

Endo GIA™ Reloads with Tri-Staple™ Technology

Technical Brochure

**Outstanding Performance
Across a Broader Range
of Tissues and Applications**



Introducing Tri-Staple™ Technology

Operate With Confidence

We are delighted to introduce you to Covidien's new revolutionary endostapling technology. With significant investments into research and development over the years, Endo GIA™ reloads with Tri-Staple™ technology and Endo GIA™ Ultra Universal staplers have been developed with the intent to fulfill the unmet needs of surgeons across different surgical specialties.

Covidien's revolutionary new endostapling system enables surgeons to operate with confidence to handle a broader range of tissue thickness and applications with outstanding performance.

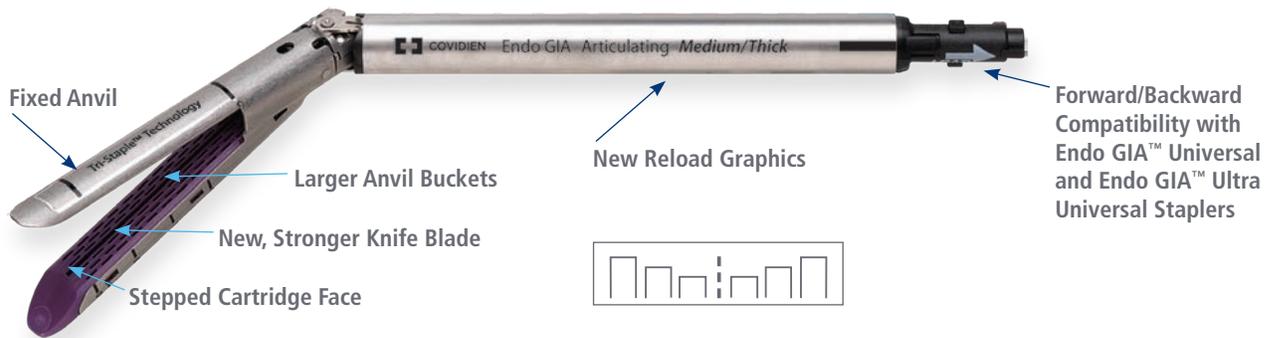
This technical brochure is intended to show the data and evidence behind many of the innovative features and benefits of Tri-Staple™ technology. It explains the methodology and outcomes of the following tests performed in bench top and pre-clinical settings:

- Broader indicated tissue thickness ranges – *Staple Reload Selection*
- Uncompromised staple line strength – *Tyvek Pull Apart Testing*
- Superior Leak Resistance - *In-Vitro - Leak Comparison*
- Reliable results across broader tissue thickness range - *In-Vivo - Leak Comparison*
- Consistent performance over a broader range of tissue thickness – *In-Vivo - Hemostasis*
- Consistent performance over a broader range of tissue thickness – *Ex-Vivo - Pneumostasis*
- Consistent, Reliable & Safe Pre-Clinical Outcomes - *Chronic Studies*
- Improved Tissue Retention – *Relative Grasping Force*

