

First U.S. Multicenter Pivotal Trial for Magnetic Anastomosis, 79 Patients: No Anastomotic Leaks, Bleeds or Obstructions

Prospective FDA IDE pivotal study evaluated self-forming magnetic compression anastomosis with immediate lumen across six U.S. centers.

CANTON, MA, UNITED STATES, August 4, 2026 /EINPresswire.com/ -- GI Windows Surgical, a commercial-stage medical technology company advancing magnetic compression anastomosis, today announced the publication of the FLOWS (Functional Lumen Opening with Self-Forming [Magnetic Anastomosis](#)) pivotal trial in Surgical Endoscopy. The prospective, multicenter, single-arm U.S. Food and Drug Administration Investigational Device Exemption (IDE) pivotal study evaluated the Flexagon Self-Forming Magnet system with OTOLoc for creating small-bowel anastomoses with an immediately functional lumen.

Across six U.S. centers, 79 patients underwent minimally invasive small-bowel anastomosis creation using the Flexagon Self-Forming Magnet system with OTOLoc. All patients achieved the study's primary endpoint: successful creation of the magnetic anastomosis without reoperation related to the procedure, device or target anastomosis through 60 days. The study reported no small or large-bowel obstruction, anastomotic bleeding, anastomotic leak, reintervention or death. No serious



Delivery of self-forming magnets



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device-related adverse events were reported.

Despite decades of advances in [minimally invasive surgery](#) and surgical stapling, preventing gastrointestinal anastomotic complications remains a clinical challenge. The FLOWS study evaluated a minimally invasive magnetic compression anastomosis technique designed to create an immediately functional lumen while the anastomosis matures over time. “This technology represents the first major disruptive technology for surgical anastomoses in over 50 years, since the first clinical uses of a surgical stapler,” said Erik Wilson, MD, Chief Medical Officer of GI Windows Surgical.

“What makes FLOWS meaningful is the consistency of the results across six U.S. centers,” said Andre Teixeira, MD, author of the study and an investigator at Orlando Health Weight Loss and Bariatric Surgery Institute. “Every participating investigator was using the technology in patients for the first time. Seeing the technique integrate successfully across different surgeons, institutions and workflows provides an excitement for future clinical applications.” Preclinical studies cited in the publication demonstrated less fibrosis, tissue distortion, bacterial ingress and chronic inflammatory change compared with sutured or stapled anastomoses, with burst pressures approaching native tissue strength.

“Traditional anastomosis relies on immediate mechanical fixation, while magnetic compression allows controlled tissue accommodation over time,” said Shinil K. Shah, DO, EdD, corresponding author of the study and a trial investigator at McGovern Medical School at UTHealth Houston. “FLOWS provides important multicenter clinical evidence supporting an immediately functional magnetic anastomosis and establishes a foundation for continued evaluation.”

The authors concluded that the multicenter study demonstrated the technical feasibility, clinical success and short-term safety profile of magnetic anastomosis with an immediately functional lumen for laparoscopic small intestinal anastomoses.

The full manuscript, titled “The functional lumen opening with self-forming magnetic anastomosis (FLOWS) study: results from the North American pivotal trial,” is now available in Surgical Endoscopy. DOI: 10.1007/s00464-026-13211-8.

About GI Windows Surgical

GI Windows Surgical is a medical technology company developing magnetic compression platforms for gastrointestinal surgery. The company’s technology is designed to support controlled tissue approximation, reproducible healing, and minimally invasive workflow integration across bariatric, foregut, and colorectal procedures.

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