

## **Johnson & Johnson MedTech Receives IDE Approval for OTTAVA™ Robotic Surgical System**

*Company prepares to support clinical trial in the United States*

November 12, 2024 – New Brunswick, New Jersey – Johnson & Johnson MedTech, a global leader in cardiovascular, orthopaedic, surgery and vision solutions, today announced that the U.S. Food & Drug Administration (FDA) has approved the OTTAVA™ robotic surgical system investigational device exemption (IDE), which allows the clinical trial to begin at U.S. sites. The Company will now prepare clinical trial sites to receive OTTAVA systems, enroll patients, and begin surgical cases.

Johnson & Johnson MedTech is building on its global portfolio of surgical technologies to advance OTTAVA and help surgical teams and hospitals provide more patients with the benefits of robotic surgery. The system is designed to address unmet needs that persist in robotic surgery today, while driving choice and competition in an underpenetrated and high-growth market.

“We are bringing the best of J&J MedTech’s surgery expertise to the OTTAVA system and taking a holistic view of the science of surgery to enable new experiences across all surgical modalities in service of patients around the world,” said Hani Abouhalka, Company Group Chairman, Surgery, Johnson & Johnson MedTech. “Meeting this milestone brings us a step closer to delivering on our promise to make technology more human, care more adaptive, and people more connected so that surgery works better for everyone.”

“We are excited about reaching this important milestone and progressing our differentiated general surgery robotic platform for the benefit of patients and surgeons,” said Rocco De Bernardis, President, OTTAVA, Johnson & Johnson MedTech. “With approval to move to clinical investigation, our teams are focused on training clinical trial investigators and teams as they enroll patients and prepare for cases.”

### **A differentiated approach to robotic surgery**

The OTTAVA System is designed to set a new standard for the modern operating room (OR) and transform the surgical experience. The system’s unique unified architecture, surgical instrumentation powered by Ethicon expertise, and Johnson & Johnson MedTech’s digital ecosystem are intended to provide versatility to meet the needs of each patient’s care and each surgeon’s clinical approach.

The OTTAVA system features four, low-profile robotic arms incorporated into the operating table that can be stowed underneath. This unified architecture allows for a compact footprint designed to support robotic, laparoscopic, hybrid, and open surgery with more working space for clinical teams.

The system's architecture supports clinically relevant features like "twin motion," in which the table and robotic arms move together for intraoperative repositioning and multi-quadrant access without re-docking.

The OTTAVA system will exclusively feature surgeon-trusted Ethicon instrumentation, designed for performance and precision and a more consistent experience between traditional laparoscopic and robotic procedures. Ethicon instruments designed for OTTAVA are backed by decades of innovation and market leadership in minimally invasive surgery, providing leading device-to-tissue and user-to-device interactions.

Johnson & Johnson MedTech's Polyphonic™ digital ecosystem will connect the portfolio across world-class surgical technologies, robotics, and surgical software while leveraging the global scale of Johnson & Johnson. In the future, Polyphonic will empower OTTAVA with data and advanced insights that will support clinical decision making, learning, and collaboration.

The OTTAVA robotic system is under development and is not authorized to be marketed or sold in any market. For more information, visit: <http://thenext.jnjmedtech.com/surgical-robotics>.

### **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.

### **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, orthopedics, surgery and vision solutions at <https://thenext.jnjmedtech.com>. Follow us at [@JNJMedTech](https://twitter.com/JNJMedTech) and on [LinkedIn](https://www.linkedin.com/company/jnjmedtech).

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**NOTE TO INVESTORS CONCERNING FORWARD-LOOKING STATEMENTS:**

This press release contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things: future operating and financial performance, product development, and market position and business strategy. 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 Ethicon, Inc., Auris Health, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new and existing products; challenges to patents; the impact of patent expirations; the ability of the Company to successfully execute strategic plans, including restructuring plans; the impact of business combinations and divestitures; manufacturing difficulties or delays, internally or within the supply chain; product efficacy or safety concerns resulting in product recalls or regulatory action; significant adverse litigation or government action, including related to product liability claims; changes to applicable laws and regulations, including tax laws and global health care reforms; trends toward health care cost containment; changes in behavior and spending patterns of purchasers of health care products and services; financial instability of international economies and legal systems and sovereign risk; increased scrutiny of the health care industry by government agencies; the Company’s ability to realize the anticipated benefits from the separation of the Company’s Consumer Health business; and the New Consumer Health Company’s ability to succeed as a standalone publicly traded company. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended January 1, 2023, 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) or on request from Johnson & Johnson. Any forward-looking statement made in this release speaks only as of the date of this release. None of Ethicon, Inc., Auris Health, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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