

**JAN 23, 2025**

# New 12-month clinical data highlights significant and sustained benefits of the Inceptiv™ closed-loop spinal cord stimulation system

*Study shows 67% mean reduction in Low-back Visual Analog Scale (VAS) pain score at 12 months; 87% of subjects had meaningful improvements in three or more quality of life (QoL) domains*

*Data to be presented at the North American Neuromodulation Society (NANS) Annual Meeting 2025; In all, Medtronic to highlight 22 poster and oral scientific data presentations*

Medtronic, a global leader in healthcare technology, today announced 12-month data from a clinical trial (NCT05177354) demonstrating the benefits of its Inceptiv™ closed-loop spinal cord stimulator (CL-SCS) in patients with chronic Low-back pain (CLBP) and leg pain. The data will be presented at the North American Neuromodulation Society (NANS) 2025 meeting, taking place January 30 - February 1, in Orlando, Florida. In all, the company is highlighting 22 data presentations reflecting evidence from Medtronic-sponsored research and collaborations with external partners.

The Inceptiv™ spinal cord stimulator, which received FDA approval in April 2024, senses<sup>†</sup> biological signals along the spinal cord and automatically adjusts stimulation in real time. The objective of the prospective, multi-center, single-arm “Evaluation of Long-term Patient Experience with a Medtronic Closed-Loop SCS System” study is to characterize the efficacy of the Inceptiv SCS system for treating chronic neuropathic pain and improving quality of life. Patients were randomized with closed-loop On/Off periods.

Key 12-month findings from the study include:

- 93% of patients reported a reduction in overstimulation with the CL feature during in-clinic testing (n=43)
- 88% of patients preferred having the CL feature On (vs. Off; n = 43)
- At-home experience was consistent with the in-clinic testing results - 91% of participants (n = 46) reported not experiencing uncomfortable stimulation during activities of daily living
- 82% reported 50% or more reduction in low-back pain intensity with a mean reduction of 67% (n = 38)
- 50% were able to reduce or stop the use of opioid medications (n=32 with MME>0 at baseline)
- 87% of subjects (n = 46) improved in 3 or more domains of a composite endpoint that includes pain (VAS reduction  $\geq 30\%$ ), QoL (EQ-5D-5L increase  $\geq 0.074$ ), physical function (Oswestry Disability Index

- reduction  $\geq 10$ ), mood (POMS reduction  $\geq 10$ ) and sleep quality (PSQI reduction  $\geq 3.0$ )
- With the closed-loop feature on, patients made only 1 median adjustment to programming every 30 days. By comparison, in a U.S. SCS patient market research survey across multiple manufacturers, 50% of participants (n = 100) made frequent adjustments at least a few times per week.<sup>1</sup>
- 100% of subjects (n = 46) expressed satisfaction with CL-SCS therapy and 98% would recommend to friends and family

“The 12-month data demonstrate that Inceptiv with closed-loop technology provides significant benefits in improving pain, quality of life and physical function scores while substantially reducing overstimulation,” said Dr. Vahid Mohabbati, MD, director of the Sydney Pain Research Centre in Sydney, Australia and an investigator on the trial. “The findings that 50% of patients were able to decrease or discontinue opioid pain medication and the median number of times that patients adjusted their stimulation amplitude was only once every 30 days underscore that Inceptiv with closed-loop sensing can reduce treatment burden while providing effective pain relief. These results emphasize the importance of tailoring stimulation and ensuring consistency of dosing for optimal benefits from SCS therapy as patients engage in activities of daily living.”

“These results add to the growing body of high-quality evidence demonstrating the long-term efficacy of SCS in reducing pain and improving quality of life, said Dr. Ashwini Sharan, chief medical officer of the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. “We are especially pleased that so many patients in this study not only found pain relief with Inceptiv SCS, but were also comfortable letting the closed-loop feature make stimulation adjustments automatically, lessening the burden of manual therapy changes. The reduced need for manual adjustments, combined with positive therapy experience and satisfaction, may lead to better therapy compliance and durability of outcomes.”

The primary and secondary study endpoints were previously met and were presented at the 2024 annual meeting of NANS. The primary endpoint was at least a 50% reduction in overstimulation with the CL feature On vs. Off at 1 month. The secondary endpoint was the proportion of patients with at least a 50% reduction in overall, back, leg or upper limb (UL) VAS scores at 3 months (88% low-back and 77% leg, 100% UL). Study subjects will have 18- and 24-month follow-up.

† Sensing signals may not be measurable in all cases

### **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 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, visit [www.Medtronic.com](http://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.**

Contacts:

Jeff Trauring

Public Relations

+1-763-505-0159

Ryan Weispfenning

Investor Relations

+1-763-505-4626

---

<sup>1</sup> Conducted in June/July 2023 by StrataMark LLC, an independent third-party market research agency (n=100, double-blinded, 20-minute online survey) across multiple manufacturers (Medtronic, Boston Scientific, Abbott, Nevro), and types of waveforms (81% sub-perception).

<https://news.medtronic.com/New-12-month-clinical-data-highlights-significant-and-sustained-benefits-of-the-Inceptiv-TM-closed-loop-spinal-cord-stimulation-system>