Medtronic News

Medtronic receives FDA clearance for Stealth AXiS™ surgical system, first integrated planning, navigation and robotics platform for spine surgery

GALWAY, Ireland, Feb. 13, 2026 /PRNewswire/ -- Medtronic (NYSE: MDT), a global leader in healthcare technology, today announced U.S. Food and Drug Administration (FDA) clearance of the Stealth AXiS™ surgical system, a next-generation platform that brings planning, navigation, and robotics together into a single, intelligent system for spine surgery.

The Stealth AXiS™ system is cleared for spine procedures in the United States, with an underlying architecture designed to support future cranial and ENT applications, pending 510(k) clearance. Built to support a wide range of surgeon preferences, clinical complexity, and care settings, the platform is designed for use across hospitals and ambulatory surgery centers without relying on multiple standalone technologies.

Grounded in more than 50 years of Medtronic leadership in surgical navigation and robotics, the Stealth AXiS™ system creates a clear pathway for adoption by combining familiar navigation workflows with a modular robotic design, allowing institutions to deploy what they need today and expand over time as clinical needs evolve.

"The Stealth AXiS™ system represents a meaningful step forward in how we think about navigation and robotics working together," said Ronald A. Lehman, Jr., M.D., Tenured Professor of Orthopaedic Surgery (Neurological Surgery) at Columbia University, Division Chief of Spine Surgery, and Spine Medical Director at The Spine Hospital at NewYork-Presbyterian/The Allen Hospital, and a paid consultant to Medtronic. "One of the biggest challenges in spine surgery has been understanding and responding to how the spine moves during a procedure. The Stealth AXiS™ system gives surgeons real-time visibility into that motion, helping us more consistently achieve our surgical plan without interrupting workflow. To me, this is truly game changing technology."

A key innovation of the Stealth AXiS™ system is LiveAlign™ segmental tracking, an industry-first capability that allows surgeons to visualize anatomic motion, surgical adjustments, and patient alignment in real time during spine surgery, without the need for repeated imaging. This capability helps reduce reliance on manual steps and workflow disruption, supporting more consistent execution of patient-specific surgical plans.

As a cornerstone of Medtronic's AiBLE™ smart ecosystem, the Stealth AXiS™ system enables a more intuitive and seamless flow of information across the surgical continuum. By natively integrating planning, navigation, and execution within a single platform, the Stealth AXiS™ system helps streamline workflows and supports the exchange of insights before, during, and after spine surgery, allowing the broader AiBLE™ ecosystem to connect devices, software, and data in a more meaningful way.

"Spine surgery is complex, and variability remains a real challenge," said Michael Carter, Senior Vice President and President of Medtronic Cranial & Spinal Technologies. "The Stealth AXiS™ system is designed to make advanced technology more usable and clinically meaningful, helping surgeons deliver more predictable, personalized care while laying the foundation for continued innovation."

The Stealth AXiS™ surgical system reflects Medtronic's focus on building durable platforms that simplify surgical workflows today while enabling future expansion across procedures, specialties, and care settings.

For more information about the Stealth AXiS™ surgical system and the AiBLE™ smart ecosystem, visit www.Medtronic.com/StealthAxis.

About the Cranial & Spinal Technologies Business at Medtronic

As the global market leader, Medtronic Cranial and Spinal Technologies is transforming the standard of care in spine and

cranial surgery by putting patients first and addressing the complex challenges faced by spine and neurosurgeons. With a portfolio of 150 products covering more than 20 pathologies, we serve over 4 million patients annually. Building on a legacy of innovation, our AiBLE™ ecosystem integrates advanced technologies, data, and AI with a patient-centric approach, offering customizable solutions to enhance surgical precision, improve workflow efficiency, and achieve better outcomes, before, during, and beyond surgery.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway,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 95,000+ 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, visit www.Medtronic.com and follow Medtronic on 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:

Christine Stewart
Public Relations
+1-269-377-2557

Ingrid Goldberg
Investor Relations
+1-763-505-2696

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