

## Clinical summary

Medtronic provides the following synopsis of a clinical publication involving the three-row EEA™ circular staplers with Tri-Staple™ technology

### Preliminary evaluation of two-row versus three-row circular staplers for colorectal anastomosis after rectal resection: a single-center retrospective analysis.

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#### Introduction

In colorectal surgery, Anastomotic leakage (AL), haemorrhage (AH) and anastomotic stenosis (AS) represent the most feared adverse events.<sup>1,2</sup> Of these, anastomotic leakage is the most severe, associated with increased mortality, risk of cancer reoccurrence, decreased long term survival, and reduced quality of life.<sup>1,3,4</sup>

#### Purpose of the study

Tri-Staple™ technology is based on three rows of varied height staples and aims to guarantee a higher resistance of the anastomotic site, with less stress on the tissue delivered through the sloped cartridge face vs. double staple lines. No previous research has directly compared two-row circular staplers to three-row circular staplers to confirm these hypothetical benefits. This retrospective, single centre case-control study aimed to compare these two devices, with a primary outcome of the rate of post-operative anastomotic leakage. Secondary aims are the rate of AS and AH.

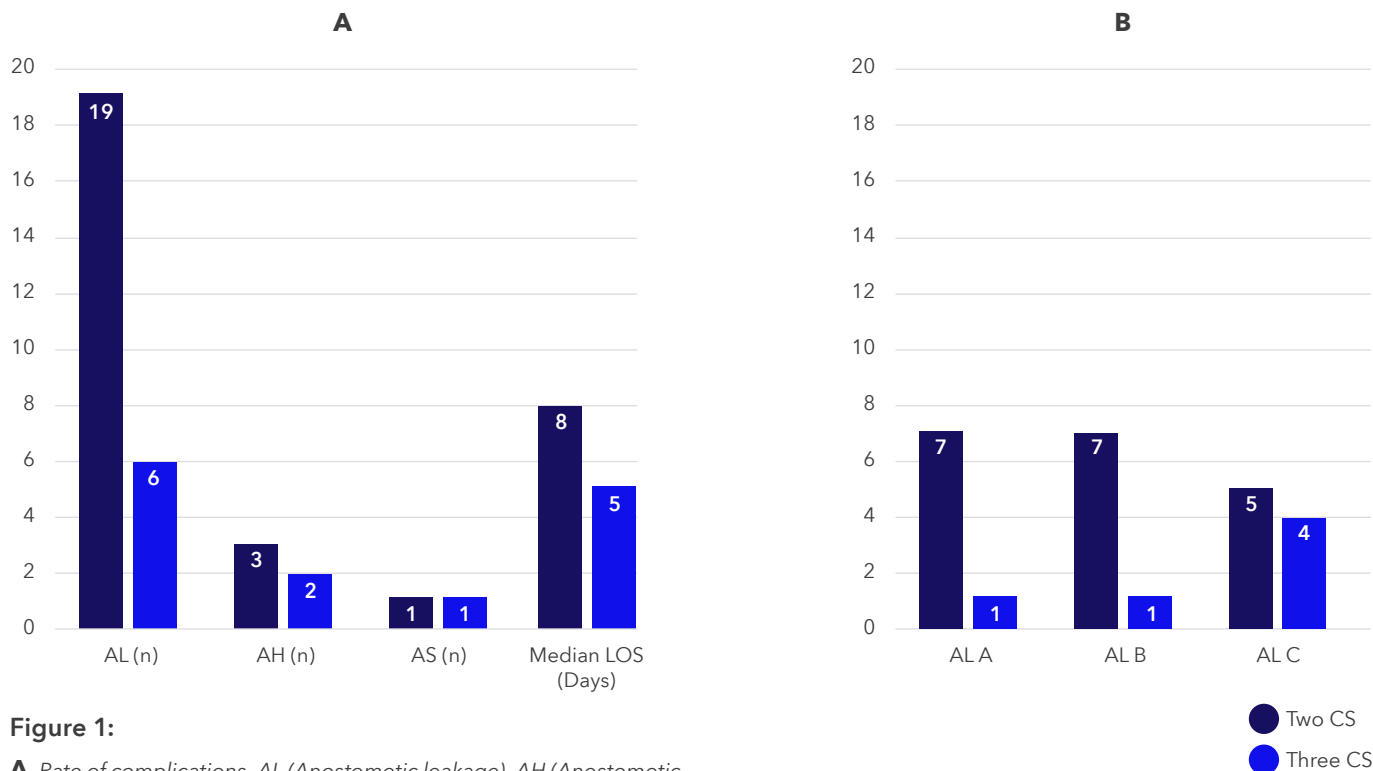
#### Methods

- 375 patients who underwent a curative rectal resection with a mechanical end-to-end reconstruction at the Digestive Surgery Unit of the Fondazione Policlinico Universitario Agostino Gemelli IRCCS of Rome. 197 procedures (52.5%) were performed using Two-CS (Ethicon™ circular stapler or Medtronic DST™ EEA™), while the Three-CS (Medtronic EEA™ circular stapler with Tri-Staple™ technology) was employed in the remaining 178 procedures (47.5%).
- AL was defined according to the International Study Group of Rectal Cancer.
- AL Severity grades; A - only radiological evidence of leak, B - leak requiring antibiotics or percutaneous drain, C - symptomatic leak requiring reoperation.

#### Results

- AL incidence was significantly higher in Two-CS patients (9.6%) vs. Three-CS patients (3.4%). No difference in two vs three-CS in AL severity.
- Median length of hospital stay was longer in the Two-CS group vs Three-CS group (8 days vs 5 days,  $p < 0.0001$ )
- No difference in the incidence of AH or AS
- No differences in patient characteristics or tumor location.
- Minimally invasive procedure was performed in 95.5% of Three-CS group and 71.5% in the Two-CS group ( $P < 0.0001$ )
- No difference in surgery duration, intraoperative blood loss, conversion rate, hydro-pneumatic test and diverting ostomy rate.

	Two-CS (n=197)	Three-CS (n=178)	P value
AL, n (%)	19 (9.6)	6 (3.4)	0.01
<b>AL severity grade, n (%)</b>			
A	7 (36.8)	1 (16.7)	0.2
B	7 (36.8)	1 (16.7)	
C	5 (26.3)	4 (66.7)	
<b>Seroma size (ml)</b>			
AH, n (%)	3 (1.5)	2 (1.1)	0.73
AS, n (%)	1 (0.5)	1 (0.6)	0.94
Length of Hospital stay	8 (6-11)	5 (4-6)	<0.0001



**Figure 1:**

**A** Rate of complications, AL (Anastomotic leakage), AH (Anastomotic haemorrhage), AS (Anastomotic stenosis), LOS (Length of hospital stay).

**B** Rate of anastomotic leakage by severity grade A C

### Predictive factors for AL incidence

- AL onset was significantly associated to a BMI >25 (P = 0.05), to tumors located in the middle/low rectum (p <0.0001) and to Two-CS (p = 0.01)

### Conclusion

This retrospective comparison analysis has shown the potential positive impact of Tri-Staple™ technology in reducing AL rate after rectal resection even for low rectal tumours, while maintaining similar rates of AS and AH in comparison to Two-CS. Further clinical evidence is needed to explore this possible positive contribution of Tri-Staple™ technology, in the form of prospective controlled trials, in reducing the incidence of AL.

### This concludes the clinical synopsis of this publication

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