

**MAY 23, 2024**

# Medtronic announces clinical studies underway for two additional indications for Hugo™ RAS system in the U.S.

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*The company is pursuing hernia and gynecology indications along with urology as it progresses plans to bring choice in robotic surgery technology and partnership to the U.S.*

Medtronic, a global healthcare technology leader, today announced hernia and gynecologic studies are underway in support of planned submissions to the U.S Food and Drug Administration (FDA) for the Hugo™ robotic-assisted surgery (RAS) system.



Medtronic is now pursuing three indications in parallel for the Hugo™ RAS system in the world's largest robotic surgery market, while the company continues to build momentum outside the U.S. with its install base growing across 25 countries on five continents and over 100 independent scientific publications globally.

The Enable Hernia Repair U.S. clinical trial commenced with a robotic-assisted bilateral inguinal hernia repair procedure performed by Jacob Greenberg, MD, the trial national principal investigator, at Duke University Hospital in Durham, N.C.

"Our team is committed to exploring new technologies to advance care for patients," Dr. Greenberg said. "This clinical trial aims to evaluate a new robotic-assisted surgery system in offering a precise and minimally invasive option for this painful condition, which affects millions of Americans every year."

As a form of minimally invasive surgery, robotic-assisted procedures offer patients fewer complications, shorter hospital stays, and faster return to normal activities.<sup>1-3,†</sup>

The Enable Hernia Repair clinical trial is a prospective, multicenter study evaluating the safety and performance of the Hugo™ RAS system in support of a planned submission to the FDA. The Expand URO clinical trial, for urologic procedures, is nearing completion.

Medtronic also announced today that it has begun a prospective clinical study for gynecologic procedures in support of a planned submission to the FDA.

“Medtronic is committed to providing safe and effective healthcare technology that helps clinicians advance patient care,” said Eric Vang, PhD, MPH, vice president of Clinical Research and Medical Science in the Surgical business, part of the Medical Surgical portfolio at Medtronic. “Hugo™ builds on that commitment as we combine the power and potential of people and technology to drive healthcare forward for all.”

Medtronic thoughtfully designed the Hugo™ RAS system – through collaboration with hundreds of surgeons and hospital leaders globally – to expand access to minimally invasive care to more patients around the world. The Hugo™ RAS system brings the precision, dexterity, ergonomics, and visualization benefits of RAS together in a modular system that provides flexibility and an open surgeon console that supports communication among the surgical team. The Hugo™ RAS system is available with Medtronic’s Touch Surgery™ Ecosystem, which seamlessly integrates simulations, surgical video, remote streaming, performance insights, and case management solutions into the surgical workflow.†

The Hugo™ RAS system is not cleared or approved in all markets. Regulatory requirements of individual countries and regions will determine approval, clearance, or market availability. In the U.S., the Hugo™ RAS system is an investigational device not for sale.

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

†Compared to open surgery.

‡Touch Surgery™ is not intended to direct surgery, or aid in diagnosis or treatment of a disease or condition; Live Stream and performance insights are **only** intended for education and training purposes.

1. Fitch K, Engel T, Bochner A. Cost differences between open and minimally invasive surgery. *Managed Care*. 2015;24(9):40-48.
2. Tiwari MM, Reynoso JF, High R, Tsang AW, Oleynikov D. Safety, efficacy, and cost effectiveness of common laparoscopic procedures. *Surg Endosc*. 2011;25(4):1127-1135.
3. Roumm AR, Pizzi L, Goldfarb NI, Cohn H. Minimally invasive: minimally reimbursed? An examination of six laparoscopic surgical procedures. *Surg Innov*. 2005;12(3):261-287.

## **About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 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](http://www.Medtronic.com) and follow Medtronic 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 U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.**

<https://news.medtronic.com/Medtronic-announces-clinical-studies-underway-for-two-additional-indications-for-Hugo-TM-RAS-system-in-the-U-S>