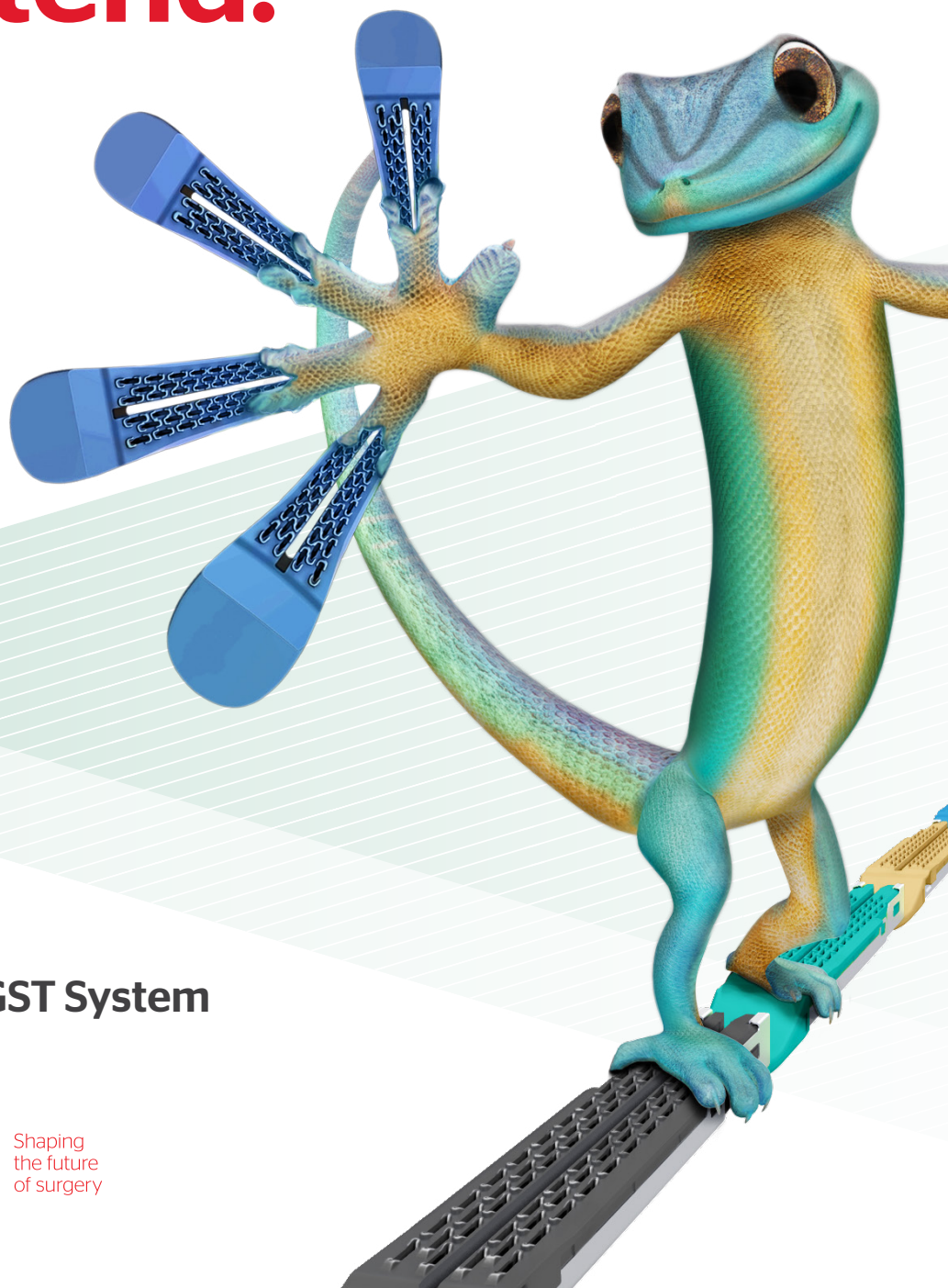


Echelon Flex™

Mastering movement.
**To transect as
you intend.**



ECHELON FLEX™ GST System

ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

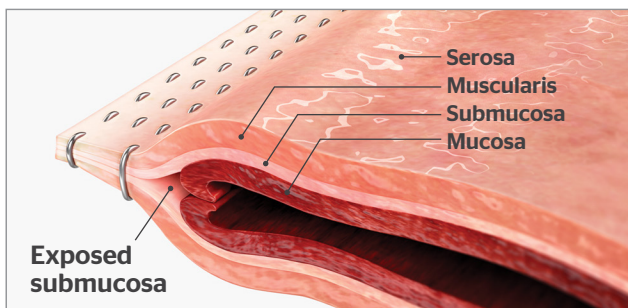
Shaping
the future
of surgery

Precise performance. Even in challenging tissue.

