

# Insight Medbotics Announces World's First FDA-Cleared, MRI-Compatible Robot

The IGAR system is the first and only robotic guidance and placement system cleared to work inside an MRI bore, one of the most challenging hospital environments

**HAMILTON, ON (September 13, 2023)** — Insight Medbotics, a medical device company combining the accuracy of MRI with the precision of robotics, today announced a successful 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the IGAR system, the company's MRI-compatible robot. The clearance applies to breast biopsy indications.

IGAR is the first and only robotics system designed to work inside an MRI bore to achieve this regulatory clearance. The MRI suite is among the most challenging hospital environments because the MRI device uses strong magnetic fields and has a confined working area for physicians. The IGAR technology platform may be adapted for future products that could move seamlessly across different care environments, such as from an MRI to a standard operating room or into a physician's office.

Insight Medbotics has demonstrated IGAR's safety and efficacy through published clinical studies in breast biopsy. The technology's other possible applications include targeting other organs and disease indications, along with therapeutic delivery and device placement.

"Our team has long believed in the untapped potential of accessible MRI imaging, artificial intelligence and robotics together to improve quality of life for patients," says Fazila Seker, CEO of Insight Medbotics. "Many teams are researching viable paths to take robotics into the MRI suite, but IGAR is the first to secure FDA clearance. This regulatory achievement advances our long-term vision, and our commitment to delivering technology that supports the future of precision medicine."

The IGAR system is the brainchild of a unique combination of world-class experts in surgery and robotics. Its story begins with Professor Mehran Anvari, a surgical robotics pioneer and the scientific director and CEO of the Centre for Surgical Invention and Innovation (CSii). His team funded the preliminary human trials for IGAR, collaborating with world-leading robotics engineers from MDA—Canada's leading space company—to create and test the device's first prototypes. MDA is known worldwide as the designer and manufacturer of the Canadarm family of space robotics.

Insight Medbotics was subsequently launched as a start-up company by CSii and MDA. The company also received significant funding to develop its technology—including product prototype and clinical testing via CSii and the Canadian Government's Network of Centres of Excellence (NCE) program.

"FDA clearance brings this technology one crucial step closer to patients," says Anvari, who is also the founding director of both the Centre for Minimal Access Surgery and the McMaster Institute for Surgical Invention, Innovation, and Education. "McMaster University and St. Joseph's Healthcare Hamilton have been significant partners in this journey. Their 20-year investment in IGAR's research concepts, early development, and patents—combined with MDA's work in space robotics—made it possible to create a robot that operates safely and effectively within the extreme environment of an MRI's magnetic field."

With the 510(k) clearance secured, Insight Medbotics will continue to advance IGAR to market.

"Our vision is to build robotics systems that make it easier to provide more targeted care everywhere," says Seker. "With this milestone, we're one step closer to making a difference in patients' lives."

## About Insight Medbotics

Insight Medbotics is developing MRI-guided robotics to advance its technology to procedures where accuracy and precision matter most to patients, physicians, and hospitals. The IGAR system has been clinically demonstrated in breast cancer patients and is the world's first and only FDA-cleared, MRI-compatible robot. With a FDA 510(k) clearance in breast biopsy, Insight Medbotics envisions development in other biopsies, therapy delivery, and device placement. Learn more at <https://insightmedbotics.com>.

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