60AMT 1.325lbf & EGIA60AXT 1.920lbf, all p<0.001). PRC066832 Tissue grasping force of ENDOPATH ECHELON™ Reloads (GST) and Covidien's reloads with Tri-Staple™ Technology. June 2014. Ethicon Data on File (018990-161118). **8.** Benchtop testing in porcine stomach tissue. Mean tissue movement from after clamping on tissue to after firing ECHELON FLEX™ Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and Endo GIA™ Reload with Tri-Staple™ Technology at 1.5, 2.5, 3.3 and 4.0mm tissue thicknesses (1.5mm: GST60B 1.067mm vs EGIA60AMT 2.452mm p<0.001; 2.5mm: GST60G 1.148mm vs EGIA60AMT 3.261mm p<0.001; 3.3mm: GST60T 0.642mm vs EGIA60AMT 4.806mm p<0.001; 4.0mm: GST60T 0.654mm vs EGIA60AXT 5.116mm p<0.001). PRC067394 Tissue flow and functional performance of ENDOPATH ECHELON Reloads (GST) and Covidien's reloads with Tri-Staple Technology, July 2014, Ethicon Data on File (018980-140728) **9.** Benchtop testing in porcine stomach tissue. Mean tissue movement from before clamping on tissue to release of tissue after firing ECHELON FLEX™ Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and Endo GIA™ Reload with Tri-Staple™ Technology at 1.5, 2.5, 3.3 and 4.0mm tissue thicknesses (1.5mm: GST60B 2.835mm vs EGIA60AMT 2.369mm NS; 2.5mm: GST60G 2.864mm vs EGIA60AMT 3.273mm p<0.001; 3.3mm: GST60T 0.897mm vs EGIA60AMT 6.814mm p<0.001; 4.0mm: GST60T 1.415mm vs EGIA60AXT 4.616mm p<0.001). PRC067394 Tissue flow and functional performance of ENDOPATH ECHELON Reloads (GST) and Covidien's reloads with Tri-Staple™ Technology. July 2014. Ethicon Data on File (018986-140728) **10.** Benchtop testing in porcine stomach tissue. Mean tissue movement from after clamping on tissue to after firing ECHELON FLEX™ Powered Plus Stapler (PSEE60A) and ECHELON Reload with GST vs ENDO GIA™ ULTRA Handle (EGIAUSTND) and Endo GIA™ Reload with Tri-Staple™ Technology at 1.5, 2.5, 3.3 and 4.0mm tissue thicknesses (1.5mm: GST60B 1.067mm vs EGIA60AMT 2.452mm p<0.001; 2.5mm: GST60G 1.148mm vs EGIA60AMT 3.261mm p<0.001; 3.3mm: GST60T 0.642mm vs EGIA60AMT 4.806mm p<0.001; 4.0mm: GST60T 0.654mm vs EGIA60AXT 5.116mm p<0.001). PRC067394 Tissue flow and functional performance of ENDOPATH ECHELON Reloads (GST) and Covidien's reloads with Tri-Staple™ Technology, July 2014, Ethicon Data on File (018980-140728) **11.** Endocutters were fired on porcine ileum over three ranges of compressed tissue thicknesses [tissue thickness ranges (8gm/mm2): (1) 1.50-1.99mm, (2) 2.00-2.49mm, (3) 2.50-3.00mm] PSB004500 Compare compression damage and mucosal injury created during the firing of endoscopic stapling devices, June 2016. Ethicon Data on File **12.** Porcine tissue thickness measured at 8g/mm2 prior to firing. Tissue comfortably compressed to closed staple height per IFU. PRC066855 Design Verification Test. August 2014. PRC076031 Tissue Performance Design Verification Test of 45mm Gripping Surface Technology (GST) Reloads with Echelon Flex 45mm Powered Plus Staplers. September 2016. Ethicon Data on File (020293-161103)

Please always refer to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

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