

# Johnson & Johnson Announces Pivotal Clinical Study Results for a New Soft-Tissue Surgical Robotic System

2026-05-05

Study results represent a critical milestone for the investigational OTTAVA™ Robotic Surgical System

Data demonstrates feasibility of novel system architecture with table-integrated robotic arms in space-constrained ORs

Abstract presented at the 2026 American Society for Metabolic and Bariatric Surgery (ASMBS) Annual Meeting Presidential Grand Round Sessions in San Antonio, Texas

SANTA CLARA, Calif.--(BUSINESS WIRE)-- Today, Johnson & Johnson announced results from the first clinical study of the investigational OTTAVA™ Robotic Surgical System – a prospective, multicenter clinical study evaluating the safety and performance of the system in Roux-en-Y gastric bypass procedures. The results were presented at the 2026 American Society for Metabolic and Bariatric Surgery (ASMBS) Annual Meeting (Abstract #4153).

In the 30-patient cohort, the study met its primary safety and performance endpoints through 30 days post-procedure, and investigators completed all procedures robotically on OTTAVA™ without conversion to a non-robotic approach. Average weight loss by 30 days after surgery was 30 pounds. These clinical data, together with preclinical testing, were used to support an application to the U.S. Food and Drug Administration (FDA) for De Novo classification targeting an indication covering multiple procedures in general surgery within the upper abdomen, such as gastric bypass, gastric sleeve, small bowel resection and hiatal hernia repair.

“The data show encouraging evidence regarding the safety and performance of the OTTAVA™ Robotic Surgical System in Roux-en-Y gastric bypass procedures,” said Erik Wilson\*, M.D., Chief of Minimally Invasive and Elective General Surgery, UTHealth Houston, Director of Bariatric Surgery, Memorial Hermann-Texas Medical Center, and

lead investigator for the clinical study. "Continued innovation in bariatric surgery is important to patient care, and I am pleased to present these initial clinical results."

## Addressing Bariatric Complexities

In the U.S. alone, more than two in five adults have obesity.<sup>1</sup> Metabolic and bariatric surgical procedures are effective, long-term treatment options for weight loss management. Many of these procedures, including Roux-en-Y gastric bypass, are increasingly performed robotically.<sup>2</sup> Roux-en-Y gastric bypass is an essential intervention in the management of obesity, with recent research indicating the treatment is most effective and durable for severe obesity.<sup>3,4</sup> The operation is technically demanding relative to other bariatric procedures – requiring both restrictive and reconstructive steps that typically span multiple abdominal quadrants and leveraging a broad spectrum of surgical tasks.

"This is an exciting milestone for our program as we share the role of OTTAVA™ as a robotic surgical system with a novel architecture supporting patient treatment during the clinical trial," said Hani Abouhalka, Company Group Chair, Surgery, MedTech, Johnson & Johnson. "This work also underscores our long-term commitment to bariatric surgeons and to equipping clinicians with a broad portfolio of surgical technologies to address the complexity of obesity care. Across open, laparoscopic, and robotic surgery, we remain focused on translating innovation into real-world solutions that help surgeons broaden access to precision surgical care and improve outcomes for patients."

## Designed for Optimized OR Workflows

OTTAVA™ is designed as a multi-specialty soft-tissue surgery robot, built to enable a broad range of procedures across multiple specialties, to be supported with multiple clinical trials. The system's novel architecture incorporates four robotic arms integrated into a standard size surgical table, removing the need for a separate boom or carts.

In this study, OTTAVA™ was installed and used successfully across operating rooms (ORs) at all six participating hospitals. OR sizes ranged from approximately 243 to 694 sq. ft. In five of the six sites, procedures were performed in ORs that previously had not been used for robotic surgery, including rooms historically considered challenging for robotic systems due to space constraints.

"Our progress with OTTAVA™ relies on rigorous preclinical work, disciplined data collection in the clinic, and tight collaboration with the surgeons who use it – especially the investigators in the FORTE clinical study. These results further illustrate how novel architecture supports a differentiated approach where it matters most: in real operating rooms, with real patients," said Peter Schulam, M.D., Ph.D., Chief Scientific Officer, MedTech, Johnson & Johnson. "At each step – from bench to preclinical and now human trial – we have observed that this system can allow more hospital ORs to accommodate robotics. These results demonstrate that the novel architecture can

integrate into existing infrastructure and remove practical barriers to broader adoption."

## About the FORTE Study

The Safety and Performance of the OTTAVA™ Robotic System: A Prospective Multi-Center Evaluation (FORTE) Study (NCT06709261) is a single-arm, open-label clinical trial conducted across six study sites in the U.S. The purpose of the study is to evaluate safety and performance of OTTAVA™ through 30 days after Roux-en-Y gastric bypass surgery. Data from the FORTE study, together with supporting preclinical testing, were included in an application to the U.S. Food and Drug Administration (FDA) for De Novo classification.

The OTTAVA™ Robotic Surgical System is under development and is not authorized to be marketed or sold in any market.

## About Surgical Solutions from Johnson & Johnson MedTech

Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. For over 100 years, we have helped advance surgical care through our innovative portfolio across wound closure, adjunctive hemostats, surgical stapling and instruments, robotics and digital solutions. Together, with clinicians and healthcare experts around the world we are progressing what's next in surgery to better solve patient needs in metabolic and cardiovascular disease, cancer, and aesthetics and reconstruction. For more, visit

<https://www.jnjmedtech.com/en-US/>.

## About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at <https://www.jnjmedtech.com/en-US/>. Follow us at [@JNJMedTech](#) and on [LinkedIn](#). Ethicon, Inc. is a Johnson & Johnson company.

## Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to the OTTAVA Robotic Surgical System. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying

assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com), [www.investor.jnj.com](http://www.investor.jnj.com) or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

\*Dr. Wilson is a paid consultant for Johnson & Johnson.

## References

1. Centers for Disease Control and Prevention (CDC). Adult Obesity Facts.
2. American Society for Metabolic and Bariatric Surgery (ASMBS). Estimate of Bariatric Surgery Numbers. The ASMBS total bariatric procedure numbers are based on the best estimation from available data (BOLD, ACS/MBSAQIP, National Inpatient Sample Data and outpatient estimations).
3. Brown A, Patel SS, Li E, et al. Bariatric surgery vs. GLP-1 receptor agonists among primarily medicare and medicaid patients with diabetes: a 3-year analysis. *Surg Endosc.* 2026;40(1):671-678. doi:10.1007/s00464-025-12403-y
4. Rodriguez PJ, Zhang V, Gratzl S, et al. Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity. *JAMA Netw Open.* 2025;8(1):e2457349. doi:10.1001/jamanetworkopen.2024.57349

## Media Contact:

Lindsey Diaz-MacInnis

**[LDiazMac@its.jnj.com](mailto:LDiazMac@its.jnj.com)**

## Investor Contact:

**[investor-relations@its.jnj.com](mailto:investor-relations@its.jnj.com)**

Source: Johnson & Johnson