



Advanced staple line security, even in challenging conditions^{1*}

There's a lot riding on your staple line. **The ECHELON™ + Stapler with GST Reloads** advances staple line security to deliver fewer leakage pathways at the staple line, even in challenging conditions.^{1*}



Comparative claims compare Ethicon ECHELON™+ Stapler to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple™ Reloads. Based on benchtop testing

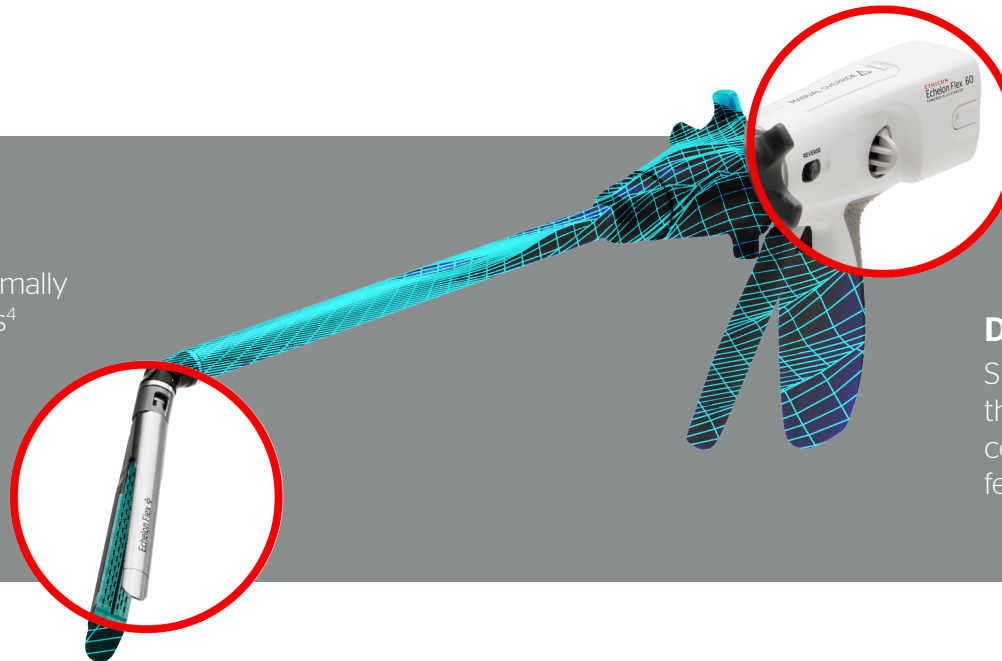
¹Advancing staple line security with fewer leakage pathways and less malformed staples. Fewer leakage pathways: benchtop testing in porcine tissue $\leq 30\text{mmHg}$ (26mmHG average pressure experienced during typical leak test), comparing Ethicon ECHELON+ Stapler PSEE60A with GST Reloads GST60B to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple™ Reloads EGI60AMT. Cumulative number of leaked tests (0/30), (7/30) & (9/30) respectively, $n=30$, $p < 0.05$. Fewer malformed staples: benchtop testing in 3.3mm and 4.0mm porcine tissue comparing malformed staples between ECHELON+ Stapler with GST Reloads (GST60B,GST60T) to Medtronic Signia™ Stapler with Tri-Staple™ Reloads (EGIA60AMT, EGI60AAXT) and Endo GIA™ with Tri-Staple™ Reloads (EGIA60AMT, EGI60AAXT). Percentage malformed results: 11.4% vs 4.28%, $p < 0.05$

Advanced staple line security even in challenging conditions^{1*}

When stapling, especially in challenging or thick tissue, proper compression is typically essential to achieve good staple line integrity and to help reduce complications like leaks and bleedings.^{2,3} **The ECHELON™+ Stapler with GST Reloads advances staple line security**—even in challenging conditions.^{1*}

ECHELON™+ Anvil

Designed for consistent compression and to optimally capture and form staples⁴



Dynamic Firing

Slows the stapler as it engages thick tissue to optimize compression and audible feedback^{5#}

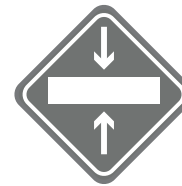
ECHELON™+ Stapler with GST reloads performance compared to Medtronic powered and manual staplers with Tri-Staple™ reloads:



