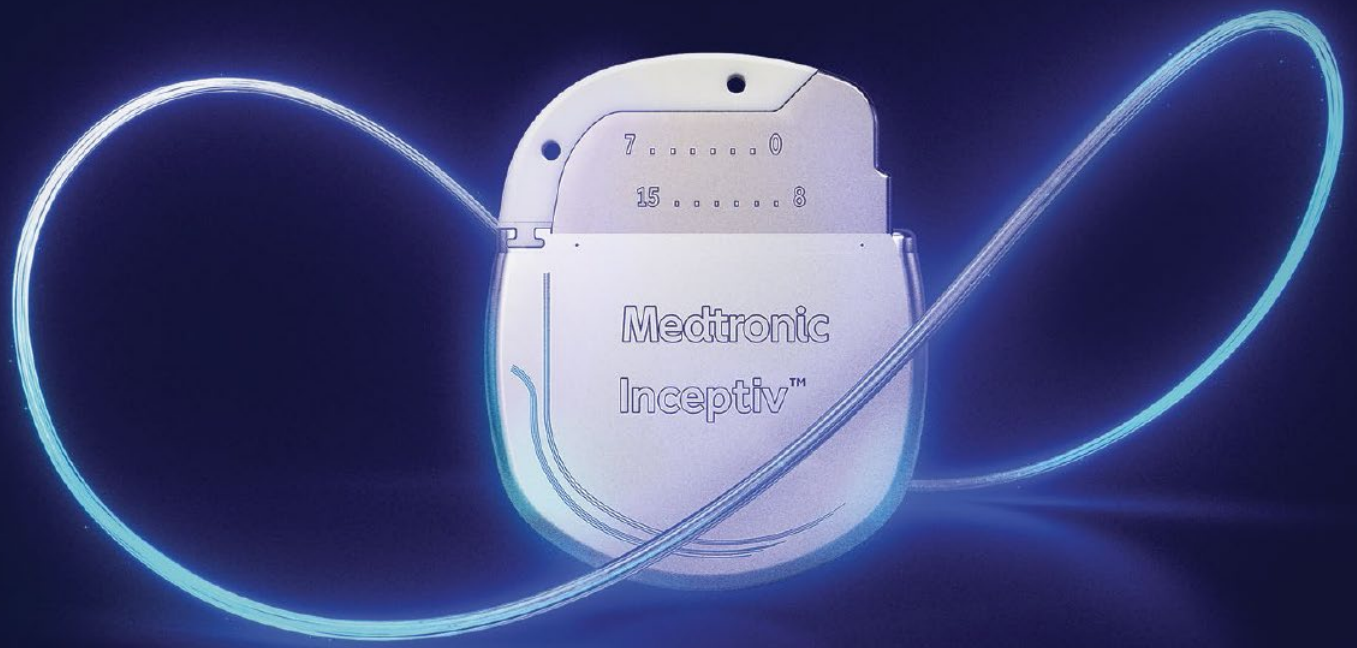
Inceptiv™
The most advanced SCS system with closed-loop technology



