

DESIGN MATTERS.

A Comparison of Two Leading Endo Staplers

Endo stapling devices are constantly evolving. That's why it's more important than ever to understand the basic principles and concepts of stapler design, and how tissue responds to these designs.

Our interactive brochure explains many of the latest features and claims of the two most prevalent endostapling devices on the market today — Endo GIA™ reloads with Tri-Staple™ technology and Echelon Flex™* reloads with gripping surface technology (GST). We've captured supporting evidence, and photos, so click through to see why design truly does matter.

STAPLER DESIGN

Cartridge Face Design

Open Channel vs. Closed Channel

Bent Tip vs. Straight Tip Staples

Click Topics to Learn More

SURGICAL PERFORMANCE

Tissue Extrusion

Cut Line Quality

Staple Formation

Tissue Trauma



Medtronic
Further, Together

KEY HIGHLIGHTS

- Due to the high pressures required to rotate the cartridge enough to misalign a staple to a staple pocket, an improvement in design by adding a closed channel is unnecessary.¹
- When compared to the extra room designed in the anvil pocket distance compared to the distance between the tips of the staple, the maximum correction in staple travel is minimal.¹
- Ethicon's claim of less tissue slippage during firing and the unlikely potential to save one reload per procedure is overcome by a longer cut line that is created by Tri-Staple™ reloads.¹
- iDrive™ Ultra using reloads with TriStaple™ technology resulted in a lower percentage of malformed staples and staples with less undercrimp than the Echelon Flex™* Powered Plus with GST reloads.²
- The iDrive™ Ultra also resulted in firings with a visually smoother appearance and a lower occurrence of wisping, cut edge roughness, and acute tissue trauma in the form of tearing.²
- The Tri-Staple™ technology reloads exhibited the least amount of bruising and tearing.¹
- The more acute tissue damage was caused by the GST reloads, which exhibited the highest bruising score and most significant damage within that score as determined by bruise size and bleeding.¹



STAPLER DESIGN

Stapler design varies significantly across leading manufacturers, including differences in cartridge face and anvil design, and the position of staple rows. While existing evidence has been published with regard to differences in clinical performance between the various designs, it is important to explore the potential surgical impact of each design aspect individually as stapler design continues to evolve.

We evaluated the designs of the two leading staplers on the market, the Endo GIA™ Reload with Tri-Staple™ Technology and the Echelon Flex™* Reload with Gripping Surface Technology (GST).