Fewer leakage pathways at the staple line^{1†}



Better staple formation in thick tissue^{6‡}



More uniform compression^{7§}



4x less tissue slippage^{8¶}

Based on benchtop testing

^{1*}Advancing staple line security with fewer leakage pathways and less malformed staples. Fewer leakage pathways: benchtop testing in porcine tissue $\leq 30\text{mmHg}$ (26mmHG average pressure experienced during typical leak test), comparing Ethicon ECHELON+ Stapler PSEE60A with GST Reloads GST60B to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple™ Reloads EGI60AMT. Cumulative number of leaked tests (0/30), (7/30) & (9/30) respectively, $n=30$, $p < 0.05$. Fewer malformed staples: benchtop testing in 3.3mm and 4.0mm porcine tissue comparing malformed staples between ECHELON+ Stapler with GST Reloads (GST60B,GST60T) to Medtronic Signia™ Stapler with Tri-Staple™ Reloads (EGI60AMT, EGI60AAXT) and Endo GIA™ with Tri-Staple™ Reloads (EGI60AMT, EGI60AAXT). Percentage malformed results: 1.14% vs 4.28%, $p < 0.05$. [#]Dynamic Firing refines the performance of the ECHELON+ Stapler to reduce variation within design specifications. The average transaction time difference between 10mm and 4.0mm porcine tissue was 4.889 vs 2.992, $p\text{-value} < 0.05$. [†]Benchtop testing in porcine tissue $\leq 30\text{mmHg}$ (26mmHG average pressure experienced during typical leak test), comparing Ethicon ECHELON+ Stapler PSEE60A with GST Reloads GST60B to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple Reloads EGI60AMT. Cumulative number of leaked tests (0/30), (7/30) & (9/30) respectively, $n=30$, $p < 0.05$. [‡]Benchtop testing in 3.3mm and 4.0mm porcine tissue comparing malformed staples between ECHELON+ Stapler with GST Reloads (GST60B,GST60T) to Medtronic Signia™ Stapler with Tri-Staple™ Reloads (EGI60AMT, SIG60AAXT) and Endo GIA™ with Tri-Staple™ Reloads (EGI60AMT, EGI60AAXT). Percentage malformed results: 1.14% vs 4.28%, $p < 0.05$. [§]Benchtop testing in 3.2mm synthetic tissue comparing staple line compression between ECHELON+ Stapler with GST Reloads (PSEE60A, GST60B,GST60G) to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple™ Reloads (EGI60AMT). Resulting in a statistically significant compression uniformity, $p < 0.05$. [¶]In benchtop testing in porcine stomach tissue, the ECHELON+ Stapler with GST Reloads (PSEE60A, GST60T) had less mean longitudinal change in 4.0mm thick tissue. 0.79mm vs. 4.09mm, compared to the Signia™ Stapling System (SIGPHANDLE, SIG60AAXT), $p\text{-value} < 0.05$.

ECHELON™+ Stapler design features



ECHELON™+ Anvil

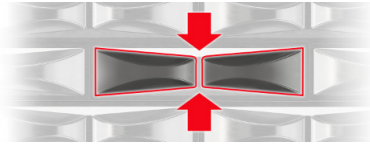
Refined curvature for consistent compression and wide tapered pockets to optimally capture and form staples.⁴



Dynamic Firing

slows the stapler as it engages thick tissue to optimize compression and audible feedback.^{5*}

Wide tapered anvil pockets
for optimal capture area and to guide staples into symmetric B-form⁴



Atraumatic tapered tip designed to achieve gentle tissue handling and optimizedotomy entry^{4#}



ECHELON™+ Stapler with GST Reloads



Built on a legacy of **Gripping Surface Technology**



Listen as the Dynamic Firing slows the stapler as it engages thick tissue to optimize compression^{5*}

Thin tissue



Thick tissue



*Dynamic Firing refines the performance of the ECHELON+ Stapler to reduce variation within design specifications. The average transection time difference between 1.0mm and 4.0mm porcine tissue was 4.889 vs 2.992, p-value <0.05 #The design of the ECHELON+ Stapler is refined with an updated anvil to reduce variation within design specifications.