Pain relief in tune with life

TIME BEST INVENTIONS 2024 SPECIAL MENTION

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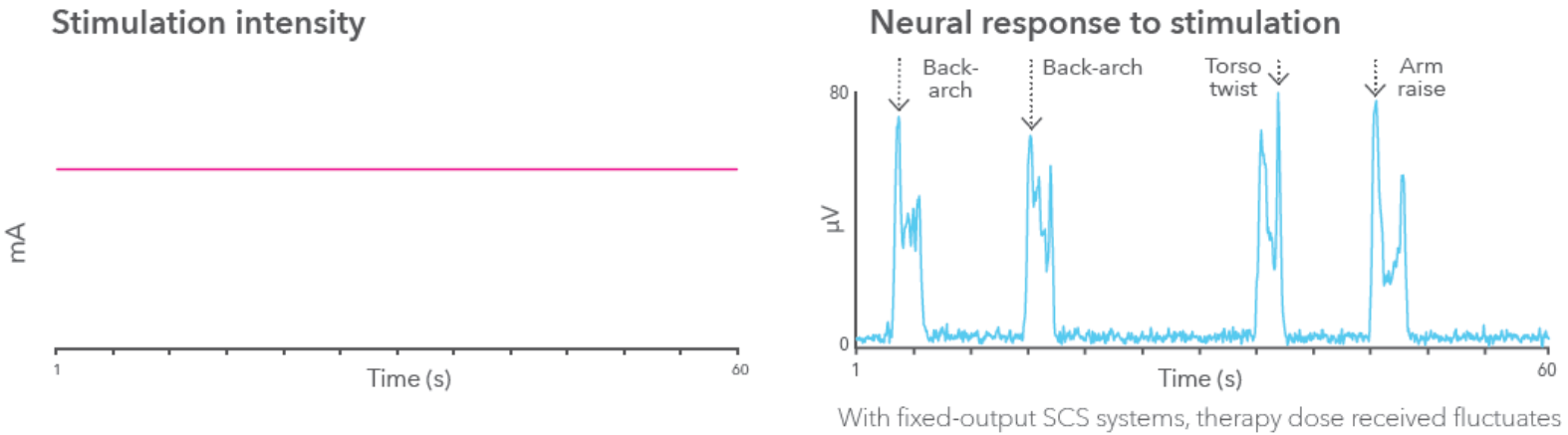
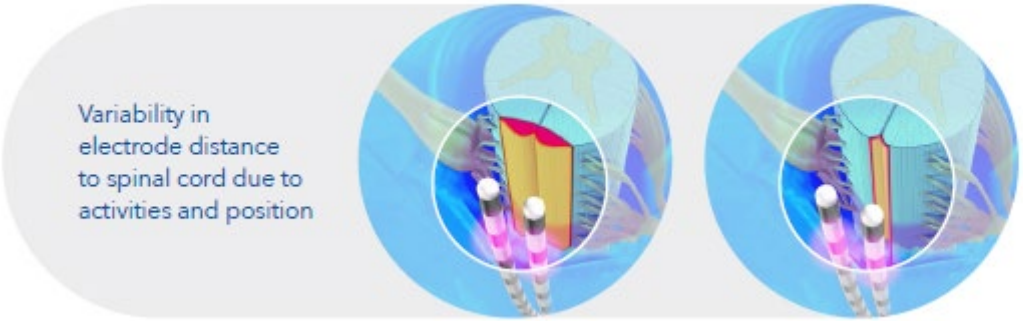
Need for consistent therapy

Fixed-output systems do not account for shifts in lead-to-spinal cord distance, which can compromise patient experience.

Fixed-output SCS delivers manually preset stimulation, which may result in inconsistent therapy dose.[1]



With fixed-output SCS systems, therapy dose received fluctuates



- Patients need to make adjustments to deliver optimal therapy, regardless of waveform.
- Inconsistent dosing can lead to variable therapy experience.

1 ECHO MAC Final Clinical Study Report V1.0 2021-08-18.

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The need for consistent therapy – Patient survey

Understanding the patient experience with fixed-output spinal cord stimulation (SCS) therapy.
Results from prospective, double-blind study of a representative sample of 100 SCS patients[1,2]

SCS patients
- **Across multiple manufacturers (Medtronic, Boston Scientific, Abbott, Nevro)**
- **Multiple types of waveforms (81% sub-perception)**

Under- and overdosing can lead to variable patient experience

While SCS therapy is proven to be safe and effective for the treatment of chronic pain, inconsistent therapy *(e.g., over- or understimulation)* occurs in over 50% of patients with fixed-output devices, **regardless of the waveform**.

58%

of patients experience overstimulation.

"My stimulator can be too strong for some activities or body positions. (example: Unwanted tingling, jolting, or shocking)."‡

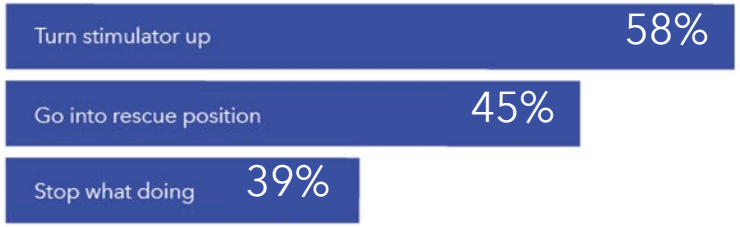
When experiencing **overstimulation**, patients do the following:

46%

of patients experience understimulation.