Product Information

Features and Order Codes

Endo GIA™ Reloads with Tri-Staple™ Technology



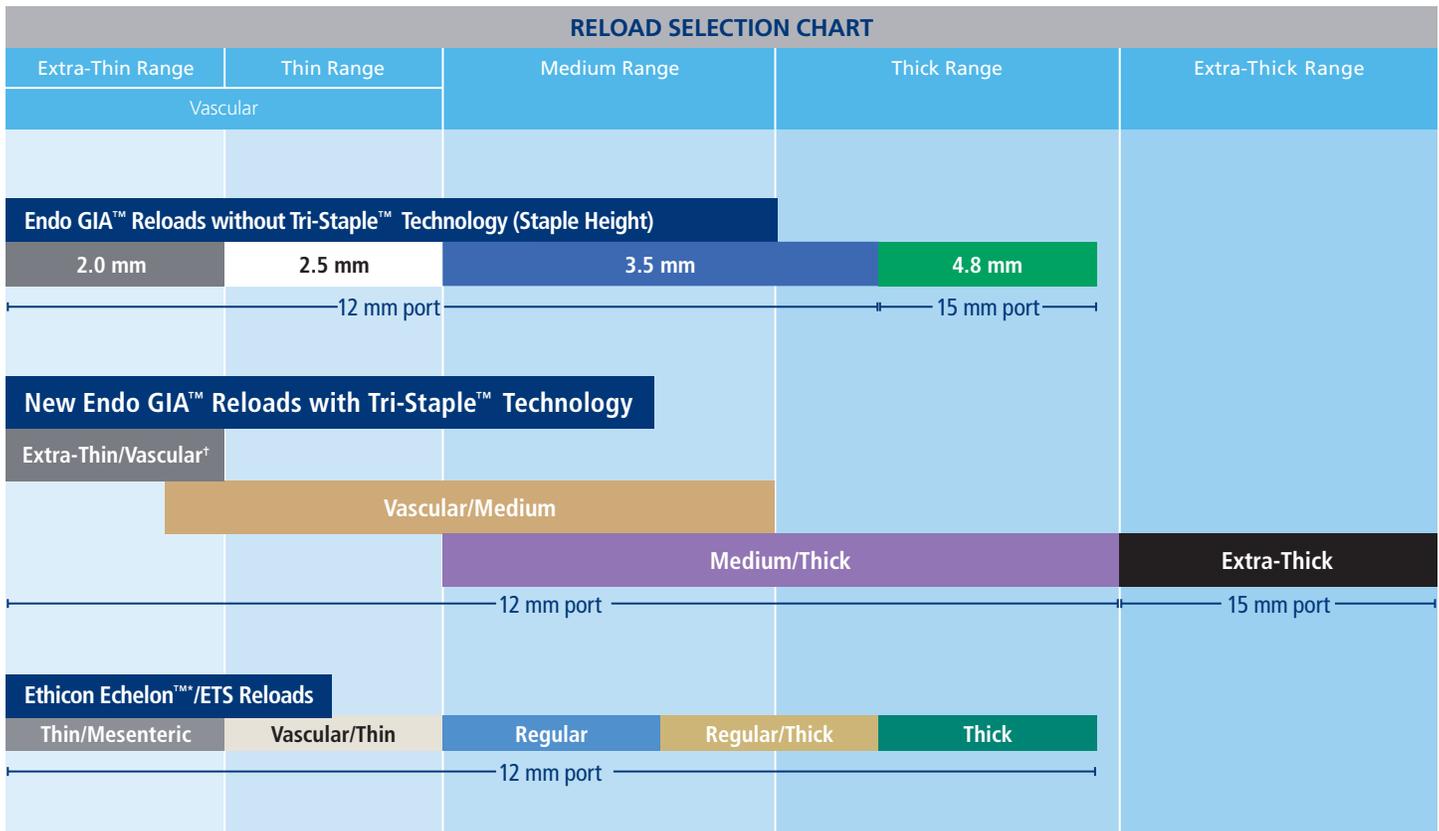
Ordering Information

| Reorder Code | Description | Cartridge Color | Staple Size (inner to outer row) |
|--------------|--|-----------------|----------------------------------|
| EGIA45AV* | Endo GIA™ 45 mm Articulating Vascular Reload | Gray | 2 mm, 2 mm, 2 mm |
| EGIA45CTAV* | Endo GIA™ 45 mm Curved Tip Articulating Vascular Reload | Gray | 2 mm, 2 mm, 2 mm |
| EGIA30AVM | Endo GIA™ 30 mm Articulating Vascular/Medium Reload with Tri-Staple™ Technology | Tan | 2 mm, 2.5 mm, 3 mm |
| EGIA30CTAVM | Endo GIA™ 30 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology | Tan | 2 mm, 2.5 mm, 3 mm |
| EGIA45AVM | Endo GIA™ 45 mm Articulating Vascular/Medium Reload with Tri-Staple™ Technology | Tan | 2 mm, 2.5 mm, 3 mm |
| EGIA45CTAVM | Endo GIA™ 45 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology | Tan | 2 mm, 2.5 mm, 3 mm |
| EGIA60AVM | Endo GIA™ 60 mm Articulating Vascular/Medium Reload with Tri-Staple™ Technology | Tan | 2 mm, 2.5 mm, 3 mm |
| EGIA60CTAVM | Endo GIA™ 60 mm Curved Tip Articulating Vascular/Medium Reload with Tri-Staple™ Technology | Tan | 2 mm, 2.5 mm, 3 mm |
| EGIA30AMT | Endo GIA™ 30 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology | Purple | 3 mm, 3.5 mm, 4 mm |
| EGIA45AMT | Endo GIA™ 45 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology | Purple | 3 mm, 3.5 mm, 4 mm |
| EGIA60AMT | Endo GIA™ 60 mm Articulating Medium/Thick Reload with Tri-Staple™ Technology | Purple | 3 mm, 3.5 mm, 4 mm |
| EGIA60CTAMT | Endo GIA™ 60 mm Curved Tip Articulating Medium/Thick Reload with Tri-Staple™ Technology | Purple | 3 mm, 3.5 mm, 4 mm |
| EGIA45AXT | Endo GIA™ 45 mm Articulating Extra-Thick Reload with Tri-Staple™ Technology | Black | 4 mm, 4.5 mm, 5 mm |
| EGIA60AXT | Endo GIA™ 60 mm Articulating Extra-Thick Reload with Tri-Staple™ Technology | Black | 4 mm, 4.5 mm, 5 mm |

*Reorder codes EGIA45AV and EGIA45CTAV, while offering a slimmer fixed anvil, are vascular reloads that do not come with Tri-Staple™ Technology.

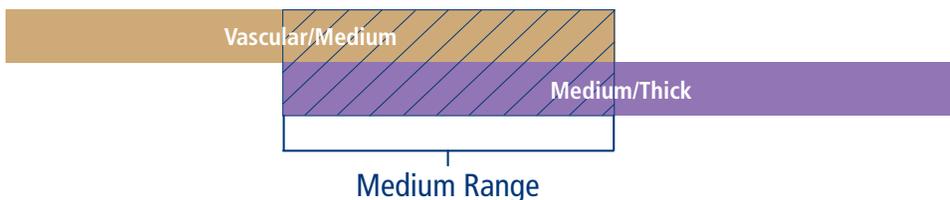
Staple Reload Selection

Broader Indicated Tissue Thickness Ranges



Endo GIA™ Reloads with Tri-Staple™ Technology – Reload Selection for Medium Tissue†

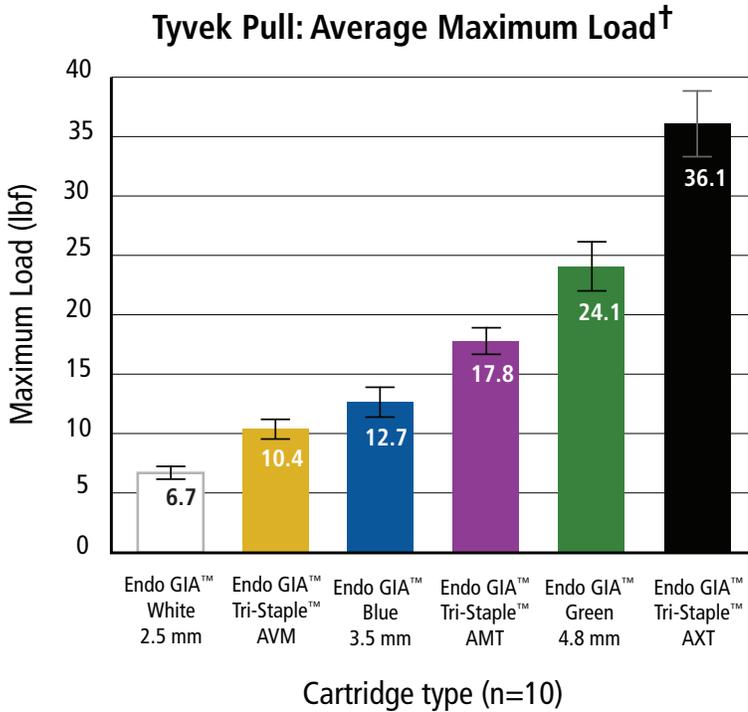
- Both tan and purple reloads with Tri-Staple™ technology are intended to be used on tissue described as “Medium”



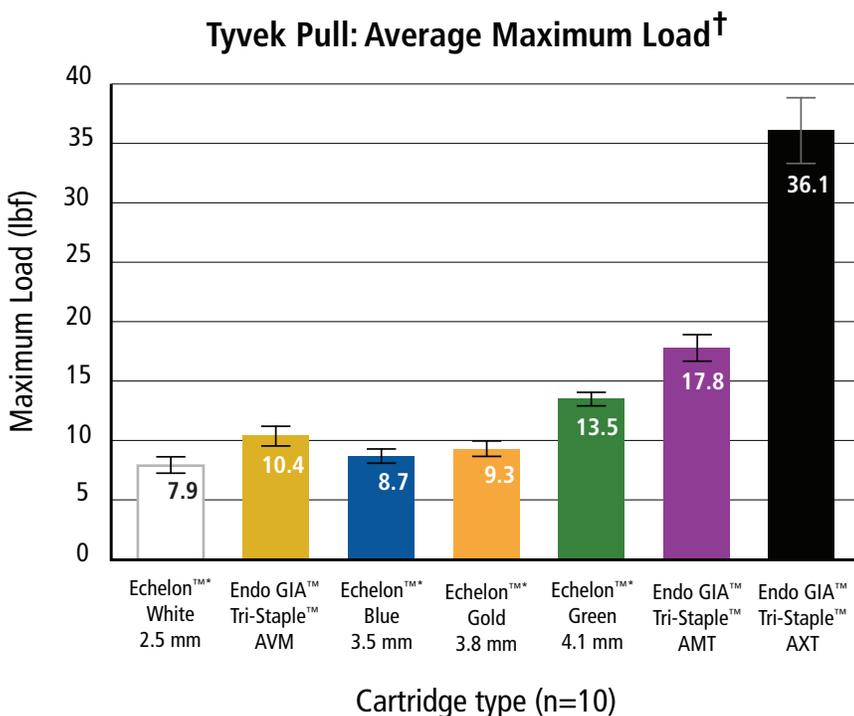
- Tan reloads may show improved performance compared to Purple Reloads at the lower end of the medium range. The lower end of the “Medium Range” of tissue thickness may be within the upper end of the intended tissue thickness range for tan reloads. If a surgeon perceives the tissue to be thinner/medium, then a tan reload may be appropriate
- Endo GIA™ reloads with Tri-Staple™ technology show equivalent performance compared to Endo GIA™ Universal reloads at the lower end of their intended range of use and improved performance compared to Endo GIA™ Universal reloads at the higher end of their intended range of use

Tyvek Pull Apart Testing

Uncompromised Staple Line Strength



Staple lines were fired into Tyvek® media and pulled apart until failure (n=10). These tests demonstrated that the Endo GIA™ with Tri-Staple™ technology provides superior ($p < 0.004$) staple line strength compared to Echelon™ and Endo GIA™ Universal™ stapling product. The Endo GIA™ AVM (tan) reload with Tri-Staple™ technology is at least 30% stronger than both Echelon™ and Universal™ white reloads. The Endo GIA™ AMT (purple) reload with Tri-Staple™ technology is at least 30% stronger than Echelon™ (blue, gold and green) and Universal™ blue reloads. The Endo GIA™ AXT (black) reload with Tri-Staple™ Technology has more than double the strength compared to the Echelon™ green reload.

