Robotic-assisted surgery (RAS) has been identified as an emerging medical technology with the potential to help standardize surgical procedures and enable minimally invasive surgery (MIS). MIS may improve patient outcomes, and reduce health system costs.\textsuperscript{1–3} RAS technology affords surgeons expanded capabilities\textsuperscript{1,2} – from more maneuverability and access in general surgery procedures, to more accuracy and precision in spine surgery.

Clinical benefits of RAS, therefore, depend on the surgical application of the technology. For example, applied in general surgery, benefits of RAS-enabled MIS may include smaller incisions, decreased blood loss, shorter hospital stays, and lower incidence of some surgical complications, as compared to open surgery.\textsuperscript{1–3} In highly complex spine procedures, RAS improves accuracy of screw placement.\textsuperscript{3}

As hospitals look to improve efficiencies and patient outcomes, RAS is poised for strong adoption. However, as with any new medical technology, factors such as initial and per-procedure costs and surgeon training may impact the speed at which RAS can be implemented and benefits realized.

A comprehensive RAS solution, therefore, likely combines the latest medical technology with a flexible model for use across many disease states, best-in-class clinical and training support, and the ability to expand based on technological advances and the evolving needs of hospitals. Collectively, these four components can help hospital systems get the most out of their long-term investment.
Understanding barriers to robotics in healthcare

Per-procedure limitations

In spine or neurosurgery, RAS equipment requirements can differ greatly from one procedure to another.

“The needs of surgeons today are complex and ever changing,” says Linnea Burman, Vice President and General Manager, Enabling Technologies: Cranial and Spinal Technologies. “Every procedure has different requirements, and therefore the demands on the robotic system are different. If you look, for example, at robotic-assisted surgery for abdominal or thoracic procedures, it’s all about telemanipulation of tissue. But for spine or neurosurgery, the needs are different, and require planning capabilities and interoperative image guidance.”

Workflow and clinical support requirements

A study at the University of California, Santa Barbara explored the challenges associated with general RAS training across more than 13 U.S. hospitals. It found that RAS provided a unique work environment for surgical residents. Compared to training for open surgery – where an attending surgeon relies on constant “hands-in-the-patient” cooperation from the surgical residents – RAS training was almost exclusively observation-based.

“Robotic-assisted surgery requires more than just training an individual on how to use a surgical tool. It includes the orchestration of many different people in the OR – from surgeons to support staff,” explains Adam Bettis, director of Spine Medical Education at Medtronic. “Today, those kinds of lab spaces, trainers, or simulations are not offered at most teaching hospitals because this is such a new space for medicine.”
Our goal is to use innovation to help standardize procedures and improve patient outcomes. It’s not about adding technology because we can. It’s about using technology to create better clinical and economic options for hospitals, surgeons, and patients.

Megan Rosengarten, President of Surgical Robotics at Medtronic

Multifaceted solutions help deliver value

The shift to RAS for health systems requires a shared commitment by clinicians, hospital administrators, and medical technology innovators to develop and adopt sustainable solutions that deliver long-term benefits. The contribution by med tech companies must be multifaceted, combining the latest technology advancements with a flexible model for use and collaborative, comprehensive clinical and training support.

Building tech-optimized systems

Backward compatibility is currently lacking in most RAS offerings. Designing systems that can be upgraded as technology evolves helps maximize a hospital’s return on investment.

“Our goal is to use innovation to help standardize procedures and improve patient outcomes,” says Megan Rosengarten, President of Surgical Robotics at Medtronic. “It’s not about adding technology because we can. It’s about using technology to create better clinical and economic options for hospitals, surgeons, and patients.”

Staying at the forefront of advances in data integration, robotic system components, and image-guided surgical techniques, Medtronic is creating RAS solutions that are not only optimized for what clinicians need today, but can also be enhanced as the technology evolves and usage expands in the years to come. This means health systems making the investment in RAS now can likely anticipate ongoing benefits as we learn more about the potential the technology holds for improving and standardizing care.

Flexible model for use

Creating solutions that incorporate robotic assistance with enabling technologies and implantable devices can help increase utilization across many procedures. For example, navigational technology common to both the Medtronic StealthStation™ system and Mazor X Stealth Edition™ system can be applied in spine procedures.

Creating platforms that are also physically more mobile – allowing RAS to be performed in multiple operating rooms instead of just one dedicated space – has the potential to increase utilization across a hospital. By adding system mobility and configurability to the equation, more RAS procedures can be conducted, with the goal of serving more patients and improving efficiencies.

Additionally, solutions that support diagnostics, pre-operative planning, intra-operative execution, and post-op outcomes...
may be even more critical as hospitals look to quantify value at both a clinical and economic level.

“The ideal RAS spine and cranial solution that we envision is a platform that helps clinicians along the entire patient care pathway,” explains Burman. “That means using technology and data to identify patients who would benefit from RAS, plan for and execute those procedures, and follow up to measure and learn from the outcomes – both short and long term.”

Comprehensive training and clinical support
A standard approach to RAS implementation is needed to develop the required expertise and infrastructure. A recent report in *Urosurgery* suggests laparoscopic RAS training, for example, can be divided into two categories:  

- **Patient-side training:** patient positioning, port placement, and basic laparoscopic surgical techniques
- **Robotic equipment training:** virtual reality simulations, dry/wet lab training, and OR training

Along with training, Medtronic brings a third category to the mix, lending dedicated clinical support for enhanced workflow management.

