

NEWS | TECHNOLOGY

Johnson & Johnson's OTTAVA Wins FDA De Novo Authorization, Advancing Table-Integrated Robotic Surgery

The OTTAVA Robotic Surgical System introduces a new approach to soft-tissue surgery with integrated robotic arms, automated workflows and connected digital capabilities.

By **Ankit Kankar** | September 13, 2026



Image Courtesy: Public Domain

Johnson & Johnson 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 reimagined 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.”

Read online: <https://worldbusinesswatch.com/news/13/106/johnson-johnsons-ottava-wins-fda-de-novo-authorization-advancing-table-integrated-robotic-surgery.html>

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