

Medtronic Receives FDA Clearance for Stealth AXiS™ Surgical System for Cranial and ENT Procedures

GALWAY, Ireland, March 27, 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 for cranial and ear, nose, and throat (ENT) procedures. Cleared for spine procedures in February, the Stealth AXiS™ surgical system unifies surgical planning, navigation, and robotics into a single intelligent system to support surgeons with greater precision and real-time insights during complex procedures. This clearance reinforces Medtronic's strategy to deliver connected technologies that support surgeons across multiple specialties on a single platform.

"Cranial procedures require an exceptional level of precision, planning, and real-time insight," said Michael Carter, Senior Vice President and President of Medtronic Cranial & Spinal Technologies. "With the Stealth AXiS™ surgical system, we are bringing together advanced navigation, robotics, and AI-enabled capabilities within the AiBLE™ smart ecosystem to support surgeons with deeper insights across the surgical workflow."

A defining capability of the platform is its AI-enabled architecture, which supports advanced planning and visualization before, during, and after surgery. For cranial procedures, the system includes AI-based automatic tractography that helps surgeons generate patient-specific brain maps and visualize critical neural pathway associated with essential brain functions. The platform also integrates intraoperative ultrasound through GE HealthCare's bkActiv™, providing additional real-time imaging during procedures.

"For complex brain surgeries, the more information you have, the better decisions you can make," said Dr. Michael Ivan, neurosurgeon at the University of Miami Health System. "Pre-operative planning with tools like tractography may help surgeons enhance surgical efficiency and support better patient outcomes." ^{1,2}

For ENT procedures, the Stealth AXiS™ surgical system delivers high-precision navigation and advanced visualization tailored to the intricate anatomy of the sinuses and skull base. Built around real-world ENT workflows, the system offers sharper anatomical detail and faster responsiveness to support confident decision-making in the OR, as well as intuitive, surgeon-centered workflows to create a familiar user experience while delivering enhanced capabilities.

"Intraoperative navigation is critical in minimally invasive endoscopic surgery of the sinuses and skull base, helping surgeons confidently delineate complex anatomy within high-risk spaces," said Dr. Vijay Ramakrishnan, board-certified otolaryngologist and professor of Otolaryngology-Head & Neck Surgery at Indiana University School of Medicine. "The Stealth AXiS™ system leverages innovative technologies to enhance surgeon workflows and support procedural efficiency and confidence in the operating room."

Additionally, the system's flexible architecture is designed to support continuous software innovation, expanded capabilities, and deeper ecosystem connectivity to help shape the next era of surgery.

"The Stealth AXiS™ surgical system represents the next era of navigation for ENT surgery," said Sean Haag, President of the Ear, Nose, & Throat business at Medtronic. "Building on 25 years of navigation leadership, this system is designed to help surgeons move with greater clarity, confidence, and control in the OR, while creating a powerful platform for the next generation of ENT innovation."

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 the Ear, Nose, & Throat Business at Medtronic

Medtronic's Ear, Nose, and Throat (ENT) business is the global market leader in ENT, delivering innovative technologies that impact nearly 3 million patients each year. For more than 25 years, we have partnered with physicians to advance care across the specialty. Our portfolio supports surgical procedures related to chronic rhinosinusitis and head and neck cancers, spanning surgical navigation, tissue health, powered instruments, localized drug delivery, intraoperative nerve monitoring, and parathyroid detection. As the global leader in ENT navigation since the introduction of the LandmarX™ image-guided surgery system in 1998, we continue to advance the field with next-generation platforms including the Stealth AXiS™ Surgical System.

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.

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¹Li Z, et al. *World Neurosurgery*. 2018;116:e291-e297.

²Guberman GI, et al. *Neurology*. 2025;105(9).

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