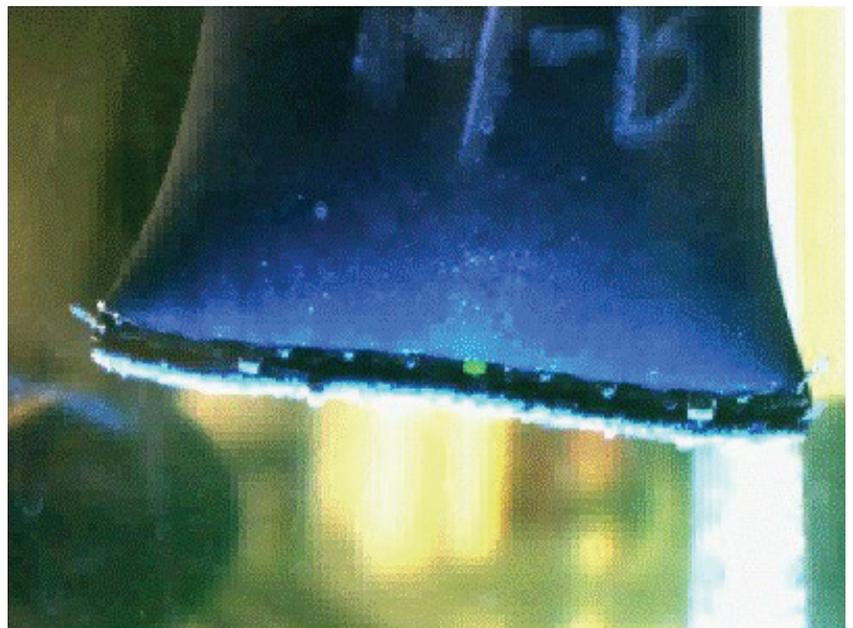
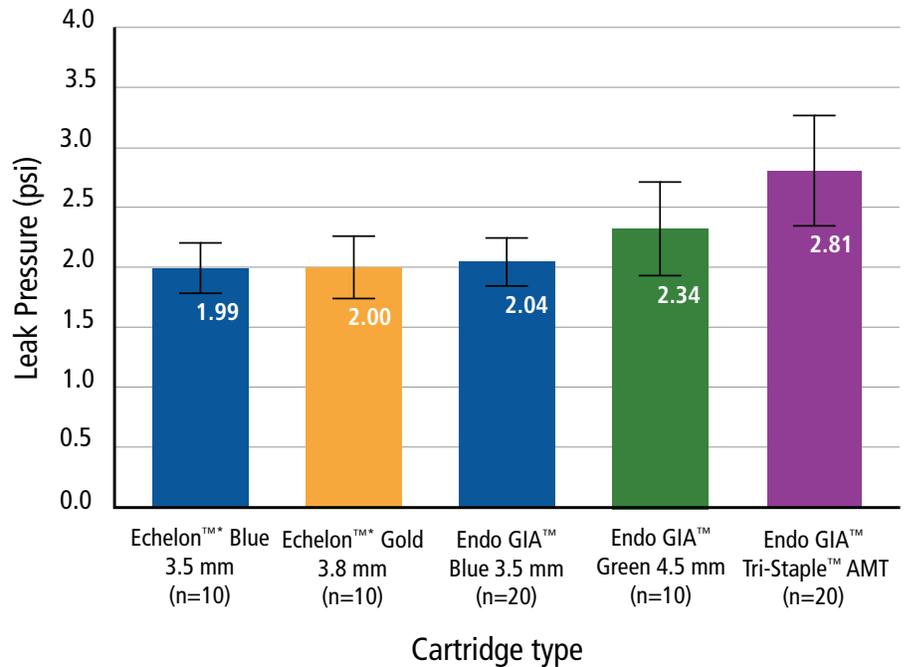


In-Vitro - Leak Comparison

Superior Leak Resistance

Reloads were fired across a synthetic media tube creating a pouch. Fluorescently dyed water was infused into the pouch until a leak was detected and the corresponding pressure was recorded. Test results demonstrate that the Endo GIA™ AMT (purple) reload with Tri-Staple™ technology improves ($p < 0.03$) intra-luminal leak pressures by 20% compared to the Universal green and almost 40% compared to the Universal™ blue and Echelon™ (blue and gold) reloads.

Preliminary In-vitro Comparison of Leak Pressure

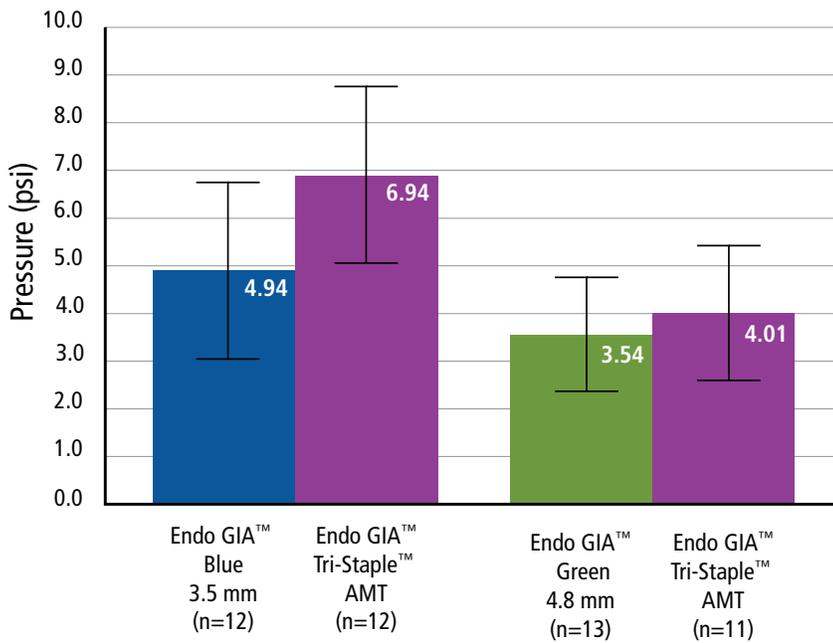


In-Vivo—Leak Comparison

Reliable Results Across

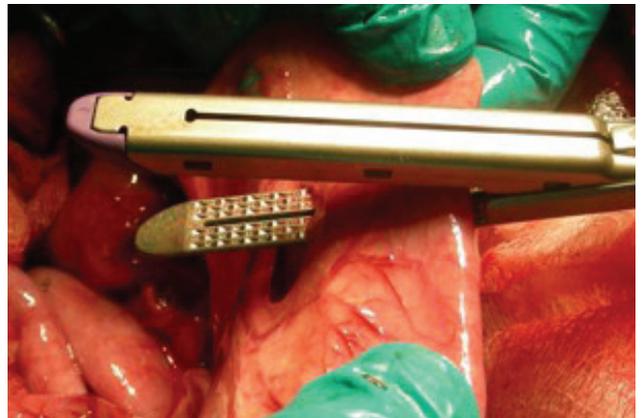
Broader Tissue Thickness Range

In-Vivo Leak Pressure†



Comparative reloads were fired across a section of bowel creating a pillow. Fluorescently dyed water was infused into the pillow until each staple line leaked and the corresponding pressures were recorded. Test results demonstrate that for intra luminal leak pressures, the Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology were:

- Superior with statistical significance (40% improvement, $p = 0.015$) to Endo GIA™ Universal blue reloads
- Statistically equivalent (10% improvement, $p = 0.47$) to Endo GIA™ Universal green reloads