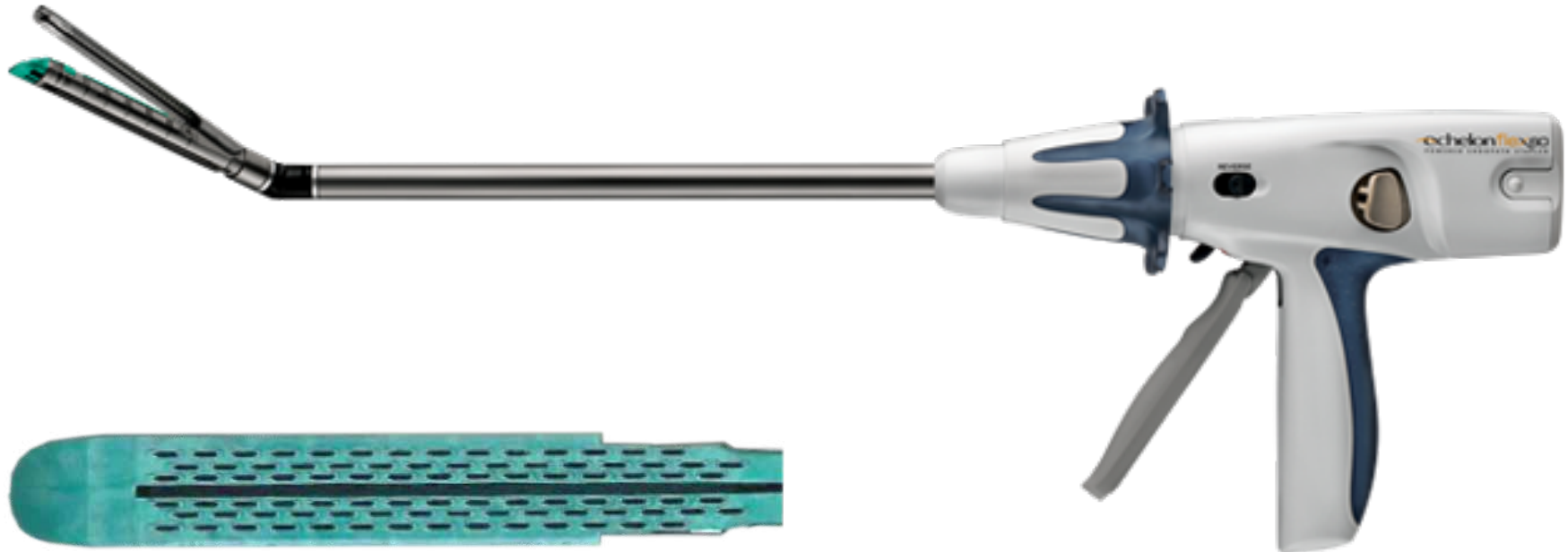


ETHICON STAPLER DESIGN

PRODUCT FEATURES³

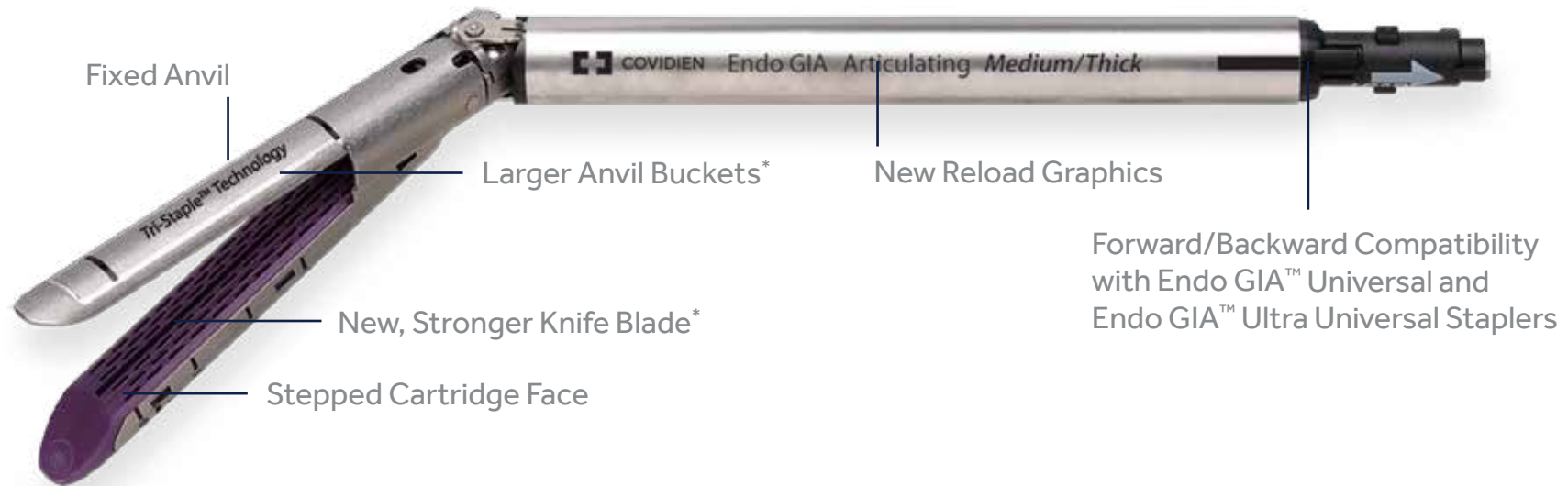
Echelon Flex™* reload with GST includes:

- Closed channel design
- Enlarged staple tips and asymmetrical staple legs
- Reloads with proprietary gripping technology



MEDTRONIC STAPLER DESIGN

ENDO GIA™ RELOADS WITH TRI-STAPLE™ TECHNOLOGY

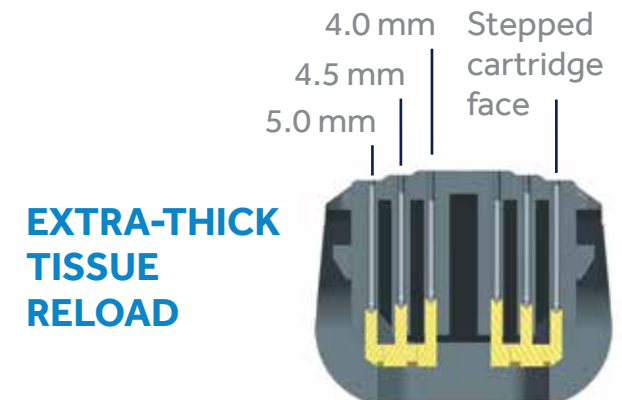
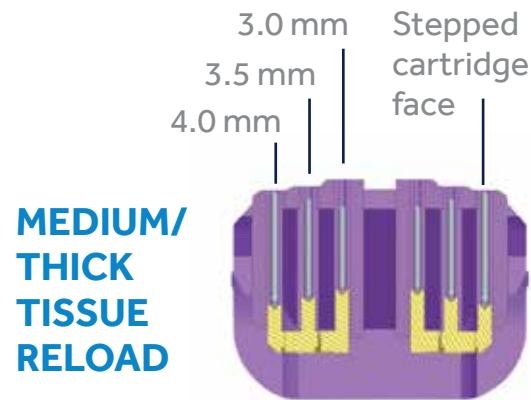
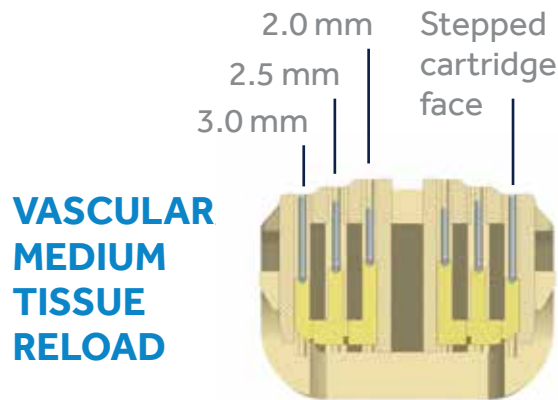


*as compared to Medtronic legacy staple reloads



MEDTRONIC STAPLE CARTRIDGE

STAPLE HEIGHTS



TRI-STAPLE™ TECHNOLOGY IS DESIGNED TO PROVIDE:



Less stress on
tissue during
compression
and clamping⁴



Greater
perfusion into
the staple line⁵



Outstanding
performance
in variable
thicknesses



COMMON CONCEPTS IN **STAPLER DESIGN**

While recent evidence highlights performance differences between various stapler designs, it is important to explore the potential surgical impact of each design aspect individually as stapler design continues to evolve. A few of these differences explored today include channel design, staple design and position and cartridge face design.

Let's take a look at some of these design differences of the two leading staplers on the market.

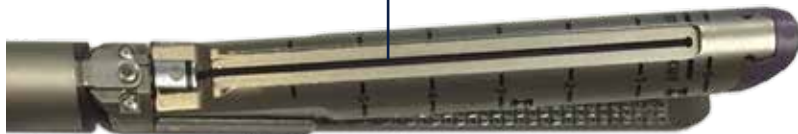


OPEN CHANNEL vs. **CLOSED CHANNEL** **STAPLER DESIGN**

IS THERE A DIFFERENCE BETWEEN AN OPEN CHANNEL VS. CLOSED CHANNEL DESIGN?