"My stimulator can be too weak for some activities or body positions."‡

When experiencing **understimulation**, patients do the following:



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
Conducted in June/July 2023 by StrataMark LLC, an independent third-party market research agency (n=100, 20-minute online survey)

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

‡Responded "Somewhat" or "Totally agree" with statement.

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The need for consistent therapy – Patient survey

Understanding the patient experience with fixed-output spinal cord stimulation (SCS) therapy.

Results from prospective, double-blind study of a representative sample of 100 SCS patients[1]

Patients need to manage their SCS therapy

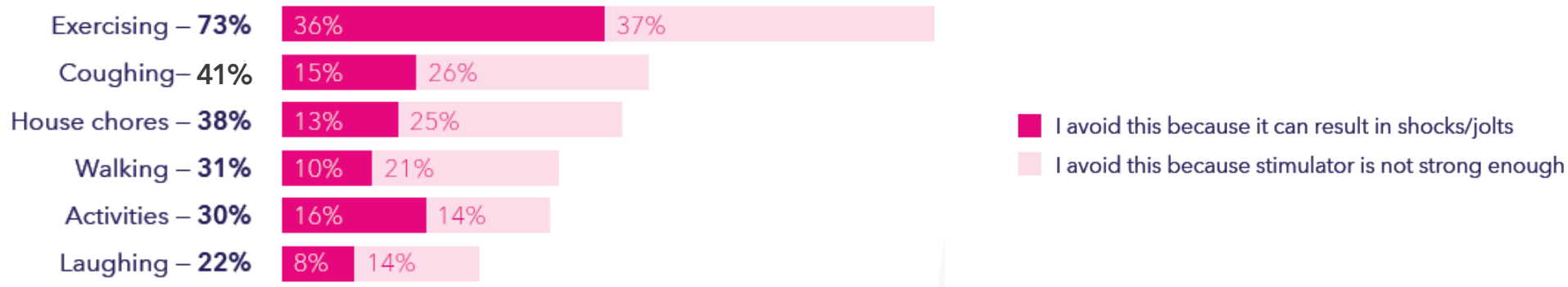
Patients manage inconsistent dosing by adjusting their stimulation, or by avoiding certain activities and making other adaptations.[1]

50% *of patients* **make frequent adjustments** at least a few times per week.

70% *of patients* **turn their stimulator up before doing something** that could increase their pain or down before doing something that could cause shock or jolt.

n=98 patients who reported making adjustments up or down to their stimulator.

Patients commonly avoid activities of daily living.



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
Conducted in June/July 2023 by StrataMark LLC, an independent third-party market research agency (n=100, 20-minute online survey), across multiple manufacturers (Medtronic, Boston Scientific, Abbott, Nevro) - patients programmed with multiple types of waveforms (81% sub-perception)

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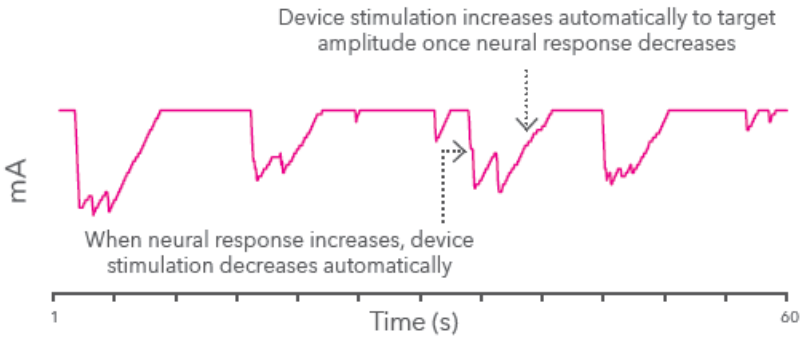
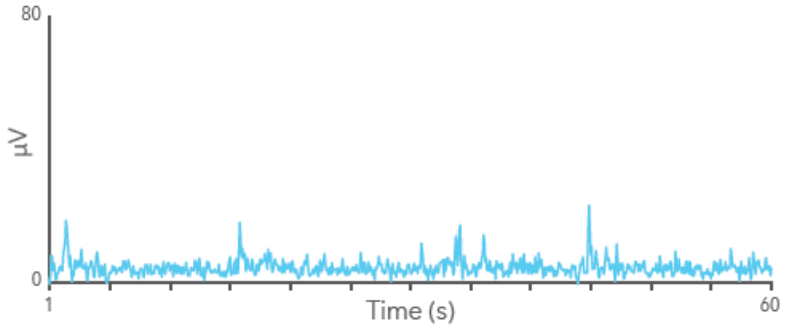
Inceptiv™ closed- loop **senses† and responds**