In-Vivo—Leak Comparison

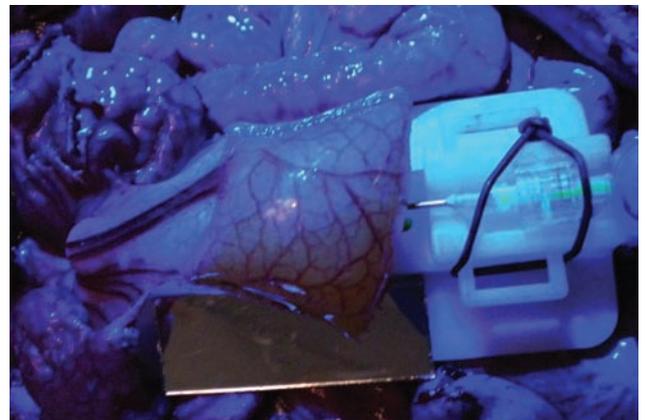
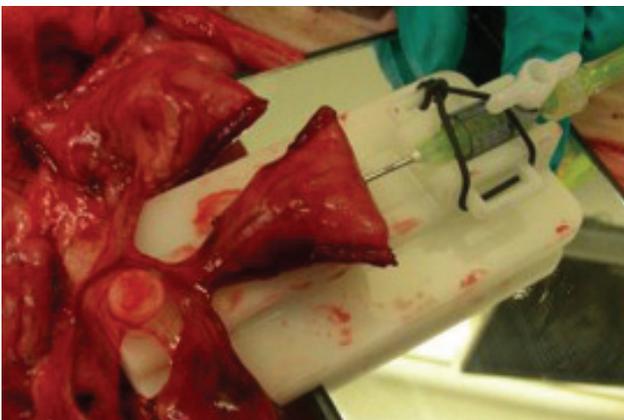
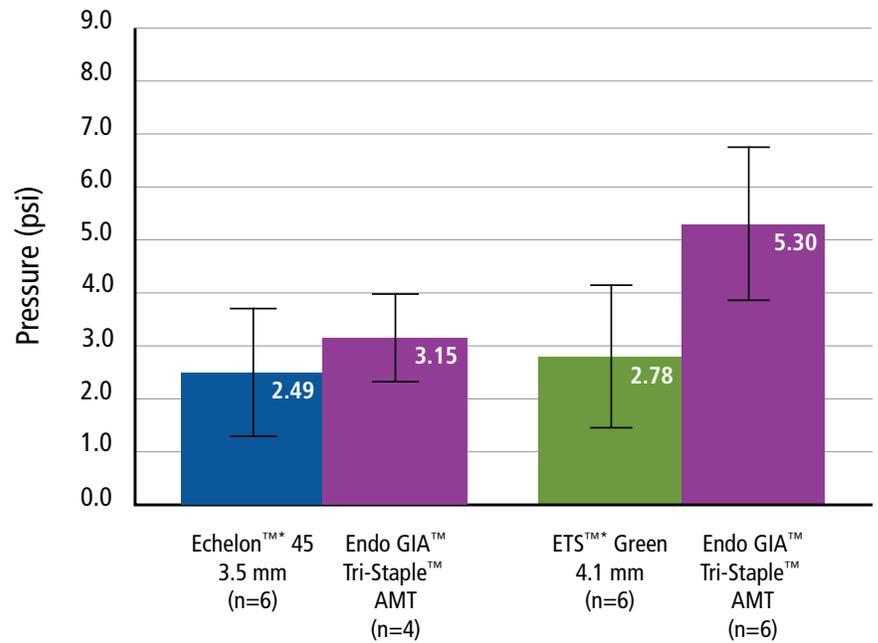
Reliable Results Across
Broader Tissue Thickness Range

Test results demonstrate that for intra luminal leak pressures, the Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology were:

- Superior with statistical significance (90% improvement, $p = 0.011$) to the ETS™* green reload
- Statistically equivalent (27% improvement, $p = 0.334$) to Echelon™* blue reloads

The in-vivo leak comparison tests were performed in canine small bowel tissue.

In-Vivo Leak Pressure†



In-Vivo—Hemostasis

Consistent Performance Across a Broader Range of Tissue

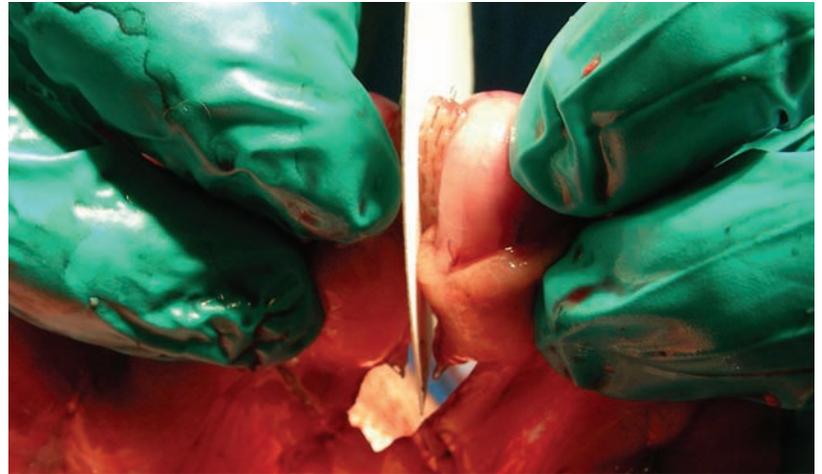
Hemostasis was performed by transecting bowel with the stapler and then collecting and weighing the amount of blood lost at the anastomotic lip. Blood was collected for 30 seconds every minute until additional blood loss was less than 5% of the total.

As per preliminary in-vivo tests, Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology showed an amount of blood loss which was statistically equivalent to that of the Endo GIA™ Universal blue reloads.

The purple reloads had less blood loss than the Endo GIA™ Universal green reloads, although the difference was not statistically significant.

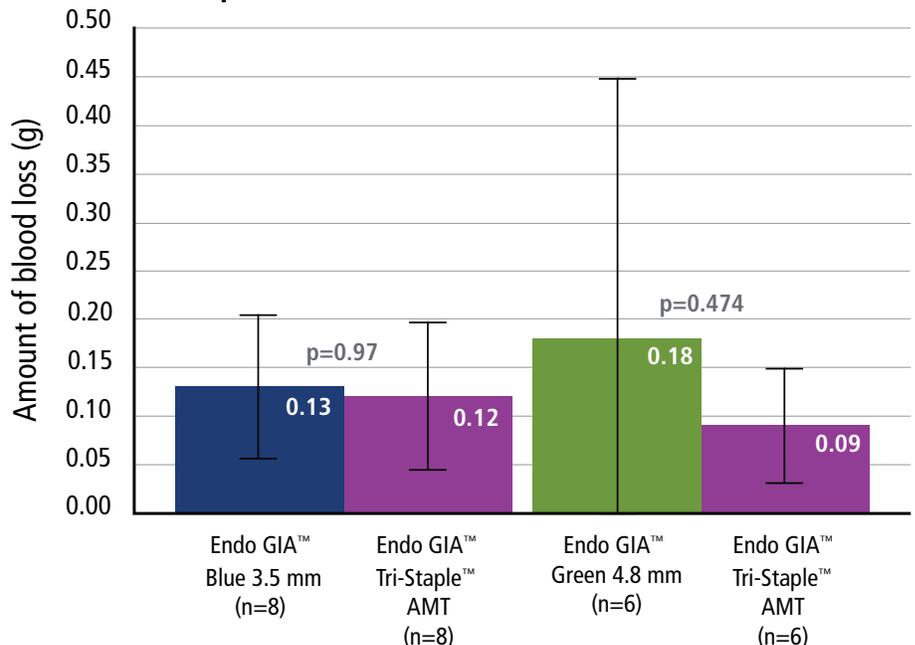
This indicates that within its applicable broader tissue thickness range, the Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology demonstrates a consistent hemostatic performance across the entire range, which covers the tissue thickness range of both blue and green reloads.

