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The Future of Robotic-Assisted Surgery in Orthopedics

WHITE PAPER

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Overview

No doubt, manufacturers of large surgical robotic systems have dominated the first era of robotic surgery. In orthopedics such systems have been acquired by the dominant implant companies and have been used to obtain long term implant performance.

But the next era of surgical robotics—both in hard tissue and soft tissue robotics—could open a path for companies creating smaller surgical robotic tools that require less space than predecessor systems.

One such example of a next-generation—or this generation—robotic surgical tool is the TMINI™ Miniature Robotic System, developed by THINK Surgical, in collaboration with Sagentia Innovation. The TMINI system, which received FDA clearance in 2023, addresses key barriers that had limited adoption of robotics in orthopedics. It has a small footprint, is an open platform that works with a range of implants, and integrates into the surgical workflows. This important innovation in surgical robotics hopes to improve outcomes, heighten patient satisfaction, and help drive further adoption of robotics in orthopedics.

Robotics can help address clinical needs in orthopedic procedures.

Surgical robotics in orthopedics emerged over two decades ago to make up for the shortfalls of knee and hip joint replacement surgery. While orthopedic implants leaders often pointed to high satisfaction rates, it is acknowledged that patient outcomes could be further improved.

In deeper study, surgeons, industry leaders, and companies in the orthopedic space looked at factors such as complication rate, patient satisfaction, and survivorship, which is the length of time that a primary implant lasts in a patient before revision surgery is needed.

Orthopedic implant manufacturers worked to improve quality focusing on product design, development, materials, and manufacturing processes to create implants that fit better. These positive innovations improved patient outcomes.

But robotic surgery developers felt more could be done to perform surgery more accurately and more reproducibly, and to personalize the surgery to the patient, rather than using a standard surgical plan.

There was definitely an opportunity to improve [knee replacement surgery]. We believe technology and more precise surgery are delivering some of that.

—Stuart Simpson, THINK Surgical

There has been relatively low adoption of robotics in orthopedics, due to significant headwinds.

Despite encouraging data when robotics is used in orthopedic surgery, and despite use by some early adopters, robotics has not yet been broadly adopted for orthopedic procedures.

Lack of adoption is due to various barriers and headwinds including:

- **Form factor.** Current robots are large pieces of equipment, at 700 or more pounds.
- **Closed systems.** The majority of surgical robotic systems on the market are closed systems, which can only be used with the implants provided by the same manufacturer that makes the robot.
- **Workflow.** Current surgical robotic systems do not seamlessly integrate into the surgical workflow.

Despite the encouraging prospects for robotics, it's still not that strongly adopted. By understanding the barriers and designing to address them, great solutions can be found to facilitate more widespread adoption.

—Rob Morgan, Sagentia Innovation

TMINI system is an innovation in robotic-assisted orthopedic surgery with potential for broad adoption.

THINK Surgical, in collaboration with Sagentia Innovation, has developed and introduced the TMINI Miniature Robotic System, an innovation in robotic-assisted orthopedic surgery.

The innovation partnership between THINK Surgical and Sagentia Innovation

THINK Surgical's leadership team had the idea for a wireless miniature handheld robot for orthopedics. After an extensive search, THINK Surgical determined that the innovation partner that could best help the company bring this concept to life was Sagentia Innovation.

THINK Surgical's decision was based on Sagentia Innovation's capabilities as a technology and product development partner with extensive R&D capabilities in medtech and extensive experience in surgical robotics.

Working together, Sagentia Innovation and THINK Surgical engaged in a process that has led to product development, manufacturing, FDA clearance, and now commercialization.

TMINI system addresses and overcomes barriers to broad adoption.

- **Form factor.** The TMINI is a miniature wireless handheld device weighing seven pounds, enabling easy integration within the operating room.

Figure 1: TMINI system handheld robot



- **An open platform.** The TMINI robotic system has an open platform that can be used with multiple implant devices, giving surgeons choices about which implant is best for each patient.
- **Workflow.** The TMINI robotic system easily integrates into the surgical workflow, affording a cohesive experience for the surgeon.

