An emergent technology, the Hugo™ Robotic-Assisted Surgery System, used for the first time in a Korean surgical study for prostatectomy and cholecystectomy

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Background

Objective of the emergent technology: The Hugo™ Robotic-Assisted Surgery (RAS) System aims to reshape robotic-assisted surgery through innovative design features such as an open surgeon console and setup flexibility with a modular four arm system. In our investigational study we aim to provide a description of our use of this emergent device in a Medtronic-sponsored trial.

Background: Since the first robotic surgeries conducted in Korea in 2005, multiple robotic surgery platforms have been introduced to the market. Medtronic has now entered into the robotic-assisted surgery field with the new investigational device, the Hugo™ RAS System. This is the first clinical study conducted in Korea using the Hugo™ RAS System.

Global Regulatory Approval

Global regulatory approval for the Hugo™ RAS System

Urology
- Australia
- Brazil
- Canada
- European Union
- Israel
- Japan
- Korea
- Malaysia
- Mexico
- Saudi Arabia
- Singapore
- Taiwan
- Thailand
- Turkey

General Surgery
- Australia
- Canada
- European Union
- Israel
- Japan
- Korea
- Malaysia
- Mexico
- Singapore
- Taiwan
- Turkey

Gynecology
- Australia
- Brazil
- Canada
- European Union
- Israel
- Japan
- Korea
- Malaysia
- Mexico
- Saudi Arabia
- Singapore
- Taiwan
- Thailand
- Turkey

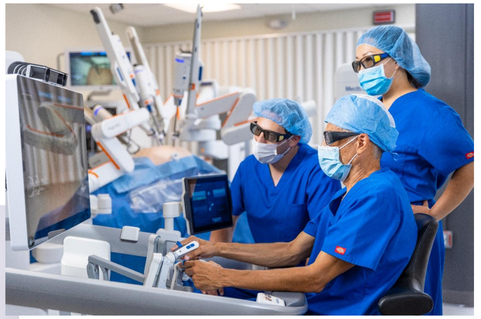
In use in unregulated geographies
- Bangladesh, Chile, Hong Kong, India, New Zealand, and Panama

The Hugo™ RAS System



Allows surgeons to manually control arms at the bedside, including the ability to use one arm as an endoscope holder





Enables the surgeon, sitting at an ergonomically adjustable console, to view the surgical field in three dimensions and control movements of the endoscope and instruments with individual robotic arms

Methods for the Korean Study Titled Hello Hugo™

The investigational study was a prospective, single-center, single-arm, confirmatory clinical study conducted at the Seoul National University Hospital where 20 radical prostatectomies and 20 cholecystectomies were performed. The primary objective of this study was to determine the completion rate, defined as the proportion of patients who underwent the surgery without conversion to laparoscopy or open surgery due to serious system malfunction and without any major complications (Clavien-Dindo grade ≥3) within 24-hours post-surgery. The secondary objectives were to assess the short-term safety and performance outcomes of the Hugo™ RAS System, which included evaluating the overall complication rate, major complication rate, readmission rate, and reoperation rate. All parameters were evaluated within 30 days post-surgery.

Non-clinical Results

Median Times	Prostatectomy	Cholecystectomy
Setup Time (min)	18.0	16.0
Console Time (min)	110.5	17.0
Operative Time (min)	147.0	55.0

Based on our initial experience, prostatectomy and cholecystectomy with the Hugo™ RAS System is feasible and safe. This trial is registered with ClinicalTrials.gov (NCT05715827). Our experience with this emergent device can be compared to other studies conducted around the world.

Where to Learn More

More about Dr. Wooil Kwon

More about the Hugo™ RAS System

Disclosures

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 European Union, the Hugo™ RAS System is CE marked. In the United States of America, the Hugo™ System is an investigational device, not for sale.