Medtronic News

Medtronic announces FDA clearance of Hugo™ robotic-assisted surgery system for urologic surgical procedures

Hugo RAS system brings choice to the U.S., coupled with the full suite of Medtronic surgical offerings, ultimately creating a connected and integrated operating room today and into the future.

GALWAY, Ireland, Dec. 3, 2025 /PRNewswire/ -- Medtronic (NYSE: MDT), a global leader in surgical innovation, today announced the U.S. Food and Drug Administration (FDA) has cleared the Hugo™ robotic-assisted surgery (RAS) system for use in urologic surgical procedures. The Hugo RAS system's clearance brings a versatile robotic-assisted platform to U.S. surgeons and health systems seeking to expand soft-tissue robotic surgery programs and access to minimally invasive care.

The U.S. leads the world in robotic surgery adoption, yet hospitals continue to face challenges in capacity and access. The introduction of the Hugo RAS system in the U.S. helps address this gap, offering an innovative approach to robotic-assisted surgery from the global leader in surgery and bringing choice to hospitals and surgeons across the country.

"This is an incredibly exciting day for healthcare in the United States. FDA clearance of the Hugo RAS system means there is now choice for hospitals looking to expand their robotic programs and increases access for patients," said Rajit Kamal, vice president and general manager of Robotic Surgical Technologies within the Surgical business of Medtronic. "As we begin our purposeful launch of the Hugo RAS system in the U.S., our focus is on building a strong foundation with leading hospitals through our differentiated approach to partnership, rooted in our enduring commitment to provide an excellent customer experience and enable surgical teams to deliver the best possible outcomes for their patients."

Thoughtfully designed with input from surgeons and hospital administrators to shape the future of surgery, the Hugo RAS system includes three main differentiators:

- **Modular Design**: The Hugo RAS system's innovative modular design means the robotic arms can be easily moved, shared, and deployed across any care setting — helping to maximize utilization and providing surgeons flexibility to customize their approach to optimize anatomical access for each patient's unique needs. The open design of the surgeon console provides greater situational awareness and visualization, reduces physical strain, and creates enhanced training opportunities for surgical teams — enabling better bedside communication and team integration.
- **Digital Ecosystem**: The Hugo RAS system connects seamlessly with the Touch Surgery™ ecosystem, which provides pre-operative training tools, remote tele-proctoring capabilities, and AI-powered post-operative case insights.† Surgeons may securely access case videos seconds after a procedure is completed, supporting continuous improvement and collaboration among hospital teams and with their peers in the global surgical community.
- **Differentiated Partnership**: Medtronic is the first and only company that can meet surgeon needs across all surgical modalities — open, laparoscopic, and robotic-assisted. The addition of the Hugo RAS system provides surgical teams access to world-class robotic training, deep clinical and technical expertise, and choice when determining the best surgical approach for each patient's unique needs, with the opportunity to use trusted Medtronic technologies and instruments as technology advances.

"The Hugo RAS system represents a new and exciting approach to robotic-assisted surgery," said Dr James Porter, a urologic surgeon and chief medical officer for Robotic Surgical Technologies and Digital Technologies within the Surgical business at Medtronic. "We're excited for surgical teams in the U.S. to experience the differentiated technology and partnership from Medtronic, which supports them at every stage of their robotic surgical journey."

With FDA clearance, the Hugo RAS system is indicated for use in minimally invasive urologic surgical procedures including prostatectomy, nephrectomy, and cystectomy — common procedures that account for about 230,000 surgeries per year in the U.S.

The Expand URO investigational device exemption clinical study —the largest ever completed for multi-port robotic-assisted

urological surgery in the U.S. — demonstrated that the Hugo RAS system met primary safety and effectiveness endpoints in urologic surgical procedures, with outcomes that are consistent with published literature.

Outside the U.S., the Hugo RAS system has been used in tens of thousands of urologic, gynecologic, and general surgery procedures in more than 30 countries across 5 continents. Medtronic intends to expand the Hugo RAS system's use in the U.S. to additional surgical specialties over time, with indications for general and gynecologic surgical procedures expected to follow the initial urology clearance.

The introduction of the Hugo RAS system in the U.S. builds on Medtronic's broad surgical offering, including the Touch Surgery ecosystem, to deliver a connected, integrated operating room — today and in the future.

For more information, visit medtronic.com/hugoishere.

†The Medtronic Touch Surgery™ ecosystem is not intended to direct surgery, or aid in diagnosis or treatment of a disease or condition. Performance Insights are available for select procedures, instruments, and anatomy.

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 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, 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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