

Inceptiv™ Closed-Loop Spinal Cord Stimulator

Category:

Best Medical Technology

Company Name:

Medtronic

Product/Solution Name:

Inceptiv™ Closed-Loop Spinal Cord Stimulator

Compound/Tech Name:

N

Trade Name:

n/a

Corporate Name:

n/a

Date of Approval:

2024-04-26

Indications:

Spinal cord stimulation (SCS) as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain associated with the following conditions:

- Failed back syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia

- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia
- Diabetic peripheral neuropathy of the lower extremities

Therapeutic Areas:

N/A

General Information File Document upload:

N/A

Background information and need for drug / device:

Patients suffering from chronic pain live in constant agony, struggling to do things most of us take for granted - day-to-day activities such as grocery shopping, walking the dog, or attending a child's school performance. Chronic pain is a long-lasting, often debilitating condition that affects millions of people with 20.4% of U.S adults experiencing chronic pain.¹

Medtronic has innovated new advances in non-opioid treatments for chronic pain management that are bringing patients much-needed relief and joy back to their day-to-day activities.

1. <https://www.cdc.gov/nchs/data/databriefs/db390-H.pdf>(opens new window) accessed 12/6/2023

Background File Document upload:

N/A

History of the development of the solution/product:

Medtronic pioneered the spinal cord stimulation (SCS) market over 50 years ago. Previous generation SCS devices included one-way, fixed-output technology. These devices deliver stimulation to the spinal cord but don't receive any feedback, leading to over- and under-stimulation.¹

By contrast, closed-loop (CL) systems incorporate specialized circuitry and a proprietary algorithm to detect ECAPs (Evoked Compound Action Potentials), which are wave-like electrical signals resulting from the stimulation of nerve fibers. ECAPs are a direct measure of how much nerve tissue is activated in the spinal cord and can be used to

inform real-time adjustments to stimulation.

Fixed output SCS devices do not account for shifts in lead-to-spinal cord distance which can lead to challenges for patients during everyday activities. If a patient laughs, bends or coughs, these devices do not adjust stimulation to maintain a consistent, therapeutic dose. According to an SCS Patient Market Research study, 85% of subjects reported avoiding one or more activities to avoid under- or overstimulation. 1 Closed-loop technology was developed to provide consistent therapy compared to traditional SCS devices.

The Inceptiv™ Closed-Loop prospective, single-arm, pre-market, multicenter 60 patient study with in-clinic randomized cross-over testing has demonstrated improvements in overstimulation, pain, and quality of life through the 12-month visit.2

In the in-clinic, randomized crossover testing with closed-loop vs. open-loop, of 43 subjects who completed in-clinic testing during the 12-month visit, 91% reported a reduction in overstimulation and 88% expressed preference for closed-loop.

At the 12-month follow-up, 8/10 subjects reported $\geq 50\%$ reduction in low back and leg pain (of 44 subjects with low-back/leg pain who completed the 12-month visit). 2 In this study, quality of life improvements were sustained through the 12-month follow-up, with 87% of participants reporting meaningful improvements in 3 or more domains (94% improved in overall pain (VAS $\nabla \geq 30\%$, $n = 46$), 89% improved in quality of life (EQ-5D-5L \blacktriangle by ≥ 0.074 , $n = 46$), 86% improved physical function (Oswestry Disability Index $\nabla \geq 10\%$, $n = 44$), 53% improved in mood (POMS $\nabla \geq 10$, $n = 45$), 75% improved in sleep quality (PSQI $\nabla \geq 3.0$, $n = 44$)).2

1. Pritzlaff et al. Patient Experience with Open-Loop Spinal Cord Stimulation Devices Across Manufacturers and Waveforms: Results of a Double-Blind Survey. Pain Physician, 2025; vol. 28 (2): Pages E205-E214.