Ethicon claims that a closed channel design reduces lateral deflection of the staples upon firing compared to an open channel design, particularly in thick tissue.³

OPEN CHANNEL DESIGN



Endo GIA™ reload with
Tri-Staple™ technology

CLOSED CHANNEL DESIGN



Echelon Flex™*
reload with GST

LET'S EXPLORE THE EVIDENCE ON THIS MATTER



OPEN CHANNEL vs. CLOSED CHANNEL CARTRIDGE DESIGN

Based on the amount of force GI tissue can physiologically withstand, closed channel design provides minimal value.¹

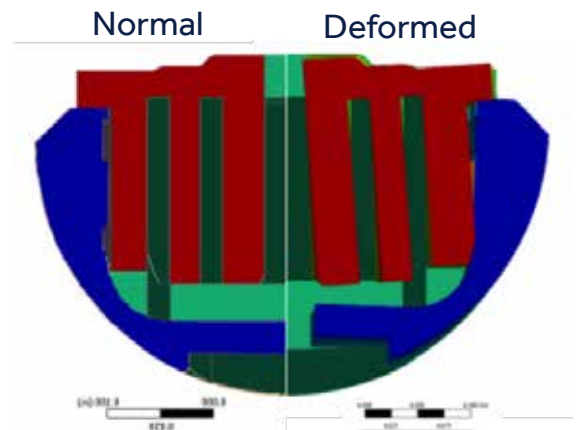
Endo GIA™ reloads with Tri-Staple™ technology provide sufficient strength for staple alignment with an open channel design. We conducted testing and here is what we found:

- Fourteen degrees of deflection (or 320 pounds of force) is needed for a staple to deflect enough to miss a bucket laterally with the reloads with Tri-Staple™ technology (Figure 1).¹
- Clamping on two pads of foam (similar to normal tissue thickness) is equivalent to approximately four pounds of force, or 0.2° deflection. ¹
- Ethicon's analysis indicating that the cartridge shifts outward with an open channel design is not accurate. Our analysis shows that the cartridge shifts inward (Figure 1). ¹

THE TRI-STAPLE™ TECHNOLOGY DESIGN WAS DESIGNED TO SUFFICIENTLY HANDLE CLINICALLY RELEVANT LOADING WITH AN OPEN CHANNEL DESIGN.¹

Example of potential impact of extreme lateral deflection.¹ Cross section of the channel of the reload. The cartridge is shown in red rotating inward and the metal channel is shown in blue rotating outward.

FIG 1



BENT STAPLE TIP DESIGN

ECHELON FLEX™* RELOADS WITH GST BENT STAPLE TIPS RESULT IN MINIMAL CORRECTION.¹

METHOD

Ethicon claims that bent staple tips and asymmetrical staple legs offer consistent staple formation in challenging tissue.¹ To find the hypothetical impact the bent staple tips have, the bend angle was measured at each tip and a hypothetical trajectory correction was calculated.

KEY FINDINGS²

- Gap from staple tip to anvil is 1.0 mm
- Translates to a 0.16 mm correction in the distal end and 0.08 mm in the proximal end of the staple[†]

The maximum trajectory correction Echelon Flex™* reloads with GST bent staples could cause is 0.16 mm – which would likely provide no meaningful difference in staple formation improvement based on measurements above.¹

Illustration of bent tip staple with measurements.¹

FIG 2



[†]Assumes the staple leg follows the bent tip angle perfectly through tissue



SURGICAL PERFORMANCE

To properly compare the surgical performance between the Endo GIA™ Reloads with Tri-Staple™ Technology and Echelon Flex™ Reloads with Gripping Surface Technology, we investigated all aspects of staple line integrity, including staple formation, cut line quality and tissue trauma.

In summary, there were clear differences in performance between these two staplers, with the Endo GIA™ Reloads with Tri-Staple™ Technology demonstrating superior results in all four categories compared to the Echelon Flex™ Reloads with Gripping Surface Technology. Let's review the results in detail.²



SURGICAL PERFORMANCE

Tissue extrusion, or slippage, is often measured by the length of the tissue extruded (or milked) from the distal end of the reload. The amount of extrusion depends on the tissue thickness being fired upon as well as the design of the reload.

A comparison of the Endo GIA™ reload with Tri-Staple™ technology and the Echelon Flex™* reload with GST confirms differences between these two staplers with respect to the amount of tissue extruded when fired in various tissue thicknesses. Let's explore these differences as well as the impact on surgical performance.²



Surgical performance TISSUE EXTRUSION ANALYSIS

IS THERE A DIFFERENCE IN THE AMOUNT OF TISSUE EXTRUDED BETWEEN THE TWO ENDOSTAPLERS?

TABLE 1: TISSUE EXTRUSION (IN MM) OBSERVED WHEN CLAMPING ON EX VIVO PORCINE STOMACH¹

Tissue Thickness (mm)	1.5	2.5	3.3	4.0
Endo GIA™ Reload with Tri-Staple™ Technology	2.542	3.261	4.806	5.116
Echelon Flex™ Reload with GST	1.067	1.148	0.642	0.065
TISSUE EXTRUSION DIFFERENCE	1.385	2.113	4.164	4.462

The variance in extrusion between the two staplers increased as tissue thickness increased, with a minimum difference of 1.4 mm in normal tissue and a maximum difference of 4.5 mm in thick tissue. Performed in ex vivo porcine stomach.

Depiction of actual tissue extrusion at distal tip.¹

FIG 3



DOES TISSUE EXTRUSION IMPACT SURGICAL PERFORMANCE?

