Medtronic News

Medtronic submits 510(k) filings to expand Hugo™ robotic-assisted surgery system into general and gynecologic specialties in the United States

Company also announces 510(k) pending for LigaSure™ RAS Maryland instrumenton the Hugo RAS system, and 510(k) clearance for ProGrip™ Advanced self-gripping polypropylene mesh for use in robotic-assisted ventral hernia repair surgeries

GALWAY, Ireland, June 3, 2026 /PRNewswire/ -- Medtronic (NYSE: MDT), a global leader in healthcare technology, today announced significant milestones to unlock expanded indications for the Hugo™ robotic-assisted surgery (RAS) system in the United States and to shape the future of surgery.

- General surgery indication including hernia repair — 510(k) clearance submitted
- Embrace Gynecology Investigational Device Exemption (IDE) clinical study — completed enrollment
- Gynecologic surgery indication — 510(k) clearance submitted
- LigaSure™ RAS Maryland instrument — 510(k) clearance submitted
- ProGrip™ Advanced mesh for use in robotic-assisted ventral hernia repair — 510(k) clearance received

These milestones build momentum for Medtronic's Surgical business and its purposeful launch of the Hugo RAS system, which received FDA clearance for urologic surgical procedures in December 2025 and is in commercial use at leading U.S. medical centers. With nearly five years of commercial experience across more than 35 countries in five continents, the Hugo RAS system has been used in tens of thousands of procedures and its safety and effectiveness is supported by hundreds of independently published scientific papers.

Medtronic is the first and only company that can meet surgeons' needs across all surgical modalities — open, laparoscopic, and robotic-assisted — giving surgeons and health systems the choice and partnership required to build and grow successful surgery programs across care settings.

"These milestones and innovative technologies will unlock our ability to enhance the value of our partnership in general and gynecologic surgical procedures," said Matt Anderson, senior vice president and president of the Surgical business at Medtronic. "This isn't just a portfolio expansion, it's part of our ongoing commitment to unite instruments, intelligence, and human hands into one unique surgical ecosystem. One that enables every patient, everywhere, access to the best possible surgery."

Expanding Hugo™ RAS indications and capabilities

The 510(k) filings for Hugo RAS system use in general surgery and gynecological procedures would significantly broaden the platform's clinical applicability in the U.S. and address growing demand for robotic-assisted minimally invasive options in these high-volume specialties. Medtronic has decades of experience collaborating with surgical teams in general surgery and gynecologic surgery to advance patient care globally; they are also indications where the Hugo RAS system is in clinical use in major markets outside the U.S.

Bringing together technology surgeons trust and furthering its commitment to continually enhancing Hugo™ RAS system capabilities, today Medtronic announced it has submitted a 510(k) filing to the FDA for the LigaSure RAS Maryland instrument.

Designed exclusively for use with the Valleylab™ FT10 energy platform on the Hugo™ RAS system, LigaSure RAS incorporates vessel-sealing technology that has been used in more than 35 million procedures across 65+ countries. LigaSure RAS was introduced on the Hugo RAS system in Europe in 2025.

"LigaSure technology has been transformative for surgery and integrating it onto the Hugo RAS system gives surgeons greater confidence and control during critical moments in complex procedures," said Dr. Matthew Kroh, chief medical officer within the

Surgical business at Medtronic and a practicing general surgeon. "As more and more surgeons and patients demand robotic-assisted surgery, we need more access to technology and training, and Medtronic brings that choice in a very powerful way."

Our most advanced robotic mesh[1-3,†]

Today Medtronic also announced it received FDA clearance for ProGrip™ Advanced, an evolution of existing mesh technologies to better align with the specific demands of robotic-assisted ventral hernia repair.

ProGrip meshes have been used in more than 6 million procedures. ProGrip Advanced supports surgical efficiency in robotic procedures by making it easier to introduce through trocars, handle, deploy, and unfold compared to previously available products and comes in a variety of sizes to meet each patient's needs.[2-3,‡]

Every year, nearly 470,000 ventral hernia repair procedures are performed in the U.S. — more and more are being done with the assistance of a robot, and an increasing number are performed at alternative sites of care as hospitals shift lower acuity procedures to ambulatory centers to support a patient-centered approach to care while managing cost pressures and capacity challenges. The Medtronic surgical ecosystem across open, laparoscopic, and robotic-assisted surgery is uniquely positioned to help solve these problems.

Enrollment complete in Embrace Gynecology IDE study for the Hugo™ RAS system

Medtronic also announced today that the company has completed enrollment in the Embrace Gynecology Investigational Device Exemption (IDE) clinical study for the Hugo™ RAS system in the U.S. Embrace Gynecology is a prospective multicenter study to evaluate the safety and effectiveness of the Hugo™ RAS system when used in robotic-assisted gynecologic procedures. The study enrolled 70 patients across 5 U.S. hospitals.

For more information, visit medtronic.com/hugoishere.

†Compared to all Medtronic meshes indicated for robotic ventral hernia repair.

‡Bench testing may not be indicative of clinical performance.

1. Based on internal report 43463CR757, Memorandum — ProGrip™ advanced self-gripping polypropylene mesh — advanced robotic mesh.
2. Based on internal report 43463CR506, Design verification report.
3. Based on internal report 43463CR740, Design validation lab of ProGrip™ advanced self-gripping polypropylene mesh by MIS and open surgical approach.

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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