

Medtronic announces FDA approval of spinal cord stimulation therapy for treating chronic pain resulting from diabetic peripheral neuropathy

Studies show significant reduction in pain and improved quality of life for patients treated with spinal cord stimulation compared to medication management alone

DUBLIN, Jan. 24, 2022 [/PRNewswire/](#) -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced it has received U.S. Food and Drug Administration approval of its Intellis™ rechargeable neurostimulator and Vanta™ recharge-free neurostimulator for the treatment of chronic pain associated with diabetic peripheral neuropathy (DPN).

DPN is a debilitating and progressive neurological disorder that affects approximately 30% of people with diabetes, significantly impacting both quality of life and functional ability, including mood, social relationships, and sleep.¹ DPN occurs when high blood sugar (glucose) damages nerves in the body, most often in the legs and feet, leading to numbness and burning or stabbing pain. In some patients, the pain can become progressively worse and excruciating. Patients may be treated with medications, but they are often only partially effective and can result in serious side effects.

This new indication offers patients with DPN access to Medtronic's industry-leading spinal cord stimulation (SCS) portfolio of rechargeable and recharge-free platforms, which include multiple programming options to personalize patient therapy, unrestricted MRI access², unrivaled battery chemistry and performance, and the Medtronic TYRX™ Neuro Absorbable Antibacterial Envelope. The surgical management of diabetic patients can be a challenge for health care providers as they often have additional risk factors and are at greater risk for infection.³ The TYRX™ antibacterial surgical mesh envelope has been shown to stabilize device placement and help reduce infection by over 60%.⁴⁻¹⁰ Clinicians may also advise patients to take advantage of CareGuidePro™, which serves as a virtual guide for patients throughout their SCS journey.

Independent studies show patients with DPN achieve significant pain relief when treated with SCS compared to conventional treatments alone.^{11,12} Overall, 70% of patients receiving treatment with SCS experienced relief of their pain symptoms compared to 6% of patients receiving only conventional treatments. Those treated with SCS experienced a 53% average reduction in pain, compared to 0% among patients receiving only conventional treatments. A recent meta-analysis showed a significant improvement in health-related quality of life in patients treated with SCS compared to those receiving only conventional treatments.¹³ A long-term analysis of patients treated in one of the studies using Medtronic SCS technology showed 80% of patients treated with SCS continued to use their devices at five years to treat their pain.¹⁴

"DPN is a significant challenge for patients with diabetes, leading to disability and a diminished quality of life," said Charlie Covert, vice president and general manager, Pain Therapies within the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "This new indication enables us to apply Medtronic's more than 40 years of proven SCS experience, as well as the company's deep diabetes expertise, to deliver better care to even greater numbers of diabetes patients."

Medtronic estimates that up to 800,000 US patients suffer from moderate to severe DPN symptoms that are not resolved through conventional medical management approaches, like drugs. The company views these patients as potential candidates for SCS, representing an approximate \$1.8 billion annual market opportunity. Today, Medtronic estimates that the US market revenue for SCS treatment of chronic pain associated with DPN, sometimes also referred to as Painful Diabetic Neuropathy (PDN), is approximately \$70 million, and the company expects market revenue to grow to \$300 million by fiscal year 2026.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, 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 90,000+ passionate people across 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 (NYSE:MDT), visit www.Medtronic.com, and follow [@Medtronic](https://twitter.com/Medtronic) on Twitter and [LinkedIn](https://www.linkedin.com/company/medtronic).

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. Sloan G, Alam, U, Selvarajah D, Tesfaye S. The Treatment of Painful Diabetic Neuropathy. Current Diabetes Reviews. July 2021
2. Under certain conditions. Refer to product labeling for full list of conditions.
3. American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes – 2021. Diabetes Care. 2021; 44, S1, S211-S219
4. Bloom HL et al. Pacing Clin Electrophysiol. 2011;34(2):133-142.
5. Mittal S et al. Heart Rhythm. 2014;11(4):595-601.
6. Kolek MJ et al. J Cardio Electrophysiol. 2015;26(10):1111-1116.
7. Shariff N et al. J Cardio Electrophysiol. 2015;26(10):783-789.
8. Henrikson CA, et al. JACC EP.2017;3(10):1158-1167.
9. Kolek MJ et al. Pacing Clin Electrophysiol. 2013;36(3):354-361.
10. Huntingdon Life Sciences Study TR-2011-054. 2. Osoro M et al. Pacing Clin Electrophysiol. 2018;41:136-142.
11. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. Pain. 2014 Nov;155(11):2426-31.
12. Slangen R, Schaper N, Faber C, et al. Spinal Cord Stimulation and Pain Relief in Painful Diabetic Peripheral Neuropathy: A Prospective Two-Center Randomized Controlled Trial. Diabetes Care. 2014;37:3016-3024.
13. Duarte RV, Nevitt S, Maden M, et al. Spinal cord stimulation for the management of painful diabetic neuropathy: a systematic review and meta-analysis of individual patient and aggregate data. Pain. March 2021.
14. Van Beek M, Geurts J, Slangen R, et al. Severity of Neuropathy Is Associated With Long-term Spinal Cord

Stimulation Outcome in Painful Diabetic Peripheral Neuropathy: Five-Year Follow-up of a Prospective Two-Center Clinical Trial. Diabetes Care. 2018;41:32–38.

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