The in-vivo hemostasis tests were performed in canine small bowel tissue.



Endo GIA™ purple medium/thick reload with Tri-Staple™ technology demonstrates consistent hemostatic performance across entire range of blue and green reloads.

Hemostasis Tri-Staple™ AMT vs Universal Blue and Green†



In-Vivo—Hemostasis

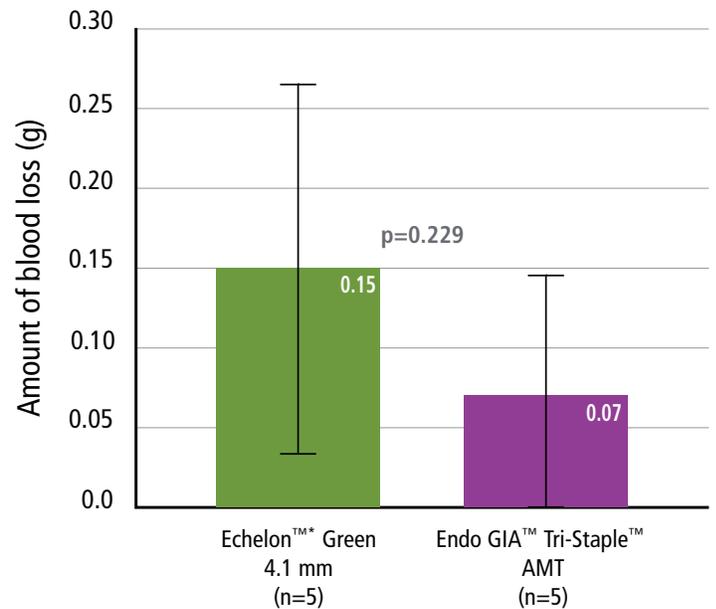
Consistent Performance Across
a Broader Range of Tissue

On preliminary in-vivo tests, Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology showed an amount of blood loss which was statistically equivalent to that of Echelon™ green reloads within the indicated tissue thickness range.

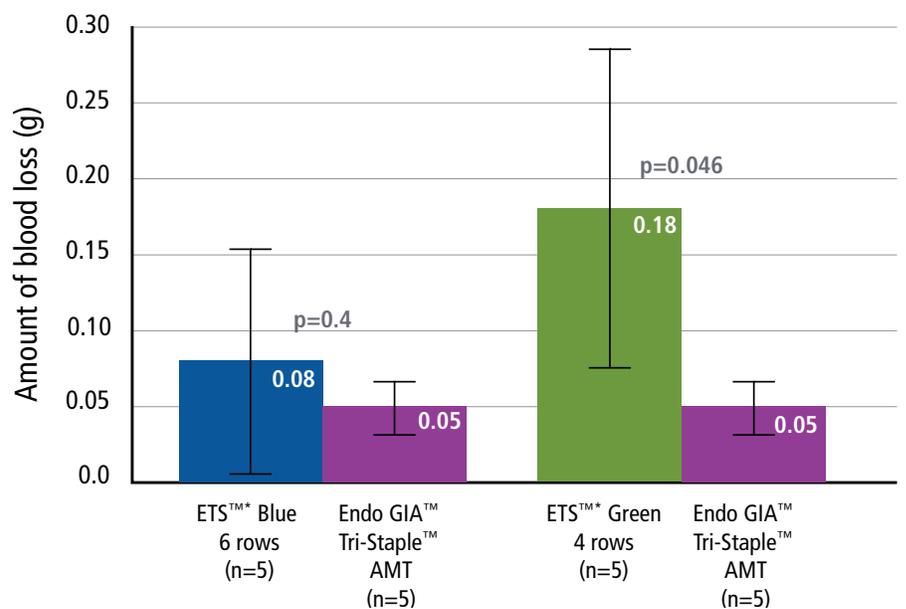
The tests also depicted that the blood loss on Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology was statistically equivalent to the blood loss on Ethicon ETS™ blue reloads within the indicated tissue thickness range.

The blood loss on Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology was lower compared to the blood loss on Ethicon ETS™ green reloads within the indicated tissue thickness range. This was a statistically significant result ($P=0.046$) and therefore demonstrates that the hemostasis on purple reload is better than hemostasis on the ETS green reload in an animal model. The in-vivo hemostasis tests were performed in canine small bowel tissue.

Acute Free Bleed: Total Blood Loss†



Acute Free Bleed: Total Blood Loss†



Ex-Vivo—Pneumostasis

Consistent Performance Across a Broader Range of Tissue Thickness

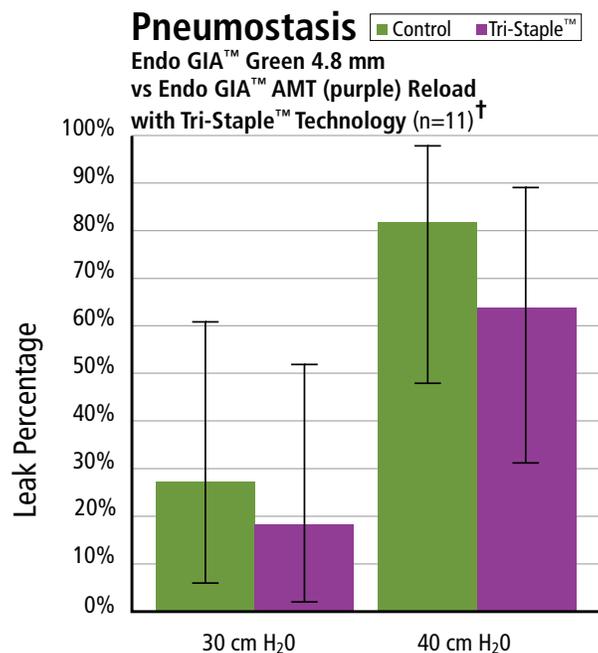
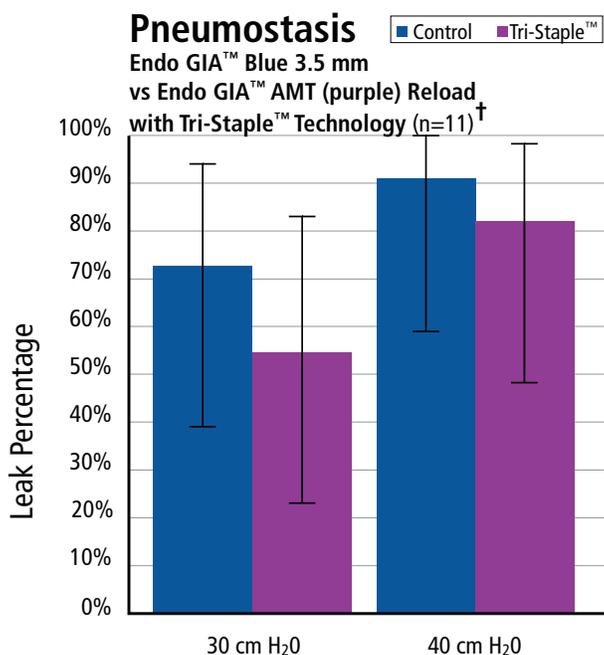
Pneumostasis testing was performed in an ex-vivo method. Lungs and heart were removed from the animal. Control and test staple lines were fired on contra-lateral lobes of the lung, which were then insufflated to 15, 20 30 and 40 cmH₂O. Pressures at which air leaked from the staple line were recorded.

