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Medtronic Receives FDA Clearance for ApexCut™ EM Navigated Blades for Sinus Surgery

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Oct. 7, 2026 - Medtronic, a global leader in healthcare technology, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance for ApexCut™ EM navigated blades for sinus surgery, expanding its next-generation portfolio of powered ENT instruments with new navigated capabilities. ApexCut™ EM navigated blades connect directly to the Stealth AXiS™ ENT navigation system, Medtronic's most advanced navigation ENT platform.

"This clearance expands what we can offer surgeons across our power and navigation portfolios, bringing new angles and capabilities together in a more integrated way," said Sean Haag, President of the Ear, Nose, and Throat business at Medtronic. "By connecting ApexCut™ EM blades directly with the Stealth AXiS™ ENT navigation system, we're giving surgeons more flexibility in how they approach sinus procedures while continuing to build a more connected ENT ecosystem."

Developed with surgeon feedback and insights, the ApexCut™ blade line is engineered to reduce clogging and deliver greater procedural efficiency during powered ENT procedures.^{§, 1} The blade design incorporates a new tooth-to-tooth mouth design, distal-to-proximal cutting pattern, as well as exclusive FlexMetric™* technology in curved blades, intended to minimize clogging interruptions and help maintain procedural flow.^{§, 1}

First clinical cases for ApexCut™ EM navigated blades in the U.S. are expected to take place later this year, following the planned release of the updated navigation software.

The FDA clearance builds on the growing global momentum of the Apex™ Power portfolio. Medtronic launched ApexCut™ non-navigated blades through a limited U.S. release in February 2026, followed by a full U.S. launch in May. Medtronic has also launched the non-navigated blades in Western Europe and completed first commercial cases in Japan and Australia.

The launch of ApexCut™ EM navigated blades represents another milestone in Medtronic's broader commitment to actively build a connected AiBLE™ ENT surgical ecosystem, bringing technologies together to support more seamless, efficient and data-enabled care.

"The FDA clearance of ApexCut™ navigated blades is another step in building our AiBLE™ ENT surgical ecosystem that will connect best-in-class capital and disposable systems across power, navigation, digital recording technology, and endoscopy partnerships," said Dan Mendelson, VP of Global Marketing for the Ear, Nose, and Throat business at Medtronic.

About the Ear, Nose, and 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™ ENT navigation 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 [Medtronic.com](https://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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[§] Efficiency is defined by the reduction of clogging and minimized interruptions, made possible by the blade's cutting design and FlexMetric™ technology in curved blades that streamline tissue removal and suction flow.

1. Non-clinical testing measuring grams resected of simulated material prior to first clog, comparing ApexCut blades vs Medtronic Tricut, RAD, and Quadcut blades. REF-32461: D01509297 ApexCut Blade Clog Resistance vs Predicate Sinus Blade Design Characterization Report. Non-clinical testing is not indicative of clinical results.

The ApexCut™ EM navigated blades are surgical instruments used in conjunction with IPC/XPS and Medtronic computer-assisted surgery systems, intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology (ENT) and head and neck surgery, and as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT- or MR-based model, or digitized landmarks of the anatomy. The system and its associated accessories should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgment.

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