Medtronic News

# Medtronic announces first patient enrolled in U.S. clinical trial for Hugo™ robotic-assisted surgery system

Expand URO is a prospective, multi-center, single-arm study to evaluate the safety and performance of the Hugo™ RAS system for urologic procedures

DUBLIN, Dec. 15, 2022 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global healthcare technology leader, today announced the first patient enrolled in the Expand URO U.S. clinical trial for the Hugo™ robotic-assisted surgery (RAS) system. The robotic-assisted prostatectomy procedure was performed by Dr. Michael R. Abern at Duke University Hospital in Durham, N.C.

"This is an exciting moment," said Dr. Abern. "Robotic-assisted surgery provides many benefits within my specialty of urology, and I'm proud to have performed the first U.S. clinical trial case with the Medtronic Hugo RAS system."

Minimally invasive surgery, including robotic-assisted surgery, offers fewer complications, shorter hospital stays, faster return to normal activities, and smaller scars.[1–3,†] Urologic procedures are one of the most commonly performed with the assistance of a surgical robot. The Hugo™ RAS system is intended to be used in this study for urologic surgical procedures including radical prostatectomy, radical cystectomy, and nephrectomy (partial or radical) procedures at sites in the U.S.

"Scientific evidence is the bedrock of healthcare technology innovation and adoption. It creates and builds trust among clinicians and patients," said Carla Peron, M.D., chief medical officer of the Surgical Robotics business, which is part of the Medical Surgical Portfolio at Medtronic. "We're proud to further that important pursuit with the Hugo RAS system in partnership with hospitals and surgical teams in the United States who share our commitment to patients."

The Expand URO clinical trial is being conducted pursuant to an Investigational Device Exemption from the U.S. Food and Drug Administration (FDA). Up to 122 patients will be enrolled in the study at six sites in the U.S.

Dr. James Porter, a urologic surgeon at Swedish Medical Center in Seattle, WA, is the principal investigator of the U.S. Expand URO study.

"This is an exciting time for healthcare in the United States and around the world, as we have the opportunity to expand robotic-assisted surgery treatment options to more patients," said Dr. Porter, who plans to perform his first cases under the trial this month. "Backed by a growing body of clinical evidence, robotic-assisted surgery is the preferred approach within urology given the anatomical access, precision, and ergonomic advantages it enables."[4]

The Hugo™ RAS system, combined with Touch Surgery™ Enterprise‡, offers a smart, digitally enabled surgical experience. Outside the U.S., it is in use at hospitals across three continents in a range of procedures within urology, gynecology, and general surgery.

The Hugo™ RAS system is commercially available in certain geographies. Regulatory requirements and status in individual countries and regions will determine market availability of the Hugo™ RAS system and approved indications. In the U.S., the Hugo™ RAS system is an investigational device not for sale.

For more information, visit medtronic.com/hugo.

†Compared to open surgery.
‡Touch Surgery™ Enterprise is not intended to direct surgery, or aid in diagnosis or treatment of a disease or condition.

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.
4. Honda M, Morizane S, Hikita K, Takenaka A. Current status of robotic surgery in urology *Asian J Endosc Surg.* 2017;10(4):372–381.

**About Medtronic**

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, 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, 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 and follow @Medtronic on Twitter and 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.**

Contacts:

| | |
|---|---|
| Gary Jeanfaivre | Ryan Weispfenning |
| Public Relations | Investor Relations |
| +1-203-833-2104 | +1-763-505-4626 |

SOURCE Medtronic plc

---

https://news.medtronic.com/2022-12-15-Medtronic-announces-first-patient-enrolled-in-U-S-clinical-trial-for-Hugo-TM-robotic-assisted-surgery-system