ECHELON™+ Stapler with GST reloads performance compared to Medtronic powered and manual staplers with Tri-Staple™ reloads

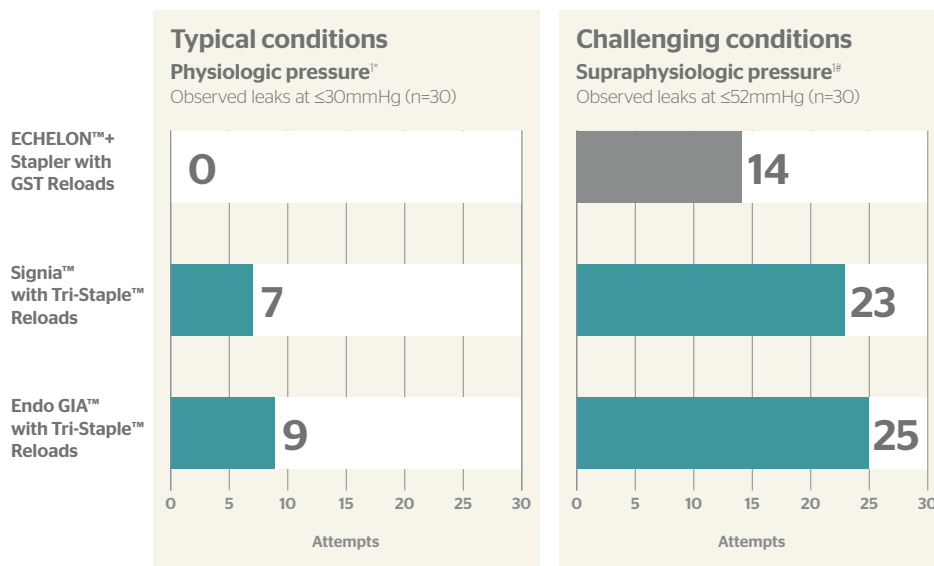


Fewer leakage pathways at the staple line¹



Better staple formation in thick tissue^{6†}

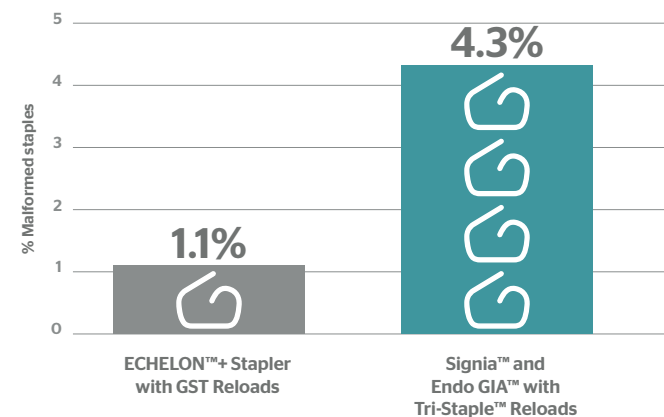
Observed leaks at the staple line¹



26mmHg average pressure experienced during intraoperative leak test

Based on benchtop testing

Percentage of malformed staples in thick tissue^{6†}



^{*}Benchtop testing in porcine tissue ≤ 30mmHg (26mmHG average pressure experienced during typical leak test), comparing Ethicon ECHELON+ Stapler PSEE60A with GST Reloads GST60B to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple Reloads EGIA60AMT. Cumulative number of leaked tests (0/30), (7/30) & (9/30) respectively, n=30, p < 0.05. [#]Benchtop testing in porcine tissue ≤ 52mmHg (Double the 26mmHG average pressure experienced during intra-operative leak test), comparing Ethicon ECHELON+ Stapler PSEE60A with GST Reloads GST60B to Medtronic Signia Stapler with Tri-Staple Reloads EGIA60AMT and Medtronic EndoGIA with Tri-Staple Reloads EGIA60AMT. Cumulative number of leaked tests (14/30), (23/30), (25/30) respectively, n=30, p < 0.05. [†]Benchtop testing in 3.3mm and 4.0mm porcine tissue comparing malformed staples between ECHELON+ Stapler with GST Reloads (GST60B,GST60T) to Medtronic Signia™ Stapler with Tri-Staple™ Reloads (EGIA60AMT, SIG60AXT) and Endo GIA™ with Tri-Staple™ Reloads (EGIA60AMT, EGIA60AXT). Percentage malformed results: 1.14% vs 4.28%, p < 0.05

ECHELON™+ Stapler with GST reloads performance compared to Medtronic powered and manual staplers with Tri-Staple™ reloads