Under match paired ex-vivo testing, Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology showed a decrease in acute air leaks when compared with the Endo GIA™ Universal blue reload. The decrease was about 26% at 30 cm H₂O pressure and about 9% at 40 cm H₂O pressure. The testing was done within the indicated tissue thickness ranges and the results are shown with 95% confidence intervals based on sample size.

Under similar testing conditions, Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology showed a decrease in acute air leaks when compared with the Endo GIA™ Universal green reload. The decrease was about 33% at 30 cm H₂O pressure and about 23% at 40 cm H₂O pressure. The testing was done within the indicated tissue thickness ranges and the results are shown with 95% confidence intervals based on sample size.

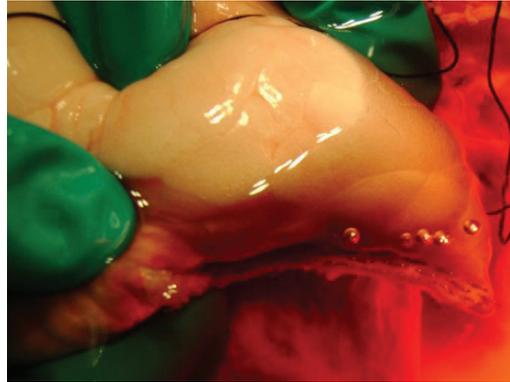


The ex-vivo pneumostasis tests were performed in porcine and canine lung tissue.



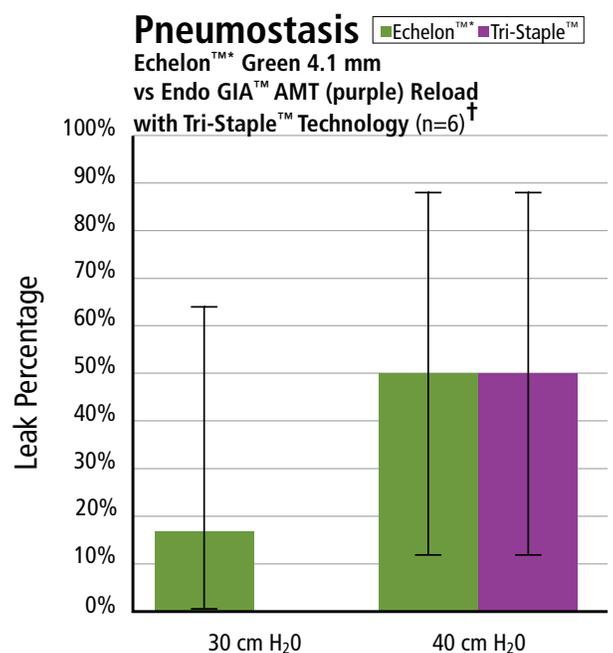
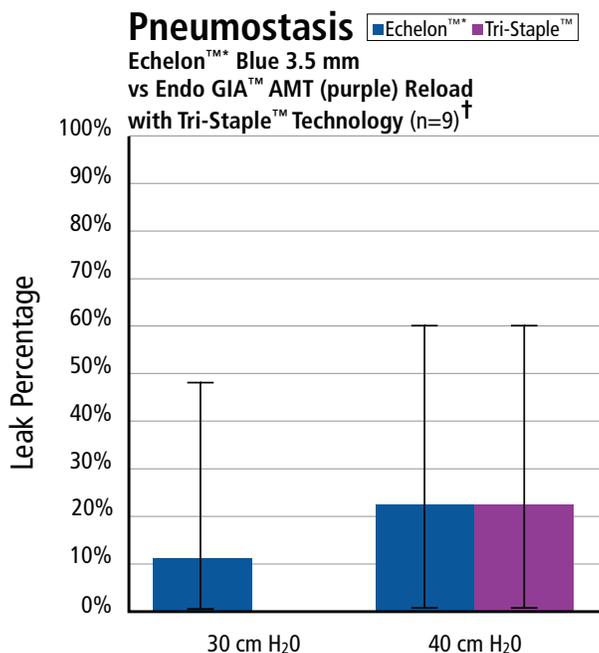
Ex-Vivo—Pneumostasis

Consistent Performance Across
a Broader Range of Tissue Thickness



Under match paired ex-vivo testing, Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology showed no acute air leaks at 30 cm H₂O pressure while Echelon™* blue reloads showed a 10% incidence of acute air leaks at 30 cm H₂O pressure. At 40 cm H₂O pressure both reloads exhibited similar incidence of acute air leaks. The testing was done within the indicated tissue thickness ranges and the results are shown with 95% confidence intervals based on sample size.

Under similar testing conditions, Endo GIA™ AMT (purple) reloads with Tri-Staple™ technology showed no acute air leaks at 30 cm H₂O pressure, while Echelon™ green reloads showed a 17% incidence of acute air leaks of 30 cm H₂O pressure. At 40 cm H₂O pressure both reloads exhibited similar incidence of acute air leaks. The testing was done within the indicated tissue thickness ranges for each type of reload/cartridge tested and the results are shown with 95% confidence intervals based on sample size.



G.I. Chronic Study

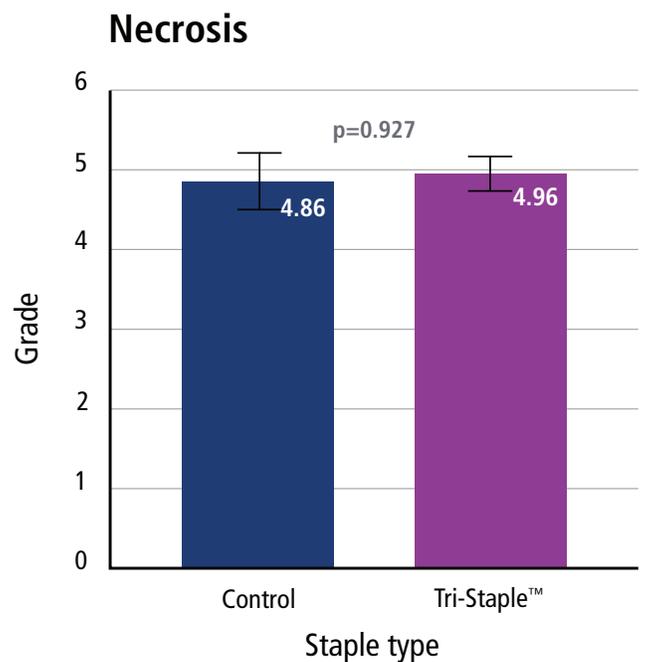
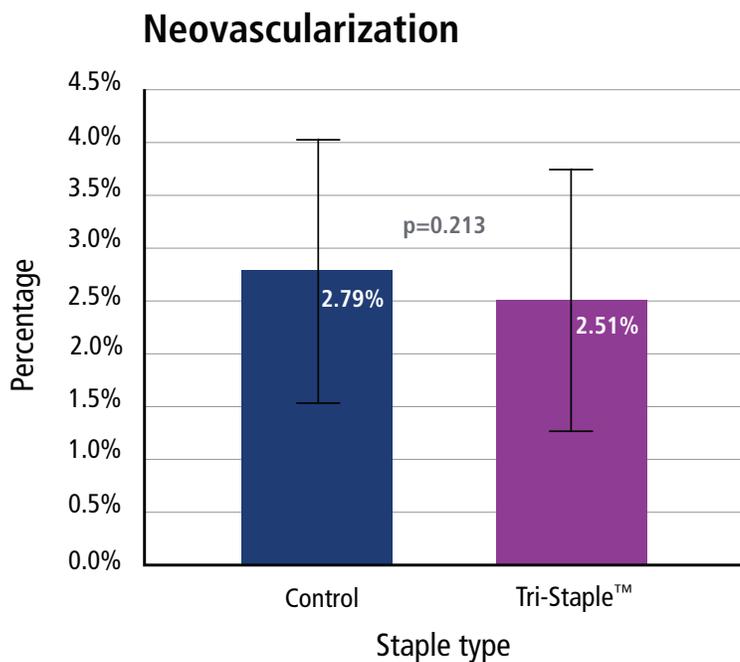
Consistent and Reliable Outcomes