The TMINI system is a camera-based system that enables precise robotic positioning. It automatically compensates for surgeon hand movement, helping the surgeon locate pins precisely on the defined target of the operative bones so cutting blocks can be accurately placed. Despite its small form factor, it still has all of the personalization capability that large robots have.

Figure 2: Precise robotic positioning of the TMINI system

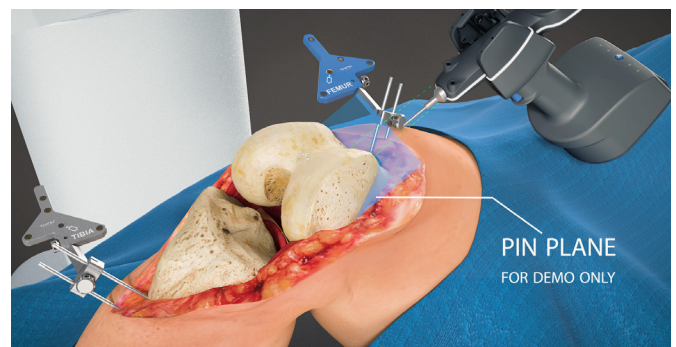
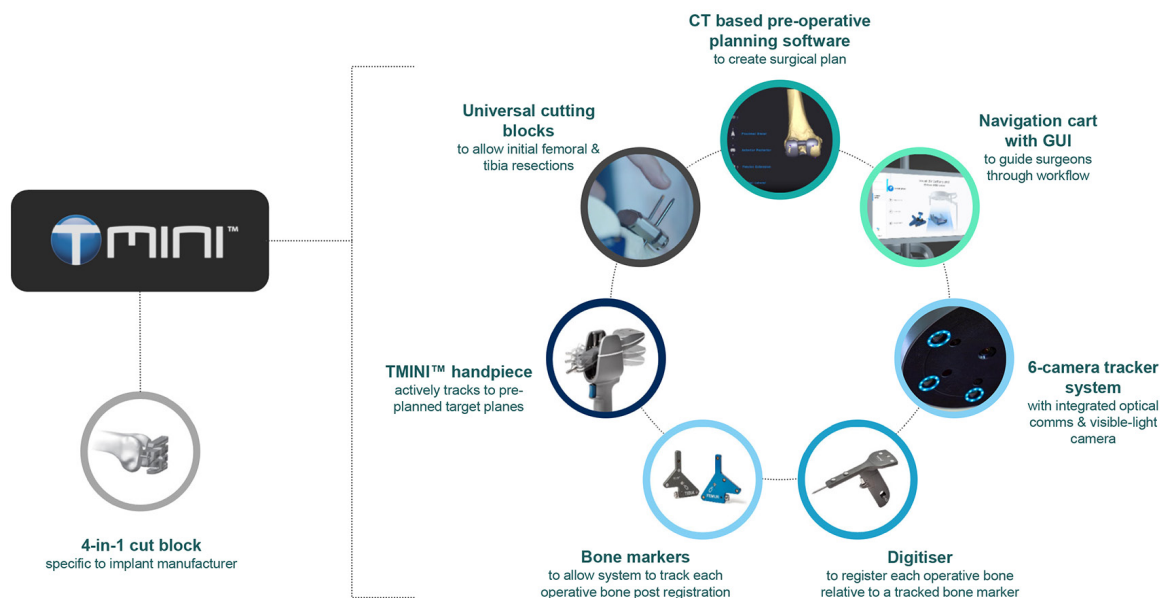


Figure 3: Technology integrated within the TMINI Robotic System



While the TMINI system concept is straightforward, the engineering behind this robotic system is complex in bringing together and integrating a collection of technologies.

These technologies include:

- **CT-based pre-operative planning software.** This software is used to create the patient specific surgical plan.
- **Navigation cart with GUI.** These carts guide the surgeon and technician through the various steps in the surgical workflow from set-up through to bone resection.
- **Six-camera tracker system.** Attached to the navigation cart is the six-camera tracker, with integrated two-way communications with all of the actively tracked devices. It also has an integrated, visible light camera that helps position the tracker within the tracker’s field of view relative to the patient.
- **Digitiser.** This is used to register each of the operative bones relative to the bone markers.
- **Bone markers.** These are used by the system to track each of the operative bones post-registration.
- **TMINI handpiece.** This has the capability to track to the pre-planned target planes to accurately place bone pins which allow placement of cut blocks used to make the necessary resections.