The variance in tissue extrusion between the two endostaplers is minimal, and did not have a negative impact on observed surgical performance.¹



Surgical performance

TISSUE EXTRUSION'S IMPACT ON THE **NUMBER OF FIRINGS PER PROCEDURE.**

Analysis of the Ethicon *ex vivo* study shows that it would take 14 sequential firings before reducing the need for an additional reload when using Echelon Flex™* reloads with GST™ as compared to Endo GIA™ reloads with Tri-Staple™ technology.¹

CAN TISSUE EXTRUSION IMPACT CUT LINE LENGTH?

Claims regarding the ability of a stapler to reduce the number of reloads needed in one procedure due to less tissue extrusion have been made.³ We explored this concept further and concluded that although tissue extrusion does have minimal and varying impacts on the number of reloads needed to complete a procedure, other factors such as procedure, tissue thickness and cut line length are more important contributors to the number of firings per procedure.¹

DO CERTAIN RELOADS OFFER A REDUCTION IN FIRINGS NEEDED PER PROCEDURE?

As previously mentioned, it would take 14 sequential firings to save one firing with the Echelon Flex reloads. It is highly unlikely that any one procedure would ever require 14 sequential firings. Therefore, we concluded that the Ethicon cartridge design does not offer any reduction in reloads compared to Endo GIA™ reloads with Tri-Staple™ technology.¹



Surgical performance

CLEAR DIFFERENCES IN CUT LINE LENGTH.

Differences in cut line length have been observed between various stapler designs. Those differences are generally attributable to cartridge design, tissue extrusion and tissue thickness.¹

When it comes to the Endo GIA™ reloads with Tri-Staple™ technology and the Echelon Flex™* reload with GST, very clear differences were observed.²



Surgical performance RELOADS WITH TRI-STAPLE™ TECHNOLOGY HAVE A LONGER CUT LINE.

KEY FINDINGS*

Reloads with Tri-Staple™ technology have a longer cut line than reloads with GST (n = 12).^{2*}

Ethicon claims stating that reduced tissue slippage may lead to a one-reload reduction during a procedure is highly unlikely.^{1**}

TABLE 2: CUT LINE LENGTH BY TISSUE THICKNESS INDICATION*

Tissue Indication	Reload with Tri-Staple™ Technology - length (mm)	Reload with GST - length (mm)	Difference in Length (mm)	P-Value
Indicated	56.2	51.2	5.0	0.005
Over Indicated	54.4	47.8	6.6	0.001
Abuse	50.7	45.5	5.2	0.001

In fact, the maximum tissue slippage difference of 4.5 mm stated earlier is negated – and even exceeded – by the longer cut line made by the Endo GIA™ reload with Tri-Staple™ technology. Any claim of a reload reduction due to tissue slippage is simply not substantiated.²

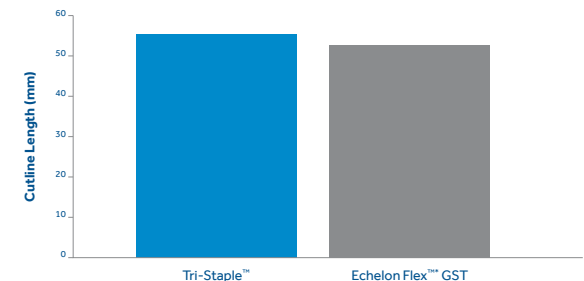
*Results from ex vivo porcine stomach model.

**With 44 firings in the thinnest of tissue and 14 firings in the thickest of tissue

†Statistically significant

FIG 4

EX VIVO PORCINE STOMACH CUTLINE LENGTH



Cut line length measured during ex vivo firings (p = .005).[†]



Surgical performance ANALYZING STAPLE FORMATION

Lab tests have already shown the Endo GIA™ reload with Tri-Staple™ technology exhibits significantly fewer malformed staples and less undercrimp than the Echelon Flex™* reload with GST.¹

Ethicon claims to have improved staple formation with a recent staple design change, so we figured we'd put those claims to the test — and, once again, some very clear differences emerge.¹ Let's take a closer look.



Surgical performance THE RESULTS ARE IN ON STAPLE FORMATION.

KEY FINDING

Endo GIA™ black reloads with Tri-Staple™ technology firings exhibited a lower percentage of malformed staples ($p = 0.004$) and less undercrimp ($p = 0.004$) in porcine stomach tissue compared to Echelon Flex™* black reloads with GST.¹

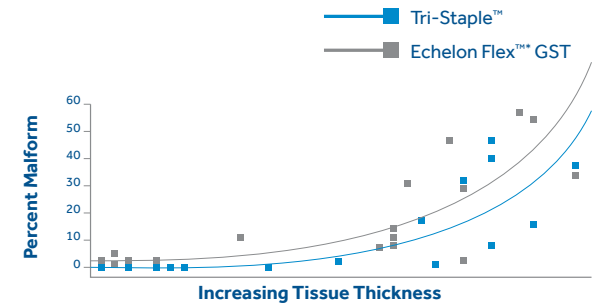
Did the new staple design of the Echelon Flex black reload with GST offer any improvement?