Healing markers (shown below) measured within the staple line and averaged among all tissue types (stomach, bowel, colon) and all end points (7, 14, 28 day)

Neovascularization: regrowth of vasculature into healing tissue. Higher percentage is more regrowth

Necrosis: tissue death; grade scale where 5 = no necrosis

The control was the Endo GIA™ Universal blue reload
Values are statistically equivalent (n=51)



G.I. Chronic Study

Consistent and Reliable Outcomes

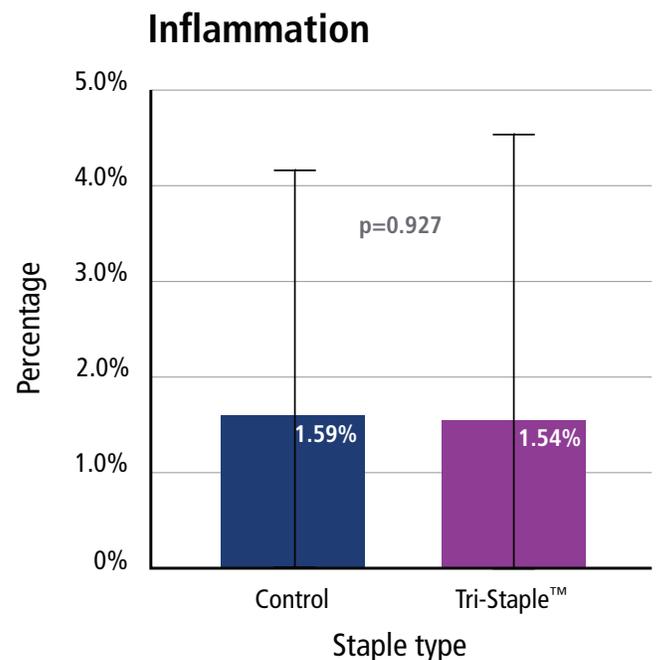
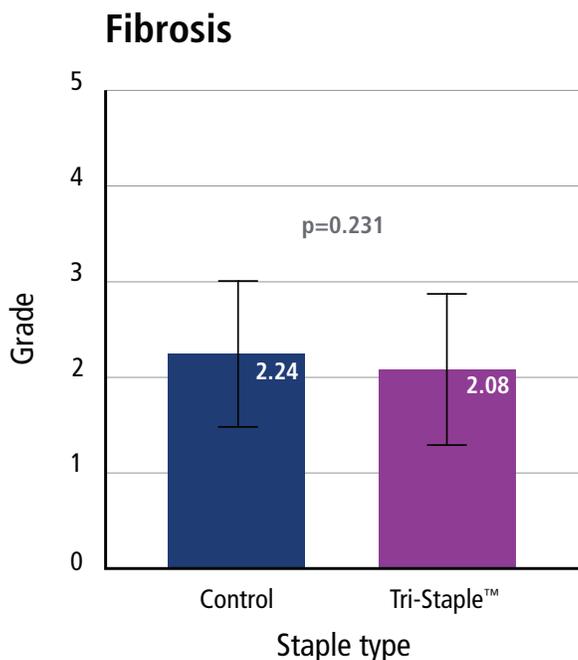
Healing markers (shown below) measured within the staple line and averaged among all tissue types (stomach, bowel, colon) and all end points (7, 14, 28 day):

Fibrosis: development of connective tissue in a reparative process; necessary for healing (Grade 5 = no fibrosis)

Inflammation: biological response of tissue, both positive and negative; it is necessary for tissue healing although it is also responding to a pathogen

The control was the Endo GIA™ Universal blue reload
Values are statistically equivalent (n=51)

Chronic study was performed at independent facility under the direction of Covidien R&D personnel. All histological and statistical analysis of the data was performed by independent companies.



Thoracic Chronic Study

Consistent and Reliable Outcomes

Healing markers measured within the staple line:

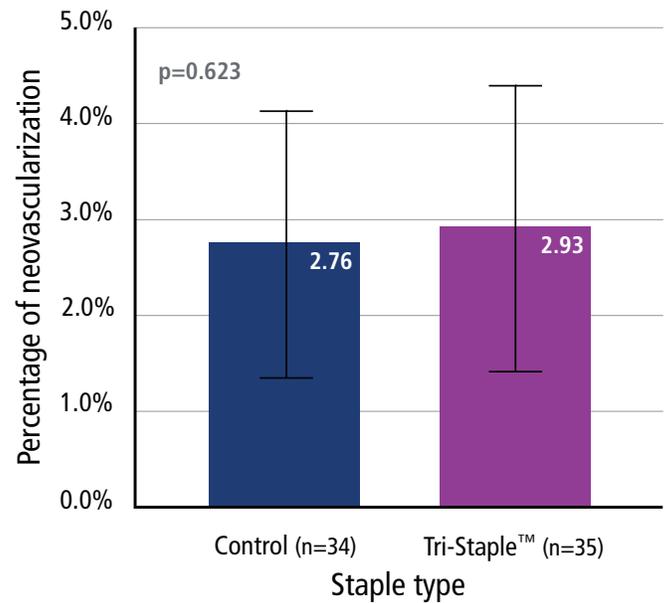
Neovascularization: regrowth of vasculature into healing tissue; a larger percentage indicates more regrowth

Necrosis: tissue death

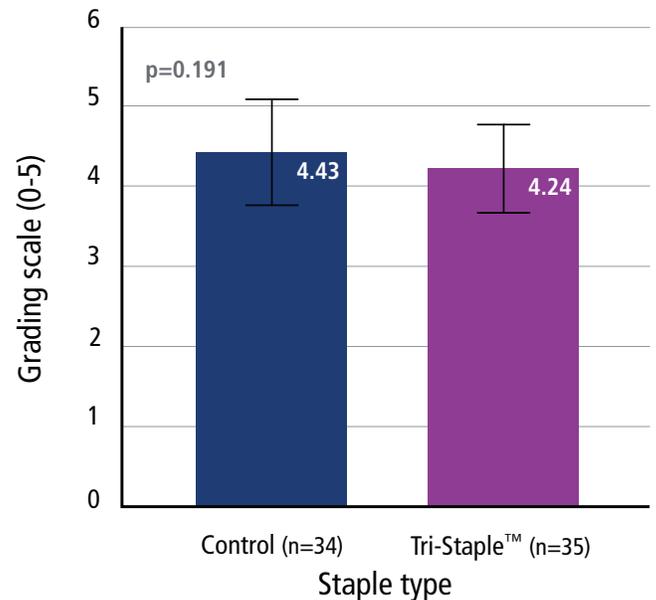
Since Grade 5 is equal to no necrosis, the relatively high grades shown to the right indicate that the tissue is repairing itself with little tissue death

The control was the Endo GIA™ Universal blue reload
Values are statistically equivalent

Neovascularization



Necrosis



Thoracic Chronic Study

Consistent and Reliable Outcomes

Healing markers measured within the staple line:

Fibrosis: development of connective tissue in a reparative process; necessary for healing

Since Grade 5 is equal to no fibrosis, the relatively low grades shown above indicate that the tissue is healing