Medtronic closed-loop senses† neural response and automatically adjusts stimulation to maintain consistent therapy during all patient activities.

Stimulation intensity



Neural response to stimulation



Closed-loop technology provides consistent therapy dose

True close-loop senses in real time

† Sensing signals may not be measurable in all cases.

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SCS therapy now adjusted moment-to-moment†

Inceptiv™ closed-loop SCS can be programmed based on patient preference with either:

Tonic Stimulation

Inceptiv™ closed-loop senses 50 times per second† and responds to maintain ECAPs within target range

OR

Modern Waveforms

Up to 1,200 Hz including DTM™ SCS

Inceptiv™ closed-loop senses 50 times per second† and responds when an ECAP appears

†Sensing signals may not be measurable in all cases

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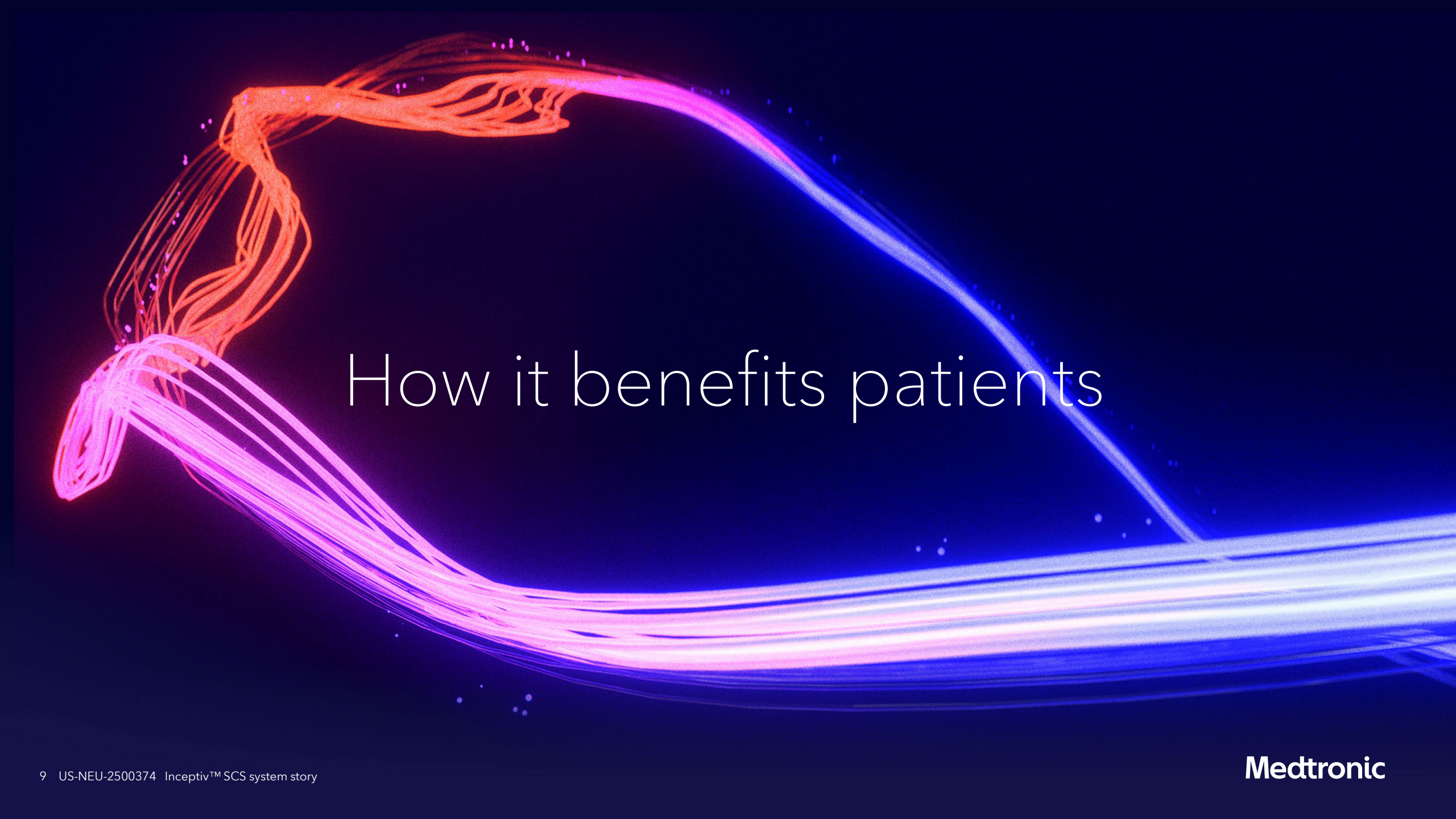

