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Medtronic Receives CE Mark for Stealth AXiS™ Surgical System for Ear, Nose, and Throat Procedures

Following recent U.S. FDA clearance, Medtronic expands access to its next-generation ENT navigation platform across Europe

June 8, 2026 - Medtronic, a global leader in healthcare technology, today announced it has received CE mark for the Stealth AXiS™ surgical system for ear, nose, and throat (ENT) procedures. The approval expands access to Medtronic's next-generation ENT navigation platform across Europe, bringing advanced visualization, navigation, and connected workflow capabilities to ENT surgeons and hospitals.

Built around real-world ENT workflows, the Stealth AXiS™ surgical system is designed to support surgeons navigating basic to complex anatomy of the sinuses and skull base. The system delivers enhanced anatomical visualization and faster system responsiveness compared to the previous-generation platforms, supporting procedural efficiency and surgical confidence in the operating room through streamlined workflows.

"Receiving CE mark for the Stealth AXiS™ surgical system in ENT procedures is an important milestone for ENT surgeons and patients across Europe," said Sean Haag, President of the Ear, Nose, & Throat business at Medtronic. "This platform builds on our long legacy in surgical navigation while introducing a more connected, intelligent system specifically designed for the future of ENT surgery."

The Stealth AXiS™ surgical system supports a broad range of ENT procedures, including minimally invasive sinus and skull base surgery, as well as sinus balloon procedures. The platform integrates into the Medtronic AiBLE™ ENT smart ecosystem, helping connect technologies and workflows across the ENT surgical experience.

"We're excited to reach this milestone and expand access to the Stealth AXiS™ surgical system across Europe," said Panos Drakoulas, Vice President of International for the Ear, Nose, and Throat business at Medtronic. "ENT surgeons are looking for technology that fits naturally into their workflow while helping them navigate basic to highly complex anatomy with confidence. The Stealth AXiS™ surgical system was built with those insights in mind, and we look forward to supporting more surgeons and patients across the region."

The CE mark follows recent U.S. FDA clearance for ENT procedures earlier this year and reflects Medtronic's continued investment in advancing surgical innovation for ENT surgeons worldwide. The Stealth AXiS™ surgical system has also received CE mark for spine and cranial procedures.

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

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.

Product availability, indications, and regulatory status vary by country. Healthcare professionals should refer to the applicable product labeling and instructions for use in their market for indications, warnings, precautions, and operating instructions.

Information contained herein is not medical advice and should not be used as an alternative to speaking with your doctor.

Discuss indications, contraindications, warnings, precautions, adverse events and any further information with your health care professional.

Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices.

The material on this website should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s).

Please note that the intended use of a product may vary depending on geographical approvals.

See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications,

contraindications, warnings, precautions, and potential adverse events.

For MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI.

*If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website
manuals.medtronic.com.*

*Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat®
Reader with the browser.*

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