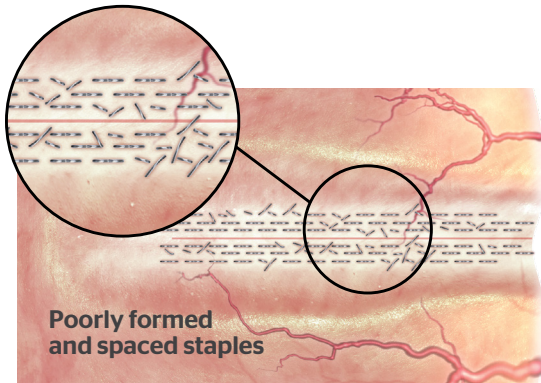
Increasingly complex patient variables leave very little margin for error when stapling laparoscopically or robotically. Unfortunately, challenging tissue—thick, thin, fragile and varying—can lead to tissue movement between the jaws of the endocutter affecting the results of an intended transection.

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.

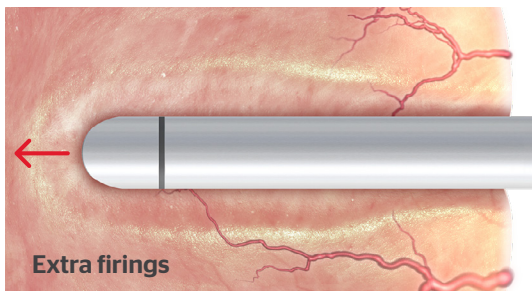
Tissue movement can result in:



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



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



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

Surgical stapling intentions

- **Bariatric:** Staple line integrity on thick gastric tissue while minimizing variables that may lead to leaks

- **Thoracic:** Staple line integrity on highly variable lung parenchyma thickness, which ranges from fragile and friable to dense and fibrotic

- **Colorectal:** Staple line integrity with minimal firings across varying tissue thickness in colon and rectum

Transect as you intend

The ECHELON FLEX™ GST System¹ controls tissue movement to enable you to transect as you intend even on the most challenging tissue.

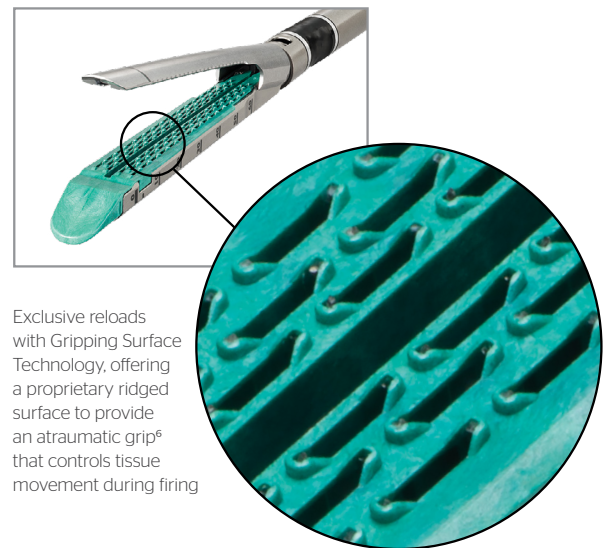
Control and capture tissue

- **4x less tissue slippage** during firing² for the most precise transection compared to Endo GIA™ Reloads with Tri-Staple™ Technology
- **7x more likely to fully capture mucosa** in the staple line³ compared to Endo GIA™ Reloads with Tri-Staple™ Technology

Transect as intended

- **Exceptional staple line integrity across the broadest range** of tissue thicknesses⁴
- In thick tissue testing, **no occurrences of compromised staple line integrity** compared to 43% with EndoWrist® Stapler 45 due to 3x fewer malformed staples⁵

Built on a market proven platform, 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 grip⁶ that controls tissue movement during firing