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Your Inceptiv™ SCS patients can now enjoy greater freedom

9 out of 10

patients preferred using the Inceptiv™ closed-loop algorithm over fixed-output stimulation.[1,2]

More consistent therapy, more time for life.

Automatic: does not depend on adjustments from the patient to maintain stimulation

Responsive: instantly adjusts therapy delivery in real time

Seamless: provides consistent therapy while patients perform a full range of daily activities

1. Will A, Fishman M, Schultz D, Danko M, et al. Improvements in Therapy Experience With Evoked Compound Action Potential Controlled, Closed-Loop Spinal Cord Stimulation-Primary Outcome of the ECHO-MAC Randomized Clinical Trial. J Pain. 2024 Nov;25(11):104646.
2. Closed-Loop SCS Study 12 Month Report v3. Data from 43 subjects with ECAPs who completed in-clinic, randomized crossover testing with CL vs. OL during 12-month visit. Study is still ongoing.

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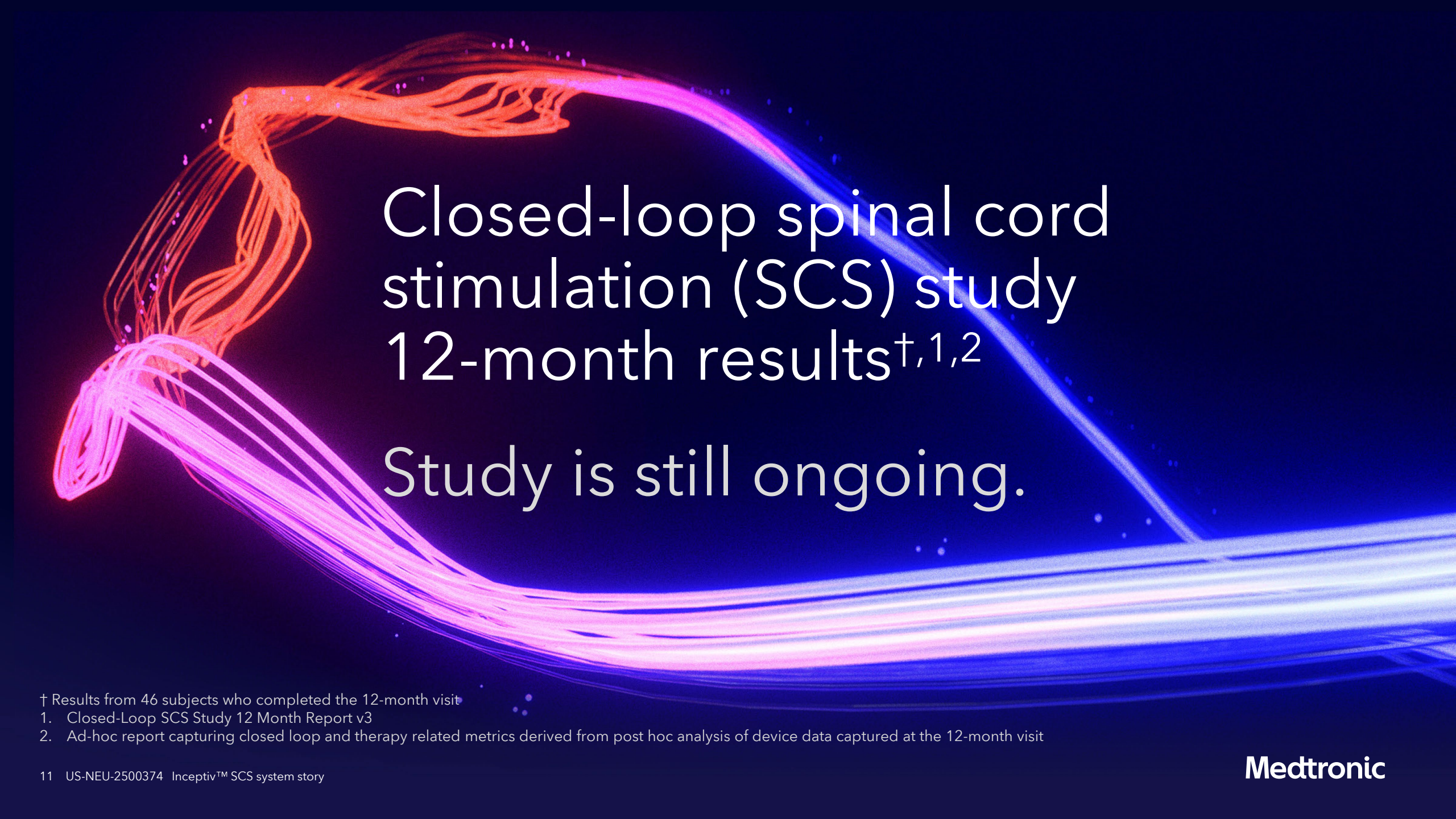

Closed-loop spinal cord stimulation (SCS) study 12-month results†,1,2

Study is still ongoing.

† Results from 46 subjects who completed the 12-month visit

1. Closed-Loop SCS Study 12 Month Report v3
2. Ad-hoc report capturing closed loop and therapy related metrics derived from post hoc analysis of device data captured at the 12-month visit

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Objectives and design[1,2]

Closed-loop spinal cord stimulation (SCS) study 12-month results. Study is still ongoing.†

Objectives

The purpose of the Closed-Loop (CL) SCS study is to further the understanding of closed-loop SCS in patients implanted with the Inceptiv™ SCS system

Design

- Prospective, single-arm, pre-market, multicenter (n = 7; Australia) study with in-clinic randomized crossover testing during 1-, 3- and 12-month visit.
- The primary endpoint was to demonstrate that the percent of low-back/leg pain subjects reporting overstimulation reduction with CL ON versus OFF exceeds a performance goal of 50% during the randomized, crossover, in-clinic testing at the 1-month visit.
- The secondary objective was to characterize the proportion of subjects with ≥ 50% reduction in overall, low-back, leg pain at the 3-month visit.
- Additional outcomes include pain scores (VAS), physical function (ODI), and health-related quality of life (QoL; PGIC, PROMIS-29 and EQ-5D). Data will be collected through 24 months.