The results of our comparative testing reach the same conclusions as previously released data. iDrive Ultra with Endo GIA™ black reloads offer superior staple formation than Echelon Flex black reloads with GST.¹

[†]Statistically Significant

FIG 5

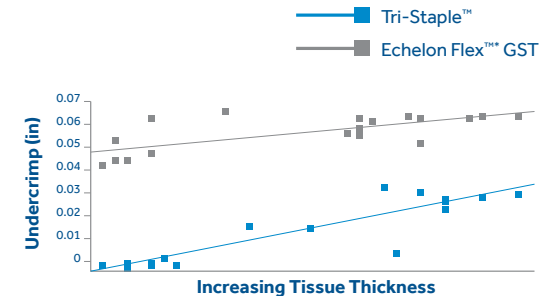
PERCENT MALFORM BY STAPLER AND TISSUE THICKNESS



Endo GIA™ black reload with Tri-Staple™ technology exhibited a lower percentage of malformed staples ($p = 0.004$) in indicated thickness of porcine stomach tissue compared to Echelon Flex™* black reloads with GST ($p = .004$).^{1†}

FIG 6

UNDERCRIMP BY STAPLER AND TISSUE THICKNESS (in)



Endo GIA™ black reload with Tri-Staple™ technology were significantly less undercrimped than Echelon Flex™* black reloads with GST in ex vivo porcine stomach ($p = .004$).^{1†}



Surgical performance CUT LINE QUALITY. **IT MATTERS.**

We know that cut line quality can be affected by many aspects of stapler design, including knife blade design, cartridge face design, and stapler firing speed. We also know that indications of poor cut line quality can be observed through jaggedness, wisping, tearing and acute tissue trauma.

Given the differences in stapler design between Endo GIA™ reloads with Tri-Staple™ technology and the Echelon Flex™* reloads with GST, and the key differences in their surgical performance, we compared each product's cut line. Let's look at the results.



Surgical performance WHICH STAPLER HAD BETTER CUT LINE QUALITY?

HOW WAS CUT LINE QUALITY ASSESSED?

The Endo GIA™ black reload with Tri-Staple™ technology and Echelon Flex™* black reload with GST were fired into *ex vivo* porcine stomach in similar locations with comparable tissue thicknesses. Cut line quality was visually inspected at each firing, and cut edge appearance (roughness), absence or presence of wisps and acute tissue trauma were evaluated.

KEY FINDING

Overall, cut lines made with the Endo GIA™ black reload with Tri-Staple™ technology were observed to be smoother and more uniform, with less wisps, tears and bleeding in the stomach.¹

The results indicate that the reload with Tri-Staple™ technology design and the slower firing speed of the iDrive™ Ultra appear to offer a superior cut line than the newly designed Echelon Flex™* reload with GST.

FIG 7

Evaluation of cut line quality using Endo GIA™ reload with Tri-Staple™ technology and Echelon Flex™* reload with GST in porcine stomach (*ex vivo*) (Tri-Staple™ n=9, Echelon Flex™* GST n=10)¹

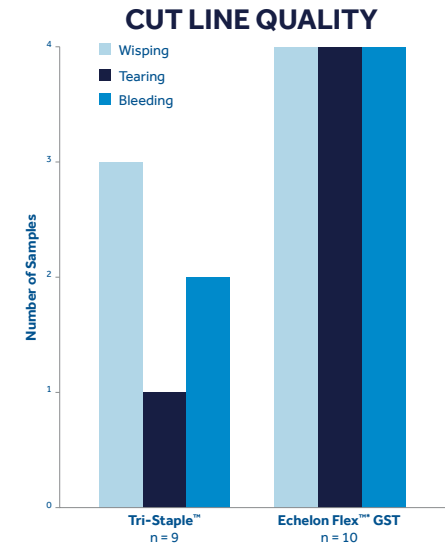
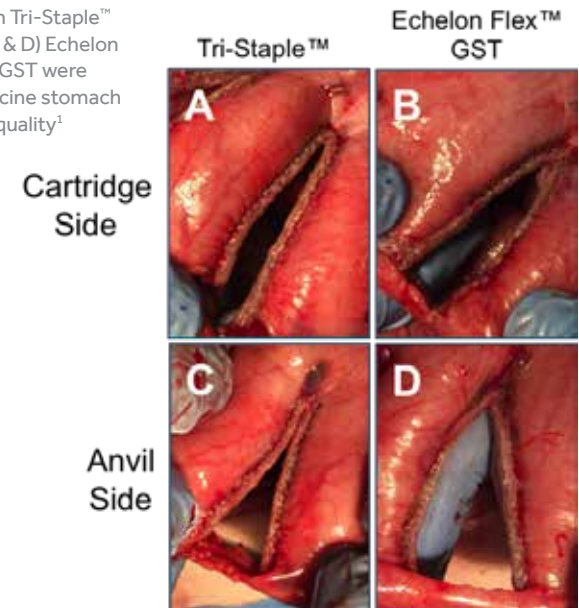


FIG 8

(A & C) Reload with Tri-Staple™ technology and (B & D) Echelon Flex™* reload with GST were fired *ex vivo* in porcine stomach to assess cut line quality¹



Surgical performance

RELOADS WITH TRI-STAPLE™ TECHNOLOGY

HAVE A LONGER AND VISUALLY SMOOTHER CUT LINE.

HOW WAS CUT LINE CONSISTENCY MEASURED?

An Endo GIA™ reload with Tri-Staple™ technology and Echelon Flex™* reload with GST were fired in ex vivo porcine lung in similar locations, with comparable tissue thicknesses (tissue thickness measurements were not taken due to the fragility of lung tissue). Cut line length was measured at each firing and a qualitative observation of cut line edge appearance (roughness), wisps (absence/presence), tears and bruises, were evaluated.²

KEY FINDING

There was an observable difference in the jaggedness of Echelon Flex™* reload with GST firings in contrast to the straight and smooth cut line of the reloads with Tri-Staple™ technology firings.¹

