

Medtronic Announces FDA Approval of its Next Generation Recharge-Free Spinal Cord Stimulation Platform

Vanta™ Implantable Neurostimulator Offers Up to 11 Year Battery Life and Personalized Pain Relief

DUBLIN, June 10, 2021 [/PRNewswire/](#) -- Medtronic plc (NYSE: MDT), the global leader in medical technology, today announced it has received U.S. Food and Drug Administration (FDA) approval for Vanta™, a high performance recharge-free implantable neurostimulator (INS) with a device life that can be optimized up to 11 years. At comparable settings, the Vanta neurostimulator offers nearly twice the device life than competitive primary cell devices.^{1,2} It also utilizes Medtronic's proprietary AdaptiveStim™ technology for personalized pain relief that adapts to the patient's movement or body position using a built-in accelerometer. AdaptiveStim technology goes beyond in-office programming by automatically adjusting stimulation to maintain each patient's optimal dose. The Vanta neurostimulator also provides unmatched full-body MRI access with Medtronic SureScan™ technology.³ Approximately 82% of SCS-implanted patients will need at least one MRI within five years of implant.⁴

"Not every patient with chronic, intractable pain is an ideal candidate for a rechargeable device, so the Vanta INS represents a welcome addition to my portfolio of available treatment options," said Krishnan Chakravarthy, M.D., Ph.D., a San Diego-based interventional pain management physician. "The extended battery life, broad MRI compatibility and personalized relief through AdaptiveStim technology allow for a more hassle-free experience and greater freedom for my patients as we manage their chronic pain."

Medtronic is continually innovating to advance spinal cord stimulation therapy technologies that improve quality of life for people with chronic pain. The Vanta neurostimulator represents a 10% increase in longevity compared to PrimeAdvanced™, Medtronic's previous generation recharge-free device. It is also 20% smaller than the PrimeAdvanced neurostimulator, with a more rounded, ergonomic contouring to offer enhanced comfort. The Vanta system provides access to Snapshot™ reporting, Medtronic's proprietary data insights solution, offering clinicians objective reporting of patient activity levels to empower objective health conversations. Clinicians and their patients wishing to trial the Vanta neurostimulator may also take advantage of CareGuidePro™, a mobile application and web portal that serves as a virtual guide for patients throughout their Medtronic spinal cord stimulation therapy journey. CareGuidePro is currently in limited commercial release with a full launch expected later this summer.

"We are committed to delivering innovative solutions that meets the needs of every patient," said Charlie Covert, vice president and general manager, Pain Therapies within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "For those who prefer or require a recharge-free device, I believe the Vanta neurostimulator offers the best hardware and features available today. We are pleased to offer this solution, which is now part of the strongest and broadest overall portfolio in this market."

Medtronic continues to focus on expanding access to its highly effective DTM™ SCS therapy through pre-clinical and clinical work. DTM SCS is currently available on the rechargeable Intellis™ SCS platform, and the company expects to share more information about its availability across the entire Medtronic spinal cord stimulator portfolio later this summer.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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.



References

1. Settings used from Abbott's Proclaim™ clinician manual. Nominal settings 12 hours per day: 50-Hz frequency, 225-μs pulse width, and 5-mA amplitude at 500-ohms impedance. Compared to flagship model 3660.
2. Settings from Boston Scientific's Alpha™ IFU. Programmed at 4.1mA, 280us, 40 Hz, 1 area, 730 Ohms, 2 contacts.
3. Under specific conditions. Refer to product labeling for full list of conditions.
4. Desai MJ, Hargens LM, Breitenfeldt MD, et al. The rate of magnetic resonance imaging in patients with spinal cord stimulation. Spine. 2015;40(9):E531-537.

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