Definitions
EQ-5D-5L – EuroQoL 5-dimension 5-level assessment
FBSS – Failed Back Surgery Syndrome
ODI – Oswestry disability Index
RCT – Randomized Controlled Trial
VAS – Visual Analogue Score

Results

- 60 subjects were implanted with the Inceptiv™ neurostimulator. 63% had a primary indication of FBSS, 57 subjects had low-back/leg pain, 3 subjects had upper limb pain. Baseline VAS was ≥ 6 cm. 46 subjects (44 with lowback/leg pain and 2 with upper-limb pain) completed the 12-month follow-up.
  - Fourteen subjects exited prior to the 12-month visit due to non-compliance with study (n = 4), lost to follow-up (n = 2), new confounding pain condition (n = 5), opted for explant in-lieu of lead revision (n = 1), IPG pocket dehiscence and infection secondary to Shingles (n = 1), and anxiety (n = 1).[1]
- Programming: at 12 months, 80.4% (n = 37) were primarily using waveforms with CL, with 73% programming to DTM™ SCS and 27% to low-rate or other tonic waveforms. Other subjects were using open-loop (OL) SCS only (15.2%; n = 7) or a mix with CL SCS (4.4%; n = 2).[2]

Safety

The device, therapy, and procedure related adverse events were similar to that observed in other SCS studies in this population. Serious device/therapy events included pain at neurostimulator site requiring repositioning (n = 5) and extradural hematoma (n = 1). Other common, non-serious, device-related adverse events through the 12-month follow-up included implant site pain (n = 4), device stimulation issue (n = 2), procedural site pain (n = 2), and migraine (n = 2).[1]

† Results from 46 subjects (44 with low-back/leg pain and 2 with upper-limb pain) who completed the 12-month visit

1. Closed-Loop SCS Study 12 Month Report v3
2. Ad-hoc report capturing closed loop and therapy related metrics derived from post hoc analysis of device data captured at the 12-month visit

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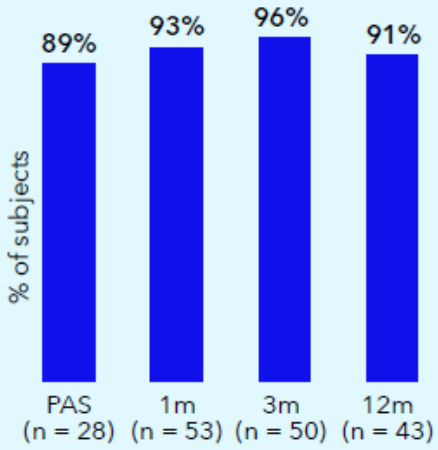
Results

Inceptiv™ closed-loop study demonstrates improvements in overstimulation and pain[1]

Closed-loop spinal cord stimulation (SCS) study 12-month results. Study is still ongoing.†

Results: In-clinic, randomized crossover testing with CL vs. OL

Reduction in over stimulation



PAS: Primary endpoint analysis set. Primary endpoint was evaluated at 1-month and included the first 28 subjects with low-back/leg pain to complete the visit.

Closed-loop preference

9/10

expressed preference for CL ON vs. OFF

Data from 43 subjects with ECAPs who completed in-clinic testing during 12-month visit.

Overall low-back/ leg pain relief

8/10

reported ≥ 50% reduction in pain

Data from 44 subjects with low-back/leg pain **that completed the 12-month visit.**

† Results from 46 subjects who completed the 12-month visit

1. Closed-Loop SCS Study 12 Month Report v3

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Results

Inceptiv™ closed-loop study demonstrates improvements in quality of life.[1]

Closed-loop spinal cord stimulation (SCS) study 12-month results. Study is still ongoing.†

87% of patients improved in ≥3 quality of life domains[1]

94% improved in overall pain (VAS ▼ ≥ 30%, n = 46)

86% improved physical function (Oswestry in disability index ▼ ≥ 10%, n = 44)

89% improved in quality-of-life (EQ-5D-5L ▲ by ≥ 0.074, n = 46)

53% improved in mood (Profile Of Moods State Score ▼ ≥ 10, n = 45)

75% improved in sleep quality (Pittsburgh Sleep Quality Index ▼ ≥ 3.0, n = 44)

Composite outcome is from post-hoc analysis of data from 12-month completers. "n" represents number of patients completing each survey.