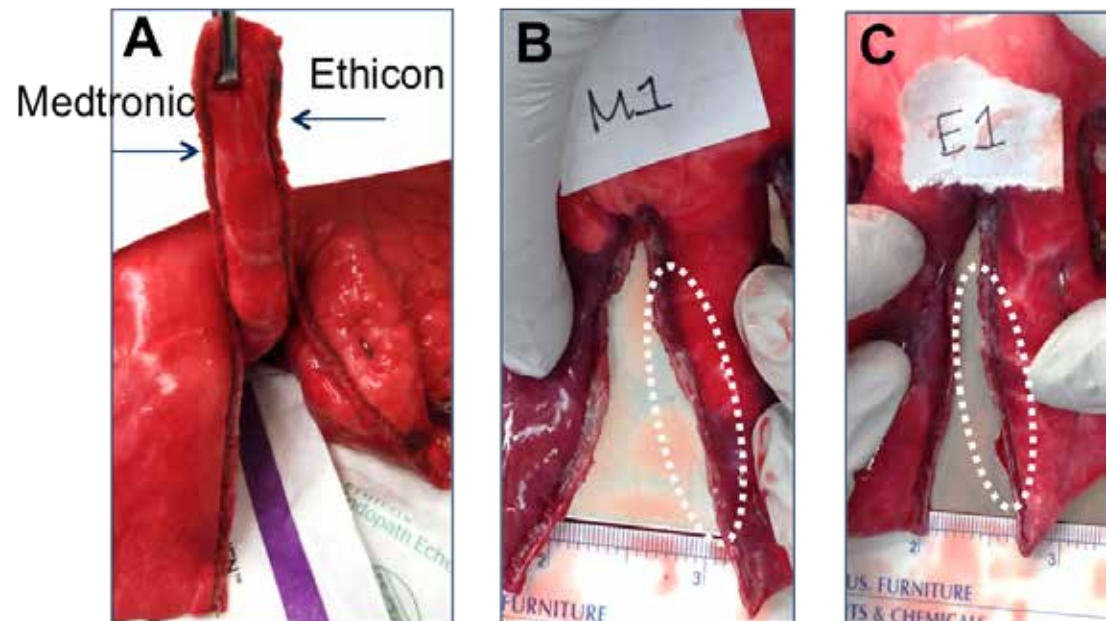


FIG 9

B) Reload with Tri-Staple™ technology and (C) Echelon Flex™* reload with GST were fired into ex vivo porcine lung and cut line quality was assessed.⁴

The reload with Tri-Staple™ technology cut line appeared to be visually smoother when compared to the Echelon Flex™* reload with GST.²



Surgical performance TACKLING THE ISSUE OF TISSUE TRAUMA.

Tissue trauma may include excessive bruising and bleeding, and it can prevent proper perfusion and disrupt the healing process.

Many different stapler design features can contribute to tissue trauma, including cartridge face design, staple design and firing speed of the stapler. Also, certain design characteristics can lead to excessive pressure concentrations on the tissue from the stapler reload.

With that in mind, we tested the Endo GIA™ reloads with Tri-Staple™ technology and Echelon Flex™* reloads with GST to determine differences in pressure and related trauma exerted on tissue.¹ The differences were striking. Let's take a closer look.

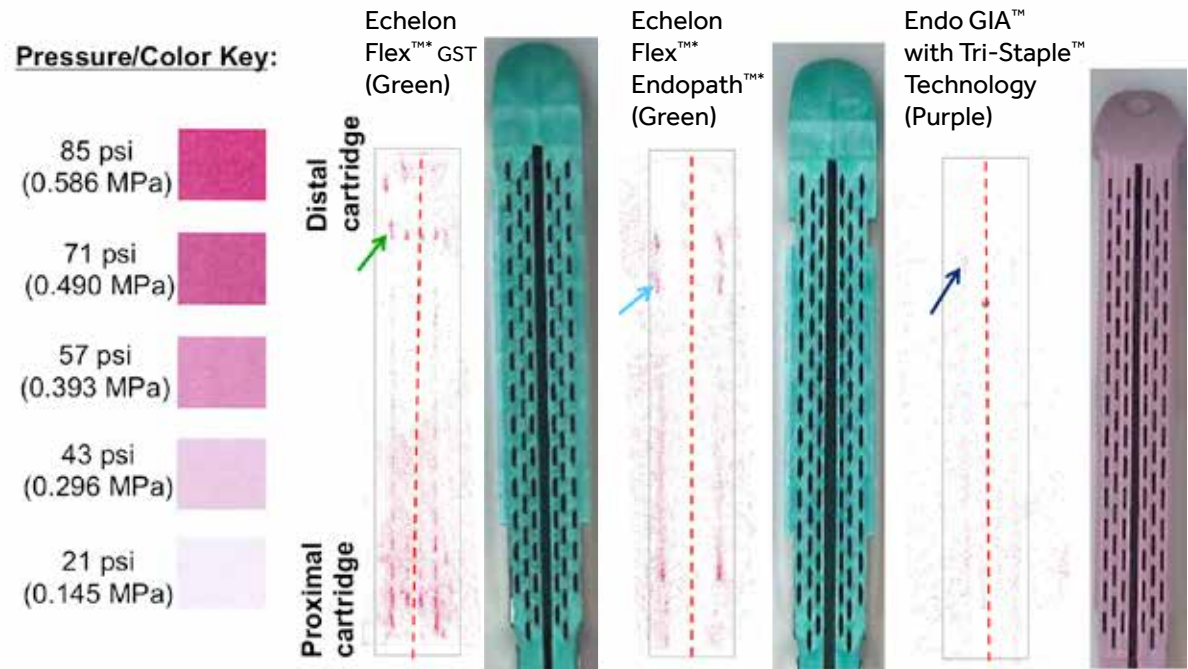


Surgical performance PRESSURE MAPPING INDICATES HIGHER CONCENTRATIONS AT RAISED RIDGE SURFACES.¹

METHOD

Echelon Flex™* reloads with GST, Echelon Flex™* Endopath™* reloads and an Endo GIA™ reloads with Tri-Staple™ technology were clamped on indicated foam and Fujifilm Prescale™* sensor film. Areas of increased pressure were analyzed and compared.