- **Universal cutting blocks.** These are placed on those inserted bone pins to allow the initial femoral and tibia resections.

“We believe that this is the opportunity for the majority of the market to start to embrace robotic joint replacement.

–Stuart Simpson, THINK Surgical

This innovation is just the tip of the iceberg; more innovation is on the way in orthopedic surgery.

The TMINI system received 510(k) clearance from the FDA in April of 2023. The company expects to scale up manufacturing in the second half of the year.

Looking ahead, it is likely that the TMINI system addresses many of the barriers that limited broad adoption of surgical robotics in orthopedics and it is likely that adoption will increase. It is also likely that over time, the use cases for the TMINI system will expand much like technologies in parallel markets such as soft tissue robotics.

What does the future hold? Advances in Augmented Reality (AR) and automation could enable further functionality for robotic surgical systems. Orthopedics can be both physically and cognitively demanding for surgeons, so a combination of assistive technologies that leverage the power of robotics and AR could win over converts who find current systems cumbersome and unnecessary. Future systems might allow a reduction in the physical demands of current surgery and better visualization of surgical planning information and 3D anatomical images. These advances in technology may then lead to less invasive joint replacement procedures and better outcomes for patients.

Additional Information

THINK Surgical, Inc. is a U.S.-based technology innovator that develops and markets orthopedic robots. These robots are open platforms providing support for implant brands from multiple manufacturers, enabling the choice of implant to be driven by the surgeon.

To learn more about THINK Surgical or the TMINI Miniature Robotic System visit thinksurgical.com.

Sagentia Innovation

Sagentia Innovation is a science and engineering R&D consultancy based in Cambridge, U.K. that offers product advisory and development services driven by insight and invention. Sagentia Innovation has an extensive track record in the development of surgical robotics spanning orthopedic, abdominal, endoluminal and endovascular systems.

To learn more about Sagentia Innovation, visit sagentiainnovation.com

White Paper Contributors



Tim Frearson

TMINI Program Manager, Sagentia Innovation

Tim is a Principal Consultant and Head of Electronics and Systems at Sagentia Innovation. He has a strong track record in the development and industrialization of Medtech products, nine of which have been awarded international patents. A mechanical engineer by training, Tim has focused on medical device development for most of his career. Before joining Sagentia Innovation, he held in-house roles with several leading infusion pump companies, and whilst at Sagentia Innovation, he has been focused on robotic-assisted surgery. In addition to his core mechanical engineering capabilities, Tim is highly skilled at project management and process optimization, making him an effective team leader.



Rob Morgan

VP Medical, Sagentia Innovation

Rob Morgan is VP Medical at Sagentia Innovation and works with clients across the medical devices industry. During his time at Sagentia Innovation Rob has led the development of a surgical robotics system and has worked in surgical devices, in vitro diagnostics and drug delivery. Prior to joining Sagentia Innovation, he worked in the orthopedics industry at Smith & Nephew, holding positions in research & development, project management and strategic marketing.



Stuart Simpson

President & Chief Executive Officer, THINK Surgical

Stuart has over two decades of experience in the medical devices industry and a deep understanding of the orthopedics and orthopedic surgical robotics market. Prior to joining THINK Surgical, Stuart had a successful 24-year career at Stryker Corp. holding roles of increasing responsibility ultimately assuming the position of president of joint replacement. He led Stryker into the robotics market in 2013 with the \$1.65 billion acquisition of Mako Surgical Corp. Stuart recognizes that a successful robotics business requires a digital and data ecosystem and he has formed strategic partnerships to bring these capabilities to THINK Surgical. Stuart has extensive experience as a board and committee member of both public and private companies and currently serves as executive chairman of Breg, Inc.