† Results from 46 subjects who completed the 12-month visit

1. Closed-Loop SCS Study 12 Month Report v3

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Key Takeaways[1]

Inceptiv™ closed-loop study demonstrates improvements in overstimulation, pain, and quality of life.[1]

Closed-loop spinal cord stimulation (SCS) study 12-month results. Study is still ongoing.†

- Subjects were programmed to DTM™ SCS, HD, or low-rate therapies based on their preference
- The study met primary end-point with 89% subjects reporting reduction in overstimulation at 1-month
- Improvements were observed in pain, physical function and quality of life at 12-months with Inceptiv™ SCS

Limitations

The limitations of this study include lack of a control group for comparison of pain and quality of life outcomes in long term follow-up, subject attrition after 12 months, and potential observer bias

† Results from 46 subjects who completed the 12-month visit

1. Closed-Loop SCS Study 12 Month Report v3

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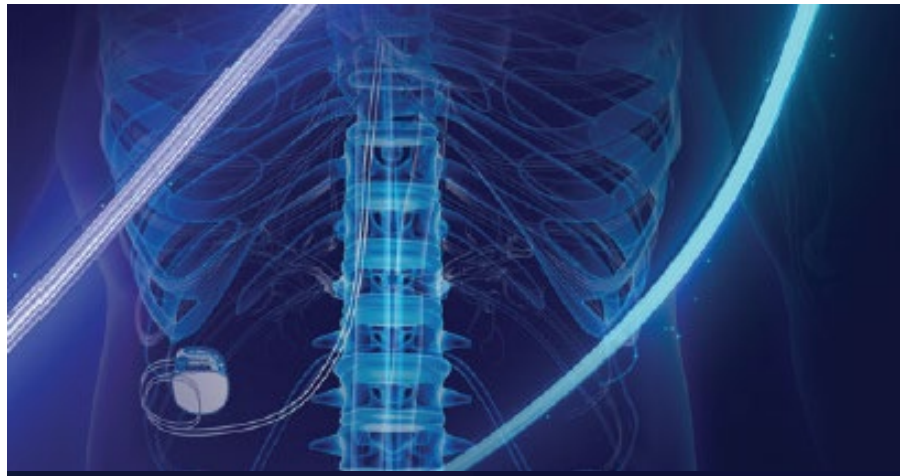
Best full-body 1.5T and 3T MRI access†

with impedance independence



98% of patients are expected to need an MRI within 10 years post implant[4]

95% access to MRI scanners[5] (1.5T & 3T vs. 68% 1.5T only)†

100% access compared to **57%** for Abbott, Boston Scientific, and Nevro patients due to high electrode impedance at 5 years†‡[6]

The Inceptiv™ system offers the most access to life-changing diagnostic imaging

Know the Medtronic difference	Medtronic[7†]	Biotronik[8]	Boston Scientific[9,10]	Saluda[11]	Nevro[12,13]	Abbott[14]
Impedance independence	✓	✗	✗	✗	✗	✗
Able to scan fully discharged device	✓	✗	✗	✗	✗	✗
1.5T full body normal operating mode **with every lead in the portfolio**	✓	✓	✗	✗	✗	✗
3T full body	✓	✓	✗	✗	✗	✗
Able to scan patient in prone position e.g., breast MR	✓	✓	✓	✓	✓	✗

✓ Proceed with full-body MRI scan ✗ Does not meet criteria

MR †Under specific conditions. Refer to product labeling for full list of conditions.
‡Assuming all other MRI conditions have been met.

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-E537.
5. Diagnostic Imaging Equipment Servicing. Market Insights. United States: Clarivate; 2022. Report No. 47031054.
6. Mullins CF, Harris S, Pang D. A retrospective review of elevated lead impedances in impedance-dependent magnetic resonance-conditional spinal cord stimulation devices. *Pain Pract*. 2023;00:1–8. https://doi. org/10.1111/papr.13301
7. MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain, http://manuals.medtronic.com. February 2021.
8. Prospera Spinal Cord Stimulation System ProMRI MRI Guidelines Technical Manual. 461825, Revision D (2023-04-03).
9. ImageReady™ MRI Full Body Guidelines for Precision™ Montage™ MRI Spinal Cord Stimulator System. 2017 Boston Scientific Corporation. 91075353-04 Rev A 2017-09.
10. Boston ImageReady™ MRI Full Body Guidelines for WaveWriter Alpha™ and WaveWriter Alpha™ Prime Systems 92395569