

# Clinical summary

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

## Three-row versus two-row circular staplers for left-sided colorectal anastomosis: a propensity score-matched analysis of the iCral 2 and 3 prospective cohorts

Marco Catarci, Stefano Guadagni, Francesco Masedu, Giacomo Ruffo, Massimo Viola, Felice Borghi, Gianandrea Baldazzi, Marco Scatizzi. *International Journal of Surgery*. 2023 Aug 1;109(8):2312-2323. doi: 10.1097/JS9.0000000000000480

### Introduction

Early anastomotic adverse events, such as leakage (AL) and bleeding (AB), remain the Achilles heel of any colorectal anastomosis. These lead to prolonged post-operative stay, increased costs, risk of reoperation, permanent colostomy as well as increasing the risk of overall morbidity and mortality<sup>1,2</sup>. Successful healing of any anastomosis relies on an effective blood supply, micro-perfusion of the anastomotic tissue and on the mechanical strength of the newly formed anastomosis<sup>3</sup>.

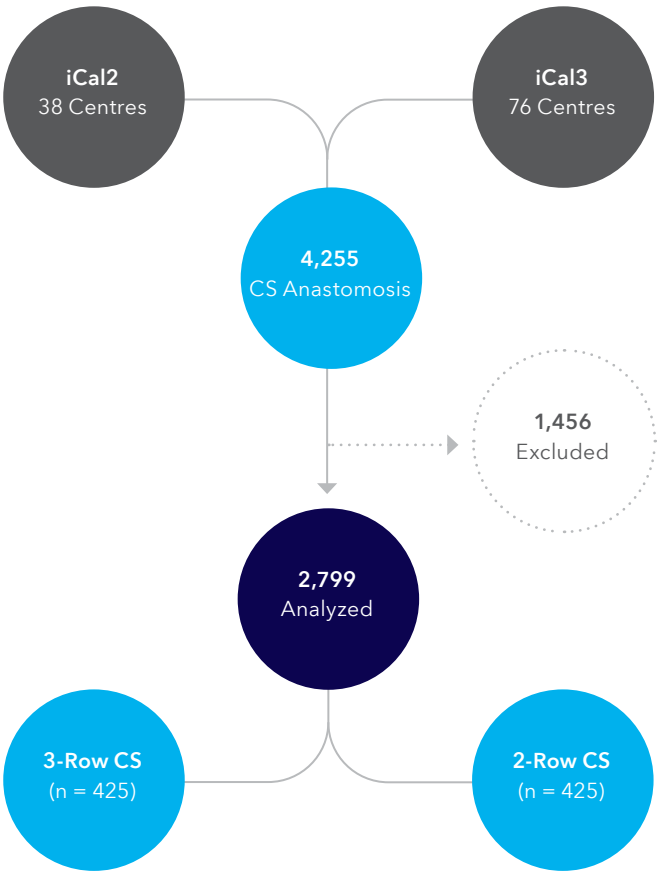
### Purpose of the study

To evaluate the effectiveness of a three-row Circular Stapler (CS) in reducing the risk of overall and major anastomotic leakage and overall anastomotic bleeding in left colectomy and/or anterior resection with end-to-end stapled colorectal anastomosis.

### Methods

This was a retrospective analysis of a prospective database of patients who underwent colorectal resection and anastomosis for malignant and benign diseases. Patients were enrolled in two consecutive studies: iCral2<sup>5</sup> and iCral3<sup>6</sup> then a PSMA (Propensity Score-Matching Analysis) was done using 20 covariates to adjust for heterogeneity between the two groups.

Procedure	Colorectal resection and anastomosis for malignant and benign diseases with anastomosis using circular stapler (lap, robotic, open, or converted)
Devices	<b>Two-row CS</b> (Medtronic, Touchstone and Ethicon [Powered and Manual]) vs. <b>Three-row CS</b> (Medtronic Manual)
Primary endpoint	Overall AL (any AL), major AL (any AL grade >II), and AB
Secondary endpoints	Overall morbidity, major morbidity (any adverse event grade >II), and mortality (any death)



**Figure 1**  
4,255 cases were screened and 2,799 were included in this analysis. Following PCM, 425 patients were included in each group.