FIG 10 Fuji Film Pressure Mapping



All firings performed on Fuji Prescale™ Ultra Low at 23.7° C and 55.4% relative humidity



Surgical performance

THE PRESSURE'S RISING ON ECHELON FLEX™* RELOADS AND ENDOPATH™ RELOADS.

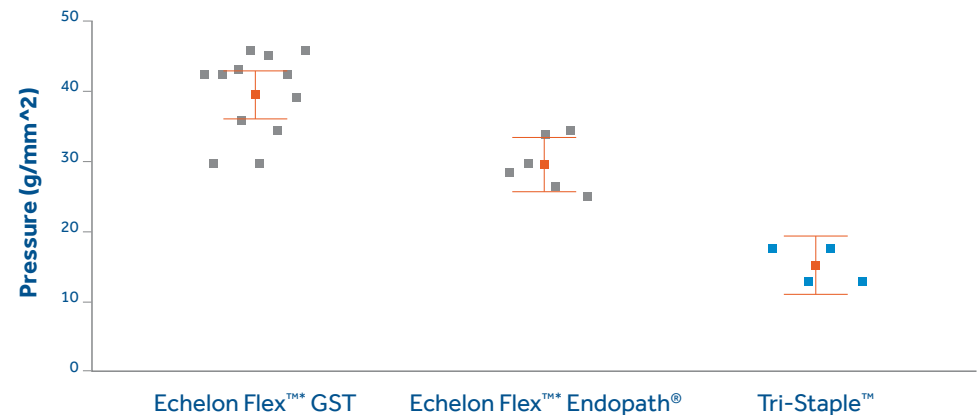
Pressure concentrations were significantly higher in both Echelon Flex™* reloads with GST and Endopath™* compared to Endo GIA™ reloads with Tri-Staple™ technology.¹

Pressure was measured in regions of highest intensities:

- Echelon Flex™* reload with GST: At the raised ridges, directly adjacent to staples (n = 12)
- Echelon Flex™* Endopath™*: On the edge of the cartridge face, away from staples (n = 6)
- Endo GIA™ reload with Tri-Staple™ technology: At the step changes in the cartridge, away from staples (n = 4)

FIG 11

MAXIMUM CLAMP PRESSURE CONCENTRATION AREA COMPARISON†



†Statistically Significant. (95% CI for the Mean)



Surgical performance IMPACT OF CLAMPING PRESSURE ON TISSUE TRAUMA.

WHEN WAS TISSUE TRAUMA ASSESSED?

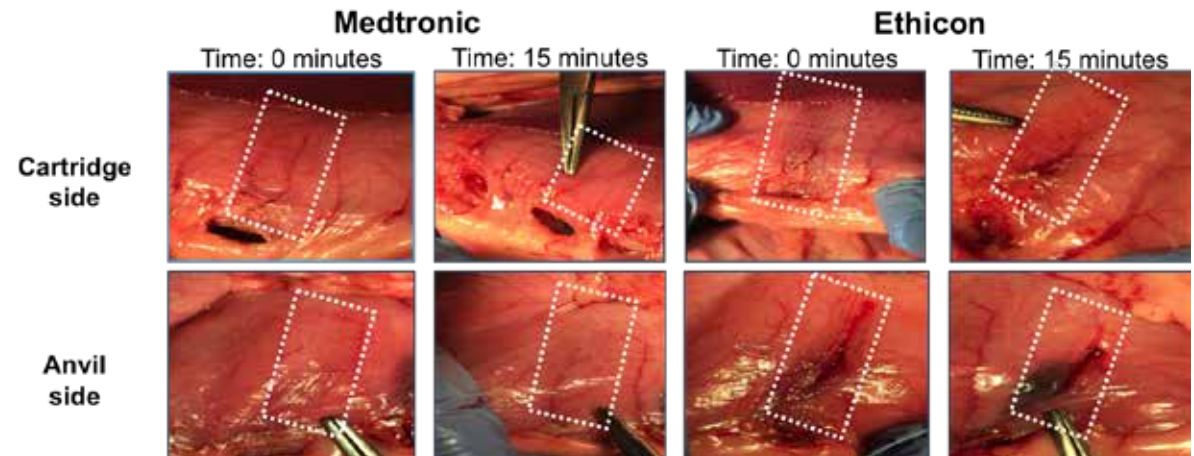
An *in vivo* porcine stomach model was used in clamping alternating staplers – in similar locations, with comparable tissue thicknesses, for one minute – to evaluate tissue trauma caused by stapler jaws. Clamped tissue was evaluated immediately following removal of the stapler and again after 15 minutes to visually assess bruising, tearing and bleeding. Edge appearance (roughness), wisps (absence/presence), tears and bruises, were evaluated.¹

In *in vivo* porcine stomach clamping with Tri-Staple™ technology had no visual bruising after 15 minutes, while the Echelon Flex™* reload with GST demonstrated bruising, and tearing on the tissue.¹

WERE DIFFERENCES IN TISSUE TRAUMA OBSERVED?

- These tests indicated that, for *in vivo* porcine stomach, there was visible tissue trauma caused by the jaws of Ethicon's Powered Plus Stapler.
- Visual assessment of the Endo GIA™ reload with Tri-Staple™ technology samples showed no tearing immediately following release of the stapler.

FIG 12 In Vivo Tissue Trauma from Clamping



No visual tissue tearing was observed while clamping the Endo GIA™ reload with Tri-Staple™ technology. The Echelon Flex™* reload with GST had visual damage to the tissue on both the cartridge and anvil side of the jaws.