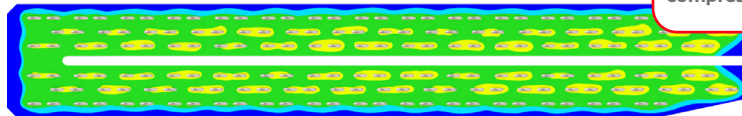
More uniform compression^{7*}



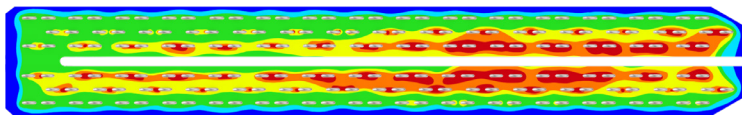
4x less tissue slippage^{8#}

Two-stage compression designed to prepare tissue for stapling and achieve a uniform staple height

32%
more uniform
compression^{7*}



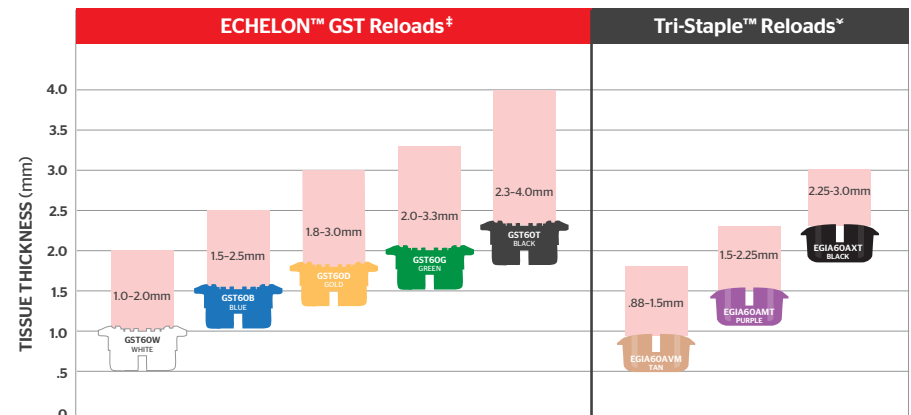
ECHOLON™+ Stapler with GST Reloads



Endo GIA™ with Tri-Staple™ Reloads



Reliable staple line integrity in thick tissue^{9†}



Based on benchtop testing

*Benchtop testing in 3.2mm synthetic tissue comparing staple line compression between ECHOLON+ Stapler with GST Reloads (PSEE60A, GST60B, GST60G) to Medtronic Signia™ and Endo GIA™ Staplers with Tri-Staple™ Reloads (EGIA60AMT). Resulting in a statistically significant compression uniformity, p<0.05. #In benchtop testing in porcine stomach tissue, the ECHOLON+ Stapler with GST Reloads (PSEE60A, GST60T) had less mean longitudinal change in 4.0mm thick tissue, 0.79mm vs. 4.09mm, compared to the Signia™ Stapling System (SIGPHANDLE, SIG60AXT), p-value <0.05. †Supported by benchtop testing in 3.3mm and 4.0mm thick porcine tissue for ECHOLON+ Stapler with GST Reloads (GST60G & GST60T). Reliable staple line integrity defined as 0.9 reliability at 90% confidence over the intended tissue thickness range for each reload. ‡Tissue thickness range: Porcine tissue measured at 8g/mm² prior to firing. †Intended tissue thickness: Per manufacturer IFU

Reduced hemostasis-related complications and reduced hospital costs in laparoscopic sleeve gastrectomy^{10*} (in a US setting)

ECHELON FLEX™ Powered Stapler with GST Reloads
vs. Medtronic Signia™ with Tri-Staple™ Reload



Hemostasis-related complications



up to 73%
(0.61% vs 2.24%)
n = 491 vs 491
p = 0.0012

Total median hospital costs (in a US setting)



7%
(\$9,771 vs. 10,487)
n = 491 vs 491
p < 0.001

Comparative effectiveness assessment of two powered surgical stapling platforms in laparoscopic sleeve gastrectomy: a retrospective matched study

Rawlins L, Johnson B, Johnston S, Elangovanraaj N, Bhandari M, Cohen RV, Rheinwalt KP, Fryrear R, Roy S
Med Devices (Auckl). 2020;13:195-204



40 hospitals



5,573 patients

* Based on a retrospective analysis of clinical and economic outcomes from 982 laparoscopic sleeve gastrectomy cases between March 1, 2017 and December 31, 2018 from US Premier Healthcare Database comparing ECHELON FLEX™ Powered Staplers with GST reloads to Signia™ Stapling System with Tri-Staple™ (hemostasis-related complications 0.61% vs. 2.24%, p=0.0012; median total hospital costs \$9,771 vs. \$10,487, p<0.001)

