

Medtronic announces CE Mark for Stealth AXiS™ surgical system

Following recent FDA clearances, Medtronic is accelerating access to integrated planning, navigation, and robotics platform across Europe

GALWAY, Ireland, April 28, 2026 /PRNewswire/ -- Medtronic, a global leader in healthcare technology, has received CE mark for the Stealth AXiS™ surgical system, a next-generation platform that brings planning, navigation, and robotics together into one single, intelligent system. The Stealth AXiS™ system is indicated for spine and cranial procedures, highlighting the platform's scalability across multiple surgical specialties for Medtronic.

"Receiving CE mark for the Stealth AXiS™ system marks an important milestone in expanding access to advanced surgical technologies across Europe," said Oli Prospero, Vice President, International Commercial, Cranial & Spinal Technologies, Medtronic. "Achieving CE mark in the current regulatory environment, under EU Medical Device Regulation (MDR), underscores our commitment to bringing meaningful innovation into a highly diverse healthcare landscape."

The Stealth AXiS™ system represents major advancement in surgical technology by integrating planning, navigation, and robotic execution into a single, modular platform. Designed to support a wide range of clinical workflows and surgical environments, the system enables hospitals to adopt capabilities based on their needs, while maintaining flexibility for future expansion.

A key innovation of the system is LiveAlign™ segmental tracking, an industry-first capability that allows surgeons to visualize anatomical motion and patient alignment in real time during spine procedures. As a cornerstone of Medtronic's AiBLE™ ecosystem, the Stealth AXiS™ system connects pre-, intra-, and post-operative workflows, enabling a more integrated approach to surgical care.

A key strength of the platform lies in its AI-driven architecture, which enables advanced planning and visualization across all stages of surgery - before, during, and after the procedure. In cranial applications, it features AI-powered automatic tractography, allowing surgeons to create patient-specific brain maps and clearly visualize critical neural pathways linked to essential brain functions.

"The introduction of the Stealth AXiS™ system to Europe reflects our focus on delivering connected platforms that improve precision, efficiency, and consistency across diverse healthcare systems," said Michael Carter, Senior Vice President and President of Cranial & Spinal Technologies at Medtronic. "By bringing planning, navigation, and robotic guidance into a unified workflow, we are helping surgeons translate insight into action in the operating room, supporting more predictable and personalized care while building a strong foundation for continued innovation."

The CE mark follows U.S. FDA clearances earlier this year, highlighting Medtronic's ability to rapidly bring advanced surgical technologies to global markets.

For more information about the Stealth AXiS™ surgical system and the AiBLE™ smart ecosystem, [visit our website](#).

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:

Maria Trenzado

Communications for Western Europe


maria.trenzado@medtronic.com

Ingrid Goldberg

Investor Relations

+1-763-505-2696

SOURCE Medtronic plc

Additional assets available online:  [Photos \(1\)](#)

https://news.medtronic.com/2026-04-28-Medtronic-announces-CE-Mark-for-Stealth-AXiS-TM-surgical-system?trk=public_post_comment-text