2. Closed-Loop SCS Study 12-month Report v3.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Inceptiv™ is transforming SCS through sensing, MRI access† and size of device. It's a \"smart\" closed-loop spinal cord stimulator (SCS) for treating chronic pain. This next-generation device is the only closed-loop sensing system that works with multiple waveforms (low and high frequency stimulation up to 1,200 Hz), including DTM™ SCS.

The small implantable device senses†1 neural signals in real time 50x per second, 24/7, and automatically adjusts stimulation, to provide personalized therapy in harmony with patient movement.

Patients suffering from chronic pain often require MRI scans for other health conditions, requiring an SCS device that allows access to MRI. Up to 84% of SCS-implanted patients are expected to need at least one MRI within five years of implant.² Relative to previous generation Medtronic SCS devices, Inceptiv offers unparalleled access to diagnostic imaging, with 1.5T and 3T full-body MRI access and no power or impedance restrictions.²

Automatic and instantaneous therapy dose control and neural signal sensing technology is arguably one of the most significant technological developments in SCS within the past two decades. The ability to sense neural signals is an incredible technological achievement that took many years of research. This is due to the fact that ECAPs are extremely small (about 1 million times smaller than an SCS pulse) and require advanced filtering technology.

Before closed-loop SCS technology, the patient was responsible for manually adjusting their therapy using a programmer to maintain optimal therapy and avoid over- or understimulation. Inceptiv closed-loop technology allows for automatic and instantaneous adjustment in stimulation to ensure each patient receives consistent therapy during all activities. Similar to other groundbreaking technological advancements such as self-driving cars or smart homes, closed-loop SCS devices leverage data to perceive, compute, adjust, and control therapies in real-time.

Medtronic is dedicated to gathering and sharing real-world evidence to add to the body of evidence on CL-SCS. Medtronic is actively conducting post-market data evaluations across various European countries as part of its Inceptiv EMEA Cohort study. The launch of Inceptiv has led to double digit growth for the Medtronic SCS business in the last fiscal year with demand far exceeding all expectations.

†Under specific conditions. Refer to product labeling for full list of conditions.

‡Sensing signals may not be measurable in all cases.

1. Vallejo R, Chakravarthy K, Will A, Trutnau K, Dinsmoor D. A new direction for closed-loop spinal cord stimulation: combining contemporary therapy paradigms with evoked compound action potential sensing. *J Pain Res.* 2021;14:3909-3918. doi: 10.2147/JPR.S344568.

2. Desai, Mehul J., et al. "The rate of magnetic resonance imaging in patients with spinal cord stimulation." *Spine*, vol. 40, no. 9, 2015, <https://doi.org/10.1097/brs.0000000000000805>

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

† Under specific conditions. Refer to product labeling for full list of conditions.

‡ Sensing signals may not be measurable in all cases.

Medtronic Inceptiv SCS Website

<https://www.cdc.gov/nchs/data/databriefs/db390-H.pdf>(opens new window) accessed 12/6/2023

Pritzlaff et al. Patient Experience with Open-Loop Spinal Cord Stimulation Devices Across Manufacturers and Waveforms: Results of a Double-Blind Survey. Pain Physician, 2025; vol. 28 (2): Pages E205-E214.

NANS 2025 Posters (Real World Experience from independent UK center with second largest number of Inceptiv patients worldwide - Pain Management Department, The James Cook University Hospital, Middlesbrough, UK)

Closed Loop Low Dose Spinal Cord Stimulation For The Treatment of Upper Extremity Neuropathic Pain, Dr Ashish Gulve, MD, Sue Copley, MSc, Victoria Goodridge, RGN, MSc Patient Experience & Burden of the Therapy with Closed Loop Multi-Waveform Spinal Cord Stimulation - Dr Ashish Gulve, MD, Sue Copley, MSc, Victoria Goodridge, RGN, MSc <https://news.medtronic.com/New-12-month-clinical-data-highlights-significant-and-sustained-benefits-of-the-Inceptiv-TM-closed-loop-spinal-cord-stimulation-system>

References File Document upload:

N/A