

Johnson & Johnson Receives FDA Market Authorization in the U.S. for its OTTAVA™ Robotic Surgical System

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Built to open new possibilities in surgery, OTTAVA™ creates a new category in soft tissue robotics

System authorized for use in multiple procedures in general surgery within the upper abdomen

System features are designed to enable surgical teams and hospitals to expand OR capacity, streamline clinical workflows, and elevate surgical performance

NEW BRUNSWICK, N.J.--(BUSINESS WIRE)-- Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has granted De Novo authorization for the OTTAVA™ Robotic Surgical System, the world's first table-integrated soft tissue robotic system. The system received marketing authorization for multiple procedures in general surgery, including Roux-en-Y gastric bypass, gastrectomy, cholecystectomy, splenectomy, gastric sleeve, small bowel resection, appendectomy, lysis of adhesions, fundoplication, and hiatal hernia repair.

"We are pioneering a new category of surgical robotics with OTTAVA," said Tim Schmid, Executive Vice President, Worldwide Chairman, MedTech, Johnson & Johnson. "This is the start of the next era in surgery as we deliver not just a new surgical robotics system, but a catalyst for fundamentally better surgical care that is informed by technology, guided by clinical insight, and delivered with care by Johnson & Johnson."

Johnson & Johnson will commercially launch the OTTAVA system with select customers in the U.S., focusing on early customer success while working in parallel to advance into additional indications and regulatory jurisdictions over time. A U.S. clinical trial for OTTAVA in inguinal hernia procedures is ongoing.

A system built differently for what's next

OTTAVA is purpose-built to advance surgery today and where it goes next. Its unique architecture, automated features, next-generation robotic surgical instruments, and connection to an open digital ecosystem create a foundation to fit seamlessly into operating rooms today – and support more digitally enabled, data-driven surgery in the future.

“Surgical robotics will play an increasingly important role in surgical care, but it’s clear that what defined the last 25 years of surgery will not define the next 25,” said Hani Abouhalka, Company Group Chair, Surgery, MedTech, Johnson & Johnson. “By opening up the way we think about architecture, data, and the very workflows of surgery itself, we have designed OTTAVA to deliver clinical and economic benefits and support surgeons and hospitals as the future of surgery unfolds.”

Designed to expand what's possible in the OR

Hospitals and clinical teams are leading efforts to advance surgical care while balancing the realities of infrastructure, OR efficiency, data access, and a growing demand for robotic-assisted surgery. OTTAVA is designed to complement these efforts, with features intended to help enhance OR capacity, streamline clinical workflows, improve visibility into surgical data, and support broader access to robotic-assisted surgical care. First-generation system features include:

- Smallest multi-port soft-tissue robotic system footprint: The novel architecture integrates robotic arms into the OR table and occupies 30–50% less space than traditional boom- and cart-mounted systems, ^{1*} creating additional room for surgeons and clinical teams to move, communicate, and care for patients, with the potential to support more streamlined clinical workflows and experiences.
- Built for automation: Sophisticated software controls coordinate the four table-integrated arms, enabling automated, pre-defined procedural poses to simplify setup and breakdown. Twin motion, which is the synchronized motion of the table and arms, provides seamless patient repositioning and multi-quadrant access to the anatomy with limited intraoperative adjustments.
- Instrumentation optimized for robotic surgery: Based on generations of clinical experience in open and laparoscopic surgery, the OTTAVA instrumentation portfolio has been reimaged to drive innovation for the more commonly used surgical tools. For instance, the system features a two-in-one needle driver designed to reduce unintended suture cutting, ² and monopolar curved scissors for consistent and complete cuts. ^{3**}
- Connected to the Polyphonic™ digital ecosystem: Polyphonic™ for OTTAVA™ is a secure digital solution designed to support surgical teams throughout the OTTAVA experience – bringing learning, media, and data-driven insights together to support continuous improvement across the surgical journey.

- Backed by Johnson & Johnson's legacy in continuous education: OTTAVA education is designed to support the learning journey for new and experienced robotic surgeons. Developed in collaboration with clinicians, educational experts, and surgical societies, OTTAVA education will support safe adoption and consistent performance through virtual, hands-on and immersive training.

"Variability of surgical outcomes remains a challenge in healthcare," said Peter Schulam, M.D., Ph.D., Chief Scientific Officer, MedTech, Johnson & Johnson. "While surgical robotics has helped augment surgical skill, the next generation of care must also integrate data and insights across the surgical ecosystem to support surgeon judgement and help improve patient outcomes. OTTAVA was designed with that connectivity in mind."

Learn more about the OTTAVA™ Robotic Surgical System online: <https://ottava.jnjmedtech.com/>

Investor Conference Call

Johnson and Johnson will host a conference call for investors at 8:00 a.m. (Eastern Time) on August 3, 2026, to discuss the announcement. Investors and other interested parties can access the conference call in the following ways:

- The webcast will be accessible at Johnson & Johnson's website www.investor.jnj.com. Specific webcast link can be found [here](#).
- By telephone: the telephone dial-in number in the U.S. is (877) 869-3847. For participants outside the U.S., the dial-in number is (201) 689-8261.
- A replay of the conference call will be available on www.investor.jnj.com approximately two hours after the live webcast.

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/>.

*Based on an evaluation of systems available as of September 2025

**Cutting performance was evaluated by observing for deviations or defects after 900 cold and 2,460 hot cuts

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](#).

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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, www.jnj.com, 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.

References:

1. Johnson & Johnson and its affiliates. OTTAVA™ Robotic Surgical System Claims Support Documentation. September 2025.
2. Johnson & Johnson and its affiliates. OTTAVA Claims Support Document - Suture Cut Exchange Time. January, 2026.
3. Johnson & Johnson and its affiliates. OTTAVA™ Robotic Surgical System Claims Support Documentation. November 2024.

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