Medtronic News

Medtronic announces FDA clearance of general surgery procedures for the Hugo™ robotic-assisted surgery (RAS) system

An expanded U.S. 510(k) extends the Hugo™ RAS system's reach intoone of the fastest-growing areas of U.S. robotic surgery.

GALWAY, Ireland, Nov. 17, 2026 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced the U.S. Food and Drug Administration (FDA) has cleared the Hugo™ robotic-assisted surgery (RAS) system for use in general surgery procedures.

The clearance covers all upper abdominal general surgical procedures, including but not limited to cholecystectomy, Roux-en-Y gastric bypass, ventral hernia, and small bowel resection. Additionally, lower abdominal procedures of inguinal hernia and appendectomy were cleared. Combined, these procedures account for about 3.5 million surgeries annually in the U.S. — more than half of all soft-tissue procedures performed in the country each year.

This clearance extends the Hugo RAS system's reach into surgical specialties where Medtronic technologies in open and laparoscopic approaches have been used for more than a half century.

"For decades, Medtronic has partnered with general surgeons, and we're bringing that same commitment to robotic surgery for U.S. customers. Hugo expands choice with a practical option to help hospitals address capacity and access challenges, while giving surgical teams more flexibility to meet patients' needs across care settings," said Matt Anderson, senior vice president and president of Medtronic's Surgical business.

The Hugo RAS system is in clinical use at a growing number of health systems and hospitals across the U.S. Globally, Hugo RAS system procedure growth is running at more than two times the robotic surgery market and is on track to surpass 50,000 procedures by the end of the Medtronic fiscal year. General surgery also represents the highest growth for Hugo RAS system procedures outside the U.S., surpassing urology and gynecology.

For U.S. hospitals, the clearance of general surgery procedures expands the range of procedures that can be performed with the Hugo RAS system beyond urology. The system's modular design allows surgical teams flexibility to use only the robotic arms needed for a given procedure, positioning them for their surgical technique and patient's anatomy, while the open console connects the surgeon with the OR team and patient. Surgeons can also use trusted Medtronic technology in their robotic cases, including the LigaSure™ RAS Maryland instrument, which brings vessel-sealing technology used in more than 45 million open and laparoscopic procedures to the Hugo RAS system.

"As an academic health system serving communities across Chicago, our priority is to ensure patients have access to high-quality surgical care and treatment options that best meet their individual needs," said Dr. Francesco Bianco, UI Health surgeon, and professor of surgery at the University of Illinois College of Medicine. "Expanding our robotic-assisted surgical capabilities with the Hugo RAS system allows us to offer additional treatment options, while supporting our commitment to advancing surgical education and training the next generation of surgeons."

Medtronic brings robotics, instruments, data, and expertise together with the goal of making surgery more precise, predictable, and personalized — and more accessible to more patients around the world. Alongside the Hugo RAS system and its connected surgical ecosystem, the company's distribution of the Sentire™* surgical system in select markets outside the U.S., is rooted in that pursuit.

Learn more at medtronic.com/HugoSpecialties.

Medtronic is the sole authorized distributor of Cornerstone Robotic's Sentire™* surgical system outside of the United States. Medtronic, the Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. ™* Third-party brands are trademarks of their respective owner. All other brands are trademarks of a Medtronic company.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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