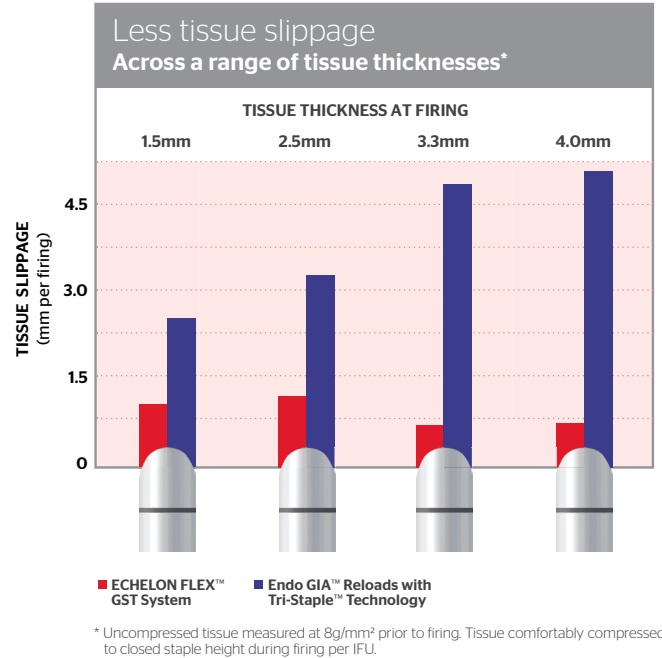
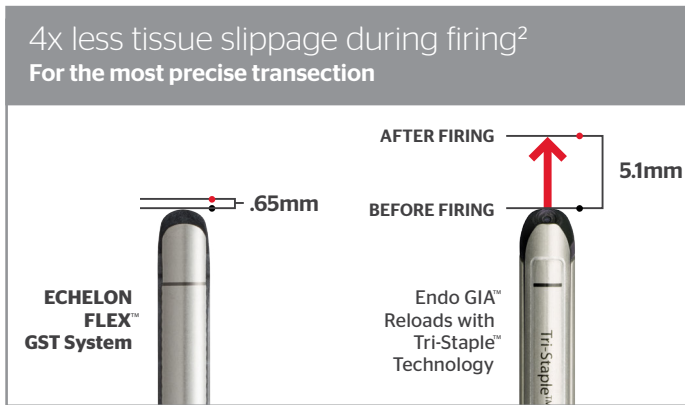
ECHELON FLEX™ GST System



Control and capture tissue

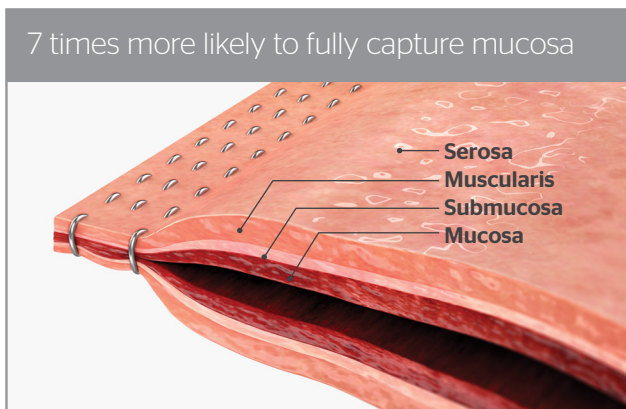
Control tissue slippage

The ECHELON FLEX™ GST System is uniquely designed for better grip⁷ to provide the least tissue slippage of any leading endocutter⁸ for the most precise transection. On each reload, the proprietary Gripping Surface Technology provides a superior tissue grip⁷ without additional trauma during firing.⁶ This means you can transect more of the tissue⁹ you intended—especially in very thick tissue—with each firing.

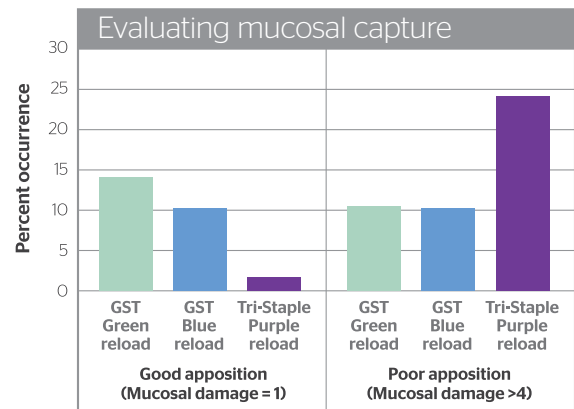


Better mucosal capture improves leak resistance

The ECHELON FLEX™ GST System is 7 times more likely to fully capture mucosa in the staple line.³ Better mucosal capture improves staple line integrity and leak resistance and provides optimal conditions for tissue healing.¹⁰ 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

