

# Clinical summary

**Medtronic provides the following synopsis of a study that discusses the impact of a three-row vs. two-row circular stapler on anastomotic leakage after rectal cancer surgery using preclinical and multicenter retrospective analysis.**

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**TITLE** Clinical impact of the triple-layered circular stapler for reducing the anastomotic leakage in rectal cancer surgery: Porcine model and multicenter retrospective cohort analysis.

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## WHY THIS IS IMPORTANT

- In porcine models, researchers demonstrated that the three-row circular stapler delivers a staple line with **significantly higher leak pressure** vs. the two-row circular stapler.
- In a multicenter retrospective cohort, researchers found that the three-row circular stapler resulted in **significantly lower anastomotic leak rate** vs. the two-row option.

## BACKGROUND

- The study compared three-row EEA™ circular staplers with Tri-Staple™ technology (TRIEEA) with two-row EEA™ circular staplers with DST Series™ technology (EEA).
- In a preclinical setting, burst pressure testing was done in porcine *ex vivo* models in both end-to-end anastomoses (TRIEEA n = 12; EEA n = 6) and side-to-side anastomoses (TRIEEA n = 6; EEA n = 3). Specimens were pressurized with air until failure. When air leakage began, bursting pressure was measured using a manometer.
- The study also examined a multicenter retrospective cohort of 194 rectal cancer patients from two hospitals in Japan (Kyushu University and National Hospital Organization Kyushu Cancer Center) who underwent colorectal anastomosis with either TRIEEA (n = 41) or EEA (n = 153).
- The median age in the clinical setting was 66 years old, with a median body mass index of 21.9 kg/m<sup>2</sup>. Male patients made up 55% of the cohort.
- Each procedure was performed or supervised by an expert colorectal surgeon who had performed a minimum of 200 laparoscopic colorectal procedures.

- Patients were matched for background characteristics; however, pathological stage was not able to be evenly matched between the two test populations. The TRIEEA patient population had overall higher staged pathology, indicating a riskier patient population ( $P < 0.001$ ).

## DISCUSSION

- In the preclinical study, the three-row stapler demonstrated significantly higher leak protection compared to the two-row stapler:
  - End-to-end anastomoses burst pressure: TRIEEA  $26.4 \pm 6.2$  mm Hg vs. EEA  $14.5 \pm 4.3$  mm Hg ( $P = .0031$ )
  - Side-to-side anastomoses burst pressure: TRIEEA  $27.7 \pm 5.0$  mm Hg vs. EEA  $18.0 \pm 2.9$  mm Hg ( $P = .0275$ )
- In the clinical study, the incidence of anastomotic leakage was 0.0% using three-row staplers compared to 5.8% with two-row staplers ( $P = .0362$ ).
- The clinical study also concluded that these two specific factors were associated with a lower incidence of anastomotic leakage:
  - Use of three-row stapling technology (odds ratio: 0.00, 95% confidence interval: 0.00-0.96,  $P = .0465$ ).
  - Female patients (odds ratio: 0.16, 95% confidence interval: 0.01-0.90,  $P = .0354$ ); researchers noted that this may be due to lower peak interrectal pressure compared to males.
- The study's authors suggest that TRIEEA "may be effective in preventing" anastomotic leakage due to its higher anastomotic bursting pressure compared to two-row staplers.

**\*\*THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION\*\***