At Jacobs Institute in New York, for example, Medtronic helps provide residents with RAS immersion education experiences including hands-on simulations, live surgery observation, and local teaching faculty. Together, Jacobs Institute and Medtronic are also exploring the latest in extended reality and gamification technology to develop teaching tools for workflow efficiencies.

Robotic-assisted surgery infrastructure components

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*Image: Diagram illustrating the components of robotic-assisted surgery infrastructure, including patient-side training, robotic equipment training, and workflow management.*
Launched in 2019, the Mazor X Stealth Edition™ system is already transforming the future of spine surgeries. Combining navigation technology and robotics, the system incorporates Stealth™ software technology into the Mazor X™ robotic-assisted surgery platform. The result is clinician workflow predictability and flexibility through real-time image guidance, visualization, and navigation informed by interactive 3D planning and information systems.

“It is rare that huge sectors of technology such as robotics and navigation merge into a sole platform,” says Jeffrey Gum, M.D., orthopedic spine surgeon at Norton Leatherman Spine in Kentucky. “Computerized surgical planning, 3D assessment of spine anatomy, robotic guidance, and live navigation feedback are designed to provide a higher degree of accuracy throughout the surgical procedure.”

In late 2020, leading spine surgeons in the U.S. began performing minimally invasive procedures with the company’s newly cleared navigated disc prep, interbodies, and Midas Rex™ high speed drills with the Mazor™ robotic guidance system.

“Robotic assistance has fundamentally changed how we as spinal surgeons operate,” said Gregory Poulter, M.D., of OrthoIndy in Indiana. “I believe in the benefits of robotics such that I would strongly recommend it to all of my friends or family if they are in need of a lumbar spine procedure.”

RAS technology is also at work in our Stealth Autoguide™ system for cranial neurosurgery and the Renaissance™ system for spinal and cranial surgery.

“Robotics and navigation have both been shown to improve accuracy and precision in spine surgery,” says Christopher R. Good, M.D., FACS, spine surgeon at Reston Hospital Center, director of Scoliosis & Spinal Deformity, and president of Virginia Spine Institute. “The marriage of robotics and navigation represents the future of computerized planning and execution in spine surgery.”
Medtronic is developing a soft-tissue robotic-assisted surgery (RAS) system designed to expand access to quality care for more patients in more places around the world.

Despite its many benefits, only about 3% of surgeries worldwide are performed using robotics.

We’re working to change that.

Combining state-of-the-art visualization and a modular, mobile design that’s compatible with Medtronic instruments, the Hugo™ RAS system is designed to overcome cost and utilization barriers that have kept RAS out of reach for many hospitals.

“The intent of our robotic-assisted surgery platform – and the role every design choice plays – is to deliver the most meaningful solution for surgeons, hospitals, and the central focus of our work, our patients,” said Megan Rosengarten, President of Surgical Robotics at Medtronic. “We’re really excited about the possibility it creates.”

The Hugo™ system will include Touch Surgery™ Enterprise, a technology available today that revolutionizes the process to record, store, and review surgical videos. Using next-generation computing, visualization, and artificial intelligence technology, Touch Surgery™ Enterprise automatically generates valuable procedural data in minutes – empowering OR teams.

Touch Surgery™ Enterprise was created by Digital Surgery, a London-based technology company Medtronic acquired last year.

“We have always believed in computational power and data as two central drivers of consistency and quality in surgery,” said Dr. Jean Nehme, Vice President, Strategic Partnerships at Medtronic and a cofounder of Digital Surgery. “Computational power has impacted our lives in so many ways, and within surgery it is almost absent. By joining forces with Medtronic, we will finally apply computing and AI to surgery on a meaningful scale with a goal of helping more patients in more places benefit from consistently high-quality surgical care.”
What’s next for robotics in healthcare?

Teams across Medtronic are working with clinicians to incorporate the benefits of RAS into surgical procedures across multiple disciplines. With clinical testing underway on some of our latest applications of the technology, we are excited to help extend the benefits of RAS to more patients, in more places around the world.

To learn more about our work in key areas of medical technology and our commitment to delivering value through improved patient outcomes, visit medtronic.com/transforminghealthcare.

References

Indications, Safety, and Warnings

*MAZOR X™ ROBOTIC GUIDANCE SYSTEM

INDICATIONS FOR USE
The Mazor X™ System is indicated for precise positioning of surgical instruments or spinal implants during general spinal and brain surgery. It may be used in either open or minimally-invasive or percutaneous procedures.

Mazor X™ 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into a volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

The Mazor X™ Navigation system tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient.

WARNINGS AND CONTRAINDICATIONS
- Do not use the Mazor X system with any patient who has been diagnosed or is suspected of having Creutzfeld-Jakob disease (CJD).
- The Mazor X system should only be used by qualified, medical professionals who have been thoroughly trained and have experience using the system.
- The Mazor X system should be used as a guidance system to assist the surgeon with the operation. The system is not intended as a replacement for the surgeon’s knowledge, expertise or judgment.
- Reuse of Mazor X disposable items may lead to infection.

**HUGO™ ROBOTIC-ASSISTED SURGERY (RAS) SYSTEM**

The Medtronic Hugo™ robotic-assisted surgery (RAS) system is an investigational device currently in development. The Hugo™ RAS system is not cleared or approved in all markets.

Features and technology of future RAS systems may vary. Regulatory requirements of individual countries and regions will determine availability and approval or clearance timelines.

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