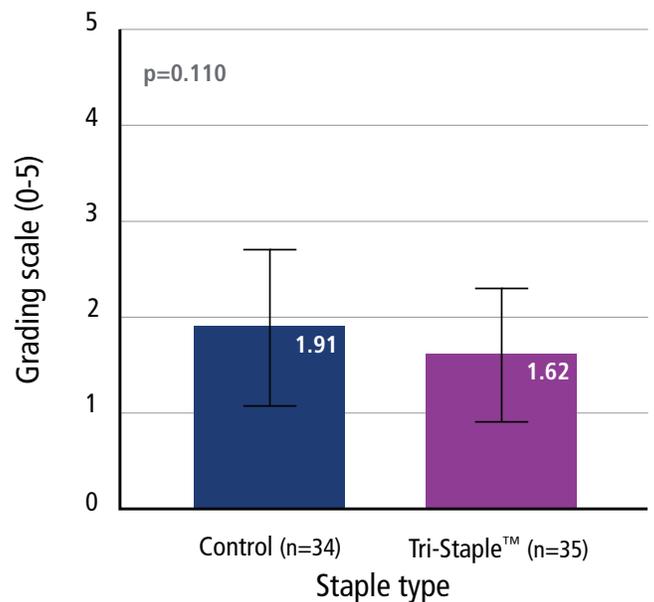
Inflammation: biological response of tissue, both positive and negative; it is necessary for tissue healing although it is also responding to a pathogen

Shown below to be decreasing as time increases, which is assumed to be a foreign body response

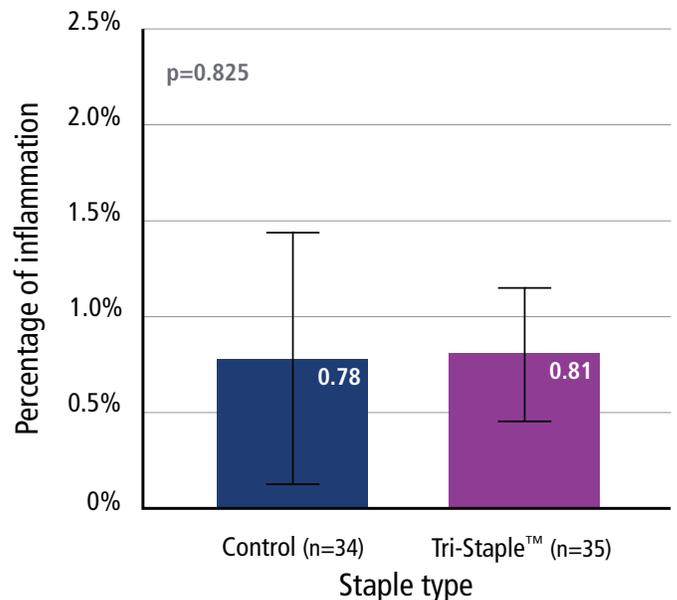
The control was the Endo GIA™ Universal blue reload
Values are statistically equivalent

Chronic study was performed at independent facility under the direction of Covidien R&D personnel. All histological and statistical analysis of the data was performed by independent companies.

Fibrosis



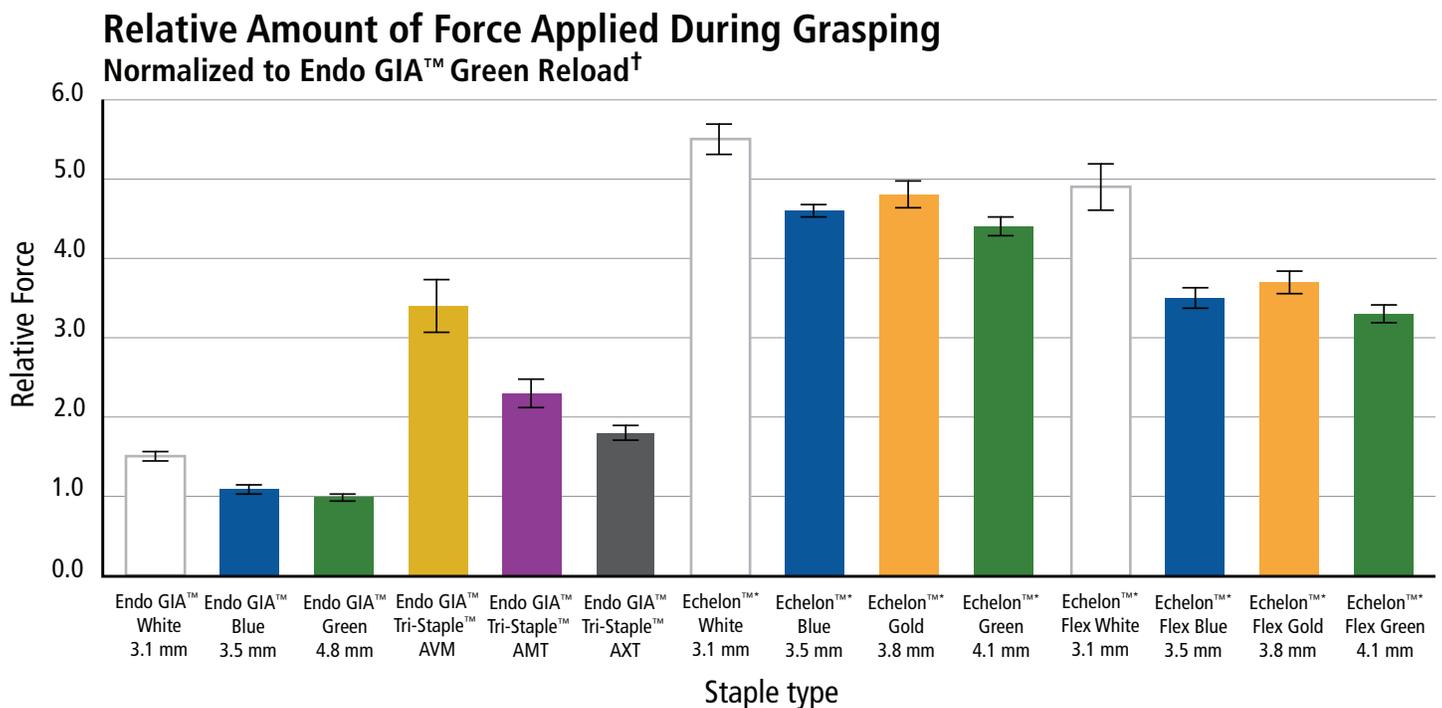
Inflammation



Relative Grasping Force

Improved Tissue Retention

Relative force during clamping was performed utilizing a thin film pressure transducer (Tekscan, Inc) positioned between two pads of red foam. Each reload type was tested five times and the initial clamping force for each reload was normalized with respect to the Endo GIA™ green reload. Results show that the Tri-Staple™ AVM (tan) and AMT (purple) reloads have over two times the clamping force compared to their respective Endo GIA™ reloads (white, blue and green). The AXT (black) reload, which has been specifically designed for extra thick tissue, has over 1.5 times clamping force compared to the Endo GIA™ green reload. The Echelon™ Straight and Flex handles, which utilize the same reload cartridges, apply 2 and 1.5 times the clamping force, respectively compared to the Tri-Staple™ AMT purple reload.



†The indicated tissue thickness ranges of the reloads/ cartridges covered within this brochure are as follows:

Endo GIA™ Universal Reloads

| | |
|-------|--------------|
| White | 1 – 1.5 mm |
| Blue | 1.5 – 2.0 mm |
| Green | 2.0 mm |

Endo GIA™ Reloads with Tri-Staple™ Technology

| | |
|--------|---------------|
| Tan | 0.88 – 1.8 mm |
| Purple | 1.5 – 2.25 mm |
| Black | 2.25 – 3.0 mm |

Ethicon Echelon™* Reloads

| | |
|-------|--------|
| White | 1.0 mm |
| Blue | 1.5 mm |
| Gold | 1.8 mm |
| Green | 2.0 mm |

Ethicon ETS™* Reloads

| | |
|-------|--------|
| White | 1.0 mm |
| Blue | 1.5 mm |
| Green | 2.0 mm |



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