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Medtronic receives FDA 510(k) clearance for Visualase™ V2 MRI-Guided Laser Ablation System

Minimally invasive laser technology now with enhanced capital system improvements, offering new user interface, workflow efficiencies, and upgrade capabilities

Medtronic, a global leader in medical technology, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Visualase™ V2 MRI-Guided Laser Ablation System. This milestone brings important capital system enhancements to the Visualase™ platform, which provides a minimally invasive surgical option for patients with focal epilepsy, brain tumors, and radiation necrosis, which impacts over 1 million people total worldwide.^{1,2}

Visualase™ allows surgeons to navigate deep within the brain with pinpoint accuracy, gently delivering laser energy to ablate diseased tissue without disturbing surrounding structures. This is done through an incision just millimeters wide. Visualase™ uses laser interstitial thermal therapy (LITT) to deliver precisely targeted energy through a small catheter, enabling surgeons to ablate soft tissue under real-time MRI guidance. Compared to traditional open neurosurgery, the Visualase™ system offers several patient benefits:

- Minimally invasive access through a small (4 mm) incision
- Reduced hospital stays and faster recovery³⁻¹⁰
- Minimal scarring
- Lower risk of infection^{9, 11-13}
- High patient satisfaction^{4,14}

“This clearance is a significant advancement for patients and clinicians alike,” said Dr. Ashwini Sharan, chief medical officer of Medtronic Neuromodulation, which is part of the Neuroscience Portfolio. “By providing a minimally invasive option with real-time MRI guidance, we’re enhancing surgical precision. This is an important advancement for neurosurgical procedures.”

The V2 offers proven precision, accuracy, and enhanced visualization capabilities, now with completely redesigned software, hardware, and interface for a more intuitive, streamlined, and efficient workflow. It is also designed to easily unlock future innovations that are expanding what’s possible in LITT without needing to upgrade any hardware.

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 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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