

## Study of Medtronic Hugo™ robotic-assisted surgery system in hernia repair meets safety and effectiveness endpoints

First-ever investigational device exemption clinical study for robotic-assisted hernia repair in the U.S. presented at the American Hernia Society annual meeting

GALWAY, Ireland and NASHVILLE, Tenn., Sept. 4, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT) today announced results from the Enable Hernia Repair clinical study evaluating the performance of the Hugo™ robotic-assisted surgery (RAS) system in inguinal and ventral hernia repair procedures. Enable Hernia Repair is the first-ever Investigational Device Exemption (IDE) clinical study completed for robotic-assisted hernia surgery in the United States.

Primary safety and effectiveness endpoints were met, supporting use of the Hugo RAS system in hernia repair procedures.

"The Enable Hernia Repair clinical study didn't just meet primary endpoints, it far surpassed them," said Dr. Jacob Greenberg, national principal investigator of the Enable Hernia Repair study and gastrointestinal surgeon at Duke University Hospital. "I am proud to have had the opportunity to advance clinical research in robotic-assisted surgery for the benefit of patients in the United States and around the world."

Enable Hernia Repair is a prospective, multi-center, single-arm pivotal study that included 193 patients undergoing either inguinal or ventral robotic hernia repair with the Medtronic Hugo™ RAS system. Key findings include:

- The study met the primary effectiveness endpoint:
  - The surgical success rate<sup>†</sup> was 100%, surpassing the pre-specified performance goal of 85%. (p<0.0001)
- The study met the primary safety endpoint for both cohorts, which were analyzed independently:
  - Inguinal: Among 92 patients available for analysis, the surgical site event<sup>‡</sup> (SSE) rate was 0.0%, which is significantly lower than, and meeting, the pre-determined performance goal of 30% (p <0.0001).
  - Ventral: Among 94 patients available for analysis, the SSE rate was 2.1%, which is significantly lower than, and meeting, the pre-determined performance goal of 30% (p <0.0001); two SSEs were recorded and resolved without complication.

"The addition of the Hugo platform to our field introduces exciting new opportunities to innovate and advance robotics in the best interests of patients, surgeons, and hospital systems while clearly offering the clinical results we expect from robotic-assisted surgery," said Dr. David Chen, a general surgeon at UCLA and lead presenter of the Enable Hernia Repair data at the American Hernia Society (AHS) meeting in Nashville, Tenn.

Every year, nearly 1.5 million hernia repair surgeries are performed in the United States, making hernia repair one of the most common surgeries for adult men and women.<sup>i,ii</sup> Hernia repair addresses conditions where part of the intestine bulges through weakened abdominal muscles. Left untreated, hernias can lead to pain, digestive troubles, swelling, or infection.<sup>iii</sup> Surgical repair is currently the leading effective treatment, with innovation in minimally invasive approaches including mesh technology helping advance patient care.

In the Enable Hernia Repair clinical study, the mean length of hospital stay was 4.7 hours for inguinal patients and 6.7 hours for ventral.

"We're grateful for the opportunity to partner with clinical teams to treat this common and often painful condition for millions of patients around the world," said Rajit Kamal, vice president and general manager of Robotic Surgical Technologies within the Surgical business of Medtronic. "Adding a digitally-powered robotic-assisted surgery system to our laparoscopic and open surgery solutions for hernia repair gives surgeons more choice and patients greater access to the care they need — and we believe that's a win for everyone."

The study builds on the growing body of evidence for Hugo including the Expand URO U.S. clinical study, which also met safety and effectiveness endpoints, and nearly 300 independent publications by surgeons using the Hugo RAS system.

Born out of Medtronic's 75-year commitment to expanding access to minimally invasive surgical options worldwide in partnership with clinicians, the Hugo RAS system is clinically used in 30+ countries on five continents.

In the U.S., the company's submission for a urology indication is under review by the Food and Drug Administration, with a U.S. urology indication expected later in the company's current fiscal year, followed by planned indication expansions into hernia repair and gynecology.

The Medtronic Hugo RAS system is commercially available in certain geographies. Regulatory requirements of individual countries and regions will determine approval, clearance, or market availability. In the EU, the Hugo™ RAS system is CE marked. In the U.S., the Hugo™ RAS system is an investigational device not for sale.

For more information, visit [medtronic.com/hugo](https://medtronic.com/hugo).

### **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 (NYSE: MDT), visit [www.Medtronic.com](https://www.Medtronic.com) and follow Medtronic on [LinkedIn](https://www.linkedin.com/company/medtronic/).

**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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†Surgical success rate is defined as the procedure not going into conversion. Conversion is defined as the switch from a robotic-assisted approach using the Hugo™ RAS system to laparoscopy, open surgery, or the use of an alternative robotic-assisted system.

‡Surgical site event (SSE) is a composite endpoint of surgical-site occurrences and surgical-site infections related to the device or procedure from the first incision through 30 days post-procedure.

<sup>i</sup> <https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/bulletin/2023/march-2023-volume-108>

[issue-3/new-approaches-trends-are-emerging-in-hernia-repair/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC95554/)

ii <https://hcup-us.ahrq.gov/reports/statbriefs/sb287-Ambulatory-Surgery-Overview-2019.pdf>

iii <https://www.ncbi.nlm.nih.gov/books/NBK395554/>

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Additional assets available online:  [Photos \(1\)](#)

<https://news.medtronic.com/2025-09-04-Study-of-Medtronic-Hugo-TM-robotic-assisted-surgery-system-in-hernia-repair-meets-safety-and-effectiveness-endpoints>