

# 3-D staples are designed for more uniform tissue compression to reduce risk of staple line leaks

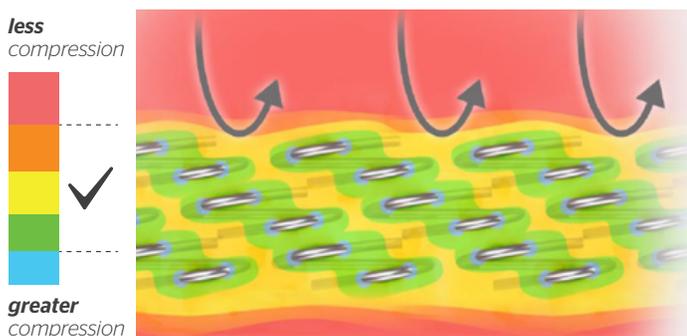
**Studies conducted by:** Dwight Henninger, Jason Jones, Jeffrey W Clymer, Ethicon, Inc., Cincinnati OH  
Results from this study have not been subject to external scientific peer review.

## Background

Although the overall rate of anastomotic leakage in gastrointestinal surgery is low, there is still room for improvement via advances in medical or procedural care. The Ethicon Linear Cutter\* (Ethicon, Inc.) offers design advantages intended to produce more uniform tissue compression to reduce the risk of staple line leaks or bleeding through the staple line.

Its innovative 3-D staple technology with offset legs distributes the tissue compression load over a greater surface area. This creates a larger effective zone of compression around the 3-D staple. A pattern of 3-D staples creates more uniform staple line compression than B-form staple because the zones of compression around each staple overlap more. This reduces the risk of low-pressure pathways in the staple line that could lead to staple line leaks or bleeding (Figure 1).

**Figure 1. 3-D staple zones of compression**



This ex vivo study was performed to evaluate staple line leak pressure for Ethicon Linear Cutter (NTLC75 Ethicon) and compare to Covidien DST Series™ GIA™† (GIA80 Medtronic).

## Methods

Devices were fired following the manufacturer's Instruction for Use on porcine bowel segments with tissue thicknesses ranging from 1.0mm to 3.0mm. A precompression period of 15 seconds was used prior to firing the devices.

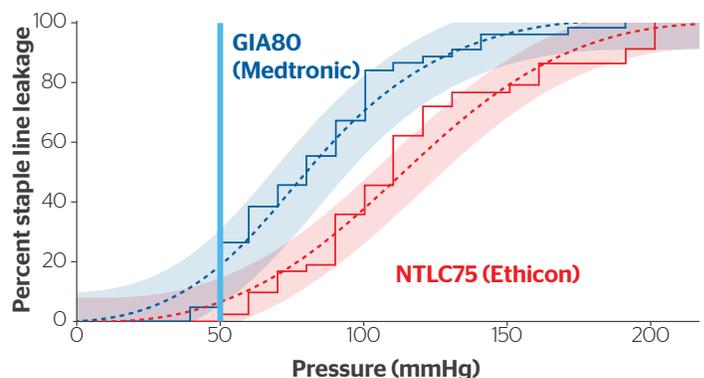
The stapled bowel segments were evaluated for staple line leaks (pressure at first leak) as intraluminal pressure was increased in 10mmHg increments from 20 - 200mmHg. A statistical analysis of staple line leakage pressure results was conducted using device, firing number, side (left, right) and tissue thickness as covariates.

## Results

There was no statistically significant difference in firing number, side, or tissue thickness between NTLC75 and GIA80. NTLC75 had 90.7% fewer staple line leaks at or below 50mmHg than GIA80 ( $p < 0.001$ ) and 40% fewer staple line leaks at or below 100mmHg than GIA80. The proportion of luminal staple line leakage occurring at or below a pressure of 100mmHg was 48% lower for NTLC75 than GIA80 ( $p = 0.008$ ).

The mean luminal staple line leak pressure was 40.3% higher for NTLC75 than GIA80 ( $p < 0.001$ ).

**Cumulative proportion of luminal staple line leakage showing a higher rate of leakage at or below 50mmHg for GIA80 (Medtronic)†, and higher mean leak pressures for NTLC75 (Ethicon)\***



## Conclusion

The Ethicon Linear Cutter had fewer staple line leaks at clinically relevant pressures and had a higher resistance to staple line leaks than the DST Series GIA.

The Ethicon Linear Cutter with innovative 3-D staple technology helps reduce staple line leakage compared to DST Series GIA.‡

‡Benchtop testing of luminal leak pressure in an excised animal tissue model. Hemostasis assessment based on visual inspection of vessels after transection in an animate porcine model.

\*Ethicon Linear Cutter (NTLC75), †Covidien DST Series™ GIA80™ (GIA808038S).

For complete product information, including full steps for use, indications, contraindications, warnings and precautions, please see the Instructions for Use. Third-party trademarks used herein are trademarks of their respective owners.

©2017 Ethicon, Inc., All Rights Reserved. 078067-170807