Ordering information

ECHELON™+ Stapler with GST Reloads (ECHELON FLEX™ Powered Plus Stapler and ECHELON ENDOPATH™ Reloads with GST)

Code	Description	Jaw length	Qty
PCEE45A	Compact Articulating Endoscopic Linear Cutter,* 280mm	45mm	3
PCEE60A		60mm	
PSEE45A	Standard Articulating Endoscopic Linear Cutter,* 340mm	45mm	3
PSEE60A		60mm	
PLEE45A	Long Articulating Endoscopic Linear Cutter,* 440mm	45mm	3
PLEE60A		60mm	



*Instrument does not contain a reload

Reloads

Code	Color	Description	Open staple height	Closed staple height	Qty
ECR45M	Gray	Gray reload intended for use in mesentery/thin tissue (Reload does not include Gripping Surface Technology)	2.0mm	0.75mm	12
ECR60M					
GST45W	White	White reload intended for use in vascular/thin tissue	2.6mm	1.0mm	12
GST60W					
GST45B	Blue	Blue reload intended for use in regular tissue	3.6mm	1.5mm	12
GST60B					
GST45D	Gold	Gold reload intended for use in regular/thick tissue	3.8mm	1.8mm	12
GST60D					
GST45G	Green	Green reload intended for use in thick tissue	4.1mm	2.0mm	12
GST60G					
GST45T	Black	Black reload intended for use in very thick tissue	4.2mm	2.3mm	12
GST60T					



References: 1. Ethicon, PRC096436A Ex-Vivo Comparison of Staple Line Leak Pressure: Echelon Flex Powered Plus Stapler with GST vs EndoGIA and Signia with Tri-Staple Technology, Aug 2020, Data on file Ethicon, PRC096858A Evaluation of Malformed Staples in Thick Tissue for Claims: Echelon Flex Powered Plus Stapler with GST vs Endo GIA and Signia with Tri-Staple Technology, Aug 2020, Data on file (159504-201117 EMEA, 158244-201105 EMEA) 2. Fegelman E, Knippenberg S, Schwiers M, et al. Evaluation of a Powered Stapler System with Gripping Surface Technology on Surgical Interventions Required During Laparoscopic Sleeve Gastrectomy, J Laparoendosc Adv Surg Tech A. 2017;27(5):489-494. 3. Nakayama S, Hasegawa S, Nagayama S, et al. The importance of precompression time for secure stapling with a linear stapler. Surg Endosc. 2011;25(7):2382-2386 4. Ethicon, 03122020 Design Intent for ECHELON+ Anvil (Project Cowbell), Dec 2020, Data on file (159848-201119 EMEA, 159850-201209 EMEA) 5. Ethicon, 08122020 Design Intent for ECHELON+ Firing Memo (Project Cowbell), Dec 2020, Data on file (159847-201119 EMEA) 6. Ethicon, PRC096858A Evaluation of Malformed Staples in Thick Tissue for Claims: Echelon Flex Powered Plus Stapler with GST vs Endo GIA and Signia with Tri-Staple Technology, Aug 2020, Data on file (158877-201112 EMEA) 7. Ethicon, PRC097500B.3 Cowbell Foam Uniform Compression Study for Claims: Cowbell Powered Plus with GST vs. Covidien Endo GIA with Tri-Staple, Oct 2020, Data on file (158247-201105 EMEA) 8. Ethicon, PRC097776A Evaluation of stomach tissue movement during stapler firing for claims: Cowbell vs Signia, Nov 2020, Data on file (160327-201124 EMEA) 9. Ethicon, PRC096858A Evaluation of Malformed Staples in Thick Tissue for Claims: Echelon Flex Powered Plus Stapler with GST vs Endo GIA and Signia with Tri-Staple Technology, Aug 2020, Data on file Ethicon, PRC095237A Project Cowbell 60mm GST Reload SLI/FSH DV Completion Report, July 2020, Data on file Ethicon, PRC093801A Project Cowbell 45mm GST Reload SLI/FSH DV Completion Report, April 2020, Data on file (159991-201121 EMEA) 10. Rawlins L, Johnson B, Johnston S, et al. Comparative Effectiveness Assessment of Two Powered Surgical Stapling Platforms in Laparoscopic Sleeve Gastrectomy: A Retrospective Matched Study. Med Devices (Auckl). 2020;13:195-204.

New branding



ECHELON™+ Stapler with GST Reloads



ECHELON FLEX™ GST System

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

The third party trademarks used herein are the trademarks of their respective owners.

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