- Randomized controlled trials (RCT) are the gold standard for comparing effects of interventions on clinical outcomes.
- Propensity score matching (PCM) is a statistical tool that can be applied to observational studies so that they can mimic aspects of RCTs<sup>4</sup>.
- PCM was used in this retrospective study to adjust for differences between the two groups.

## Results

- Three-row CS showed a significantly lower risk of overall anastomotic leakage [2.1% vs. 6.1%,  $p = 0.006$ ] and major anastomotic leakage vs. two-row CS group [2.1% vs. 5.2%,  $p = 0.022$ ].
- A significantly lower risk of major morbidity was recorded in Three-row vs two-row CS [3.5% vs. 6.6%,  $p = 0.026$ ].
- No difference for the risk of Anastomotic Bleeding, overall morbidity or mortality.

## Strengths

1. **Method** – The PSM analysis performed on these two large prospective multicentre studies matched the EQUATOR (Enhancing the QUALity and Transparency Of Health Research) network reporting guidelines, unlike previous works<sup>7</sup>.
2. Large number of enrolled patients in a large number of centers across Italy (62 hospitals involved).
3. Increasingly, data from large observational cohorts, as in this case, are increasingly being used to evaluate important clinical questions where data from RCTs is limited or does not exist<sup>8</sup>.

## Limitations

- Several potential risk factors for AL were not measured or recorded in the parent studies
- To maintain the strong PSMA methodology, individual comparisons with two row devices could not be made due to variation in the number of cases.

## Conclusion

- **Use of the three-row CS rather than a two-row CS resulted in a significant and independent 4% absolute risk reduction for overall AL** (3% for major AL and major morbidity), corresponding to the need to treat 25 patients to avoid one AL. This includes both manual and powered two-row staplers.

***This concludes the clinical synopsis of this publication***

## References

1. REF-23777. Boccola MA, Buettner PG, Rozen WM, et al. Risk factors and outcomes for anastomotic leakage in colorectal surgery: a single-institution analysis of 1576 patients. *World J Surg* 2011;35:186-95.
2. REF-23778. La Regina D, Di Giuseppe M, Lucchelli M, et al. Financial impact of anastomotic leakage in colorectal surgery. *J Gastrointest Surg* 2019;23: 580-6.
3. REF-23780. Chung RS. Blood flow in colonic anastomoses. Effect of stapling and suturing. *Ann Surg* 1987;206:335-9.
4. REF-23781. Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate behavioral research*. 2011 May 31;46(3):399-424.
5. REF-23783. Catarci M, Ruffo G, Viola MG, et al. ERAS program adherence-institutionalization, major morbidity and anastomotic leakage after elective colorectal surgery: the iCral2 multicenter prospective study. *Surg Endosc* 2022;36:3965-84.
6. REF-23784. The Italian Colorectal Anastomotic Leakage (iCral) study group. Patient reported outcomes and return to intended oncologic therapy after colorectal enhanced recovery pathway: the iCral3 prospective study. *Ann Surg Open* 2023;4:e267.
7. REF-23785. Yao XI, Wang X, Speicher PJ, et al. Reporting and guidelines in propensity score analysis: a systematic review of cancer and cancer surgical studies. *J Natl Cancer Inst* 2017;109:djw323.
8. KCX2841008. Silverman SL. From randomized controlled trials to observational studies. *Am J Med*. 2009 Feb;122(2):114-20. doi:10.1016/j.amjmed.2008.09.030

# Medtronic

© 2024 Medtronic. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. EMEA-ST-2400013-Catarci-Clinical-study-en-gb-EMEA-12108173

[medtronic.com/covidien/uk](https://www.medtronic.com/covidien/uk)