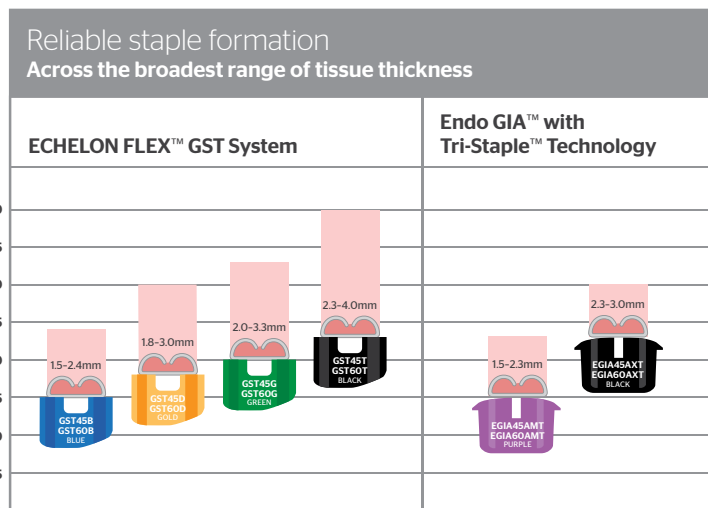
Unsurpassed staple performance

Exceptional staple formation

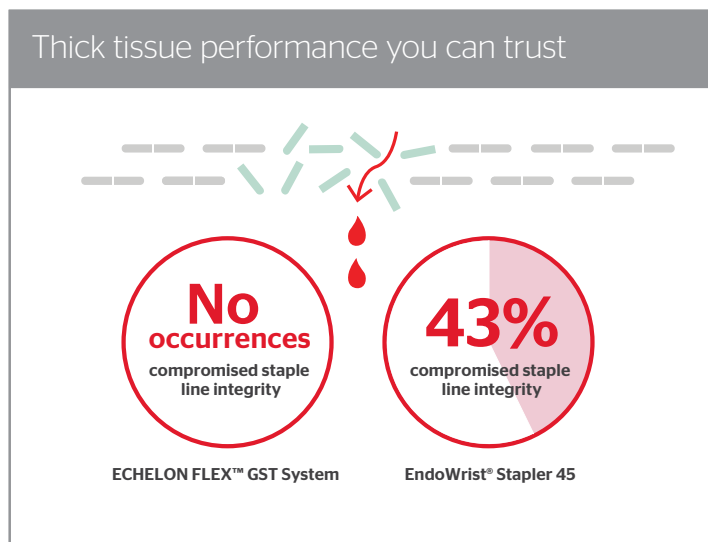
Experience closed staple height formation reliability across the broadest range of tissue thicknesses in each reload. This surgeon-controlled stapling system accomplishes this with a proprietary combination of multi-stage compression, powered firing and Gripping Surface Technology, including stronger internal reload components and redesigned staple geometry to mitigate the amount and effect of tissue slippage during firing.

Superior thick tissue performance for robotic procedures

The ECHELON FLEX™ GST System delivers superior staple line integrity in robotic procedures. In thick tissue testing, EndoWrist® Stapler 45 required multiple clamp attempts,¹² produced 3x more malformed staples and had a significantly higher occurrence of compromised staple line integrity.⁵



* 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



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 PCEE60A	Compact Articulating Endoscopic Linear Cutter,* 280mm	45mm 60mm	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



How to order

All purchase orders are made to Johnson & Johnson Health Care Systems, Inc. (JJHCS).

If you want to order direct, you may order electronically (online) at:

- <https://us.jjcustomerconnect.com> or 1-866-565-4283
- Electronic Data Interchange (EDI)—EDI Helpline: 1-800-262-2888

Or, to place a non-electric (manual) order, contact Johnson & Johnson Health Care Systems Inc. at 1-800-255-2500 between 8:30am - 6:30pm (Eastern Standard Time) or fax us at 1-732-562-2212.

Customer support

For product use assistance, clinical guidelines, service and repair, emergency assistance, copy of a 510(k) clearance letter, or complaints, please contact our Customer Support Center by calling 877-ETHICON (384-4266). Our support center is staffed 24 hours a day, 7 days a week by qualified nurses to answer your product-related questions.

A better way to staple.

Visit www.ethicon.com/gst for more information about the ECHELON FLEX™ GST System.

For complete product details, see Instructions for Use in the product insert.

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 Endo GIA™ 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). **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. **4** The ECHELON FLEX™ GST System was designed and tested to meet rigorous design requirements for staple line integrity. The GST System accommodates a tissue thickness range of 1.0mm to 4.0mm (measured at 8g/mm²; tissue comfortably compressed to closed staple height during firing per IFU) while the Medtronic Tri-Staple™ portfolio is intended for a tissue thickness range of 0.75mm to 3.0mm (per IFU & materials downloaded from Medtronic website on Nov 16, 2016). **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). **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. **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). **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). **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). **10** 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. Average apposition ratings 2.81 (GST60B) and 2.56 (GST60G) vs 3.23 (EGIA60AMT), p=0.001. **11** Endocutters were fired on porcine ileum over three ranges of compressed tissue thicknesses [tissue thickness ranges (8gm/mm²): (1) 150-199mm, (2) 200-249mm, (3) 250-300mm]. **12** Benchtop testing on excised porcine stomach of EndoWrist™ (410298, Green41445G) that measured the number of "inadequate clamp" messages encountered for each firing by the da Vinci Si system at 3.3mm tissue thickness (n=14/15 had ≥ 3 attempts).