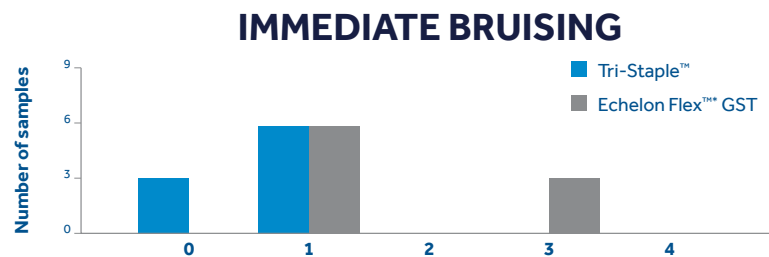
Surgical performance ONE STAPLER CAUSES LESS TISSUE BRUISING.

The Endo GIA™ with Tri-Staple™ technology was observed to have less overall bruising and decreased severity of bruising when compared to Echelon Flex™* reload with GST, when clamped onto *in vivo* porcine stomach (n = 9).¹

HOW OFTEN WAS BRUISING OBSERVED BETWEEN THESE TWO STAPLERS IMMEDIATELY AFTER CLAMPING?

Endo GIA™ reloads with Tri-Staple™ technology had six samples with a bruising grade of one after one minute of clamping. Ethicon had three samples with a bruising grade of three, and six samples with a bruising grade of one.

FIG 13



Bruising Scale (RDTS-046)	
Rank	Definition
0	No hemorrhage
1	Dissecting hemorrhage (hematoma, serosa intact)
2	Serosal tear + no bleed
3	Hemorrhage + tear + bleeding arrested
4	Hemorrhage + tear + bleeding

The design of the Endo GIA™ Reloads with Tri-Staple™ technology appears to cause less bruising than the Echelon Flex™* with GST.



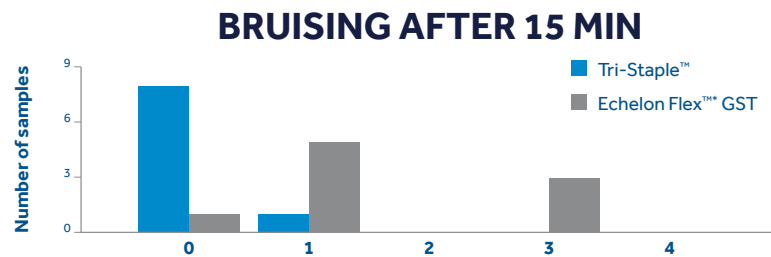
Surgical performance ONE STAPLER CAUSES LESS TISSUE BRUISING.

The Endo GIA™ with Tri-Staple™ technology was observed to have less overall bruising when compared to Echelon Flex™* reload with GST, when clamped onto *in vivo* porcine stomach (n = 9).¹

HOW OFTEN WAS BRUISING OBSERVED BETWEEN THESE TWO STAPLERS 15 MINUTES AFTER CLAMPING?

Endo GIA™ reloads with Tri-Staple™ technology had eight samples with no bruising, and one sample with a bruising grade of one. Ethicon had three samples with a bruising grade of three, and five samples with a bruising grade of one.¹

FIG 14



Bruising Scale (RDTS-046)	
Rank	Definition
0	No hemorrhage
1	Dissecting hemorrhage (hematoma, serosa intact)
2	Serosal tear + no bleed
3	Hemorrhage + tear + bleeding arrested
4	Hemorrhage + tear + bleeding

The design of the EGIA™ Reloads with Tri-Staple™ technology appears to cause less bruising than the Echelon Flex™* with GST.



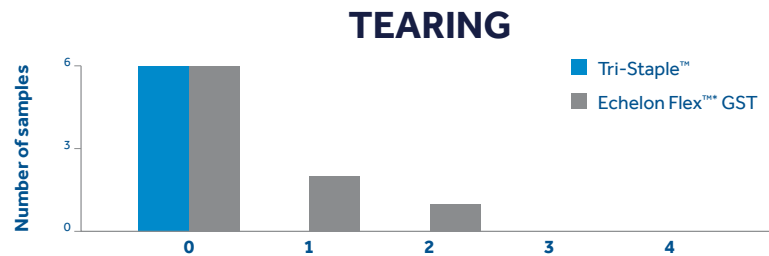
Surgical performance ONE STAPLER CAUSES LESS TISSUE TEARING.

The Endo GIA™ with Tri-Staple™ technology was observed to have less overall tearing when compared to Echelon Flex™* reload with GST, when clamped on *in vivo* porcine stomach (n = 9).¹

TEARING

Endo GIA™ reloads with Tri-Staple™ technology showed no tearing on any of the samples clamped for one minute.¹

FIG 15



Tearing Scale (RDTs-046)	
Rank	Definition *measure tear and then rank
0	No tearing
1	Mild (<10mm tear)
2	Moderate (10-30mm tear)
3	Severe (>30mm tear)

The design of the Reloads with Tri-Staple™ technology appears to cause less tearing than the Echelon Flex™* with GST.



REFERENCES

1. Medtronic Engineering Report # PCG-026-Rev1. Competitive Claims Testing: Ethicon ECHELON FLEX™** GST System vs. iDrive™ Ultra Powered Stapling System using Endo GIA™ Reloads with TriStaple™ Technology
2. Medtronic Engineering Report # PCG-027. Thoracic claims testing: Ethicon Echelon Flex™** GST System vs iDrive™ Ultra Powered Stapling System with Tri-Staple™ Technology
3. Ethicon Website: <https://www.ethicon.com/gst>. Access date December 9, 2015
4. Covidien engineering report PCG-007 rev 1 - "Perfusion Into Clamped Media".
5. Covidien engineering report No. 2128-002-2 Final analysis of Staple Line Vascularity Using MicroCT

Claims made throughout this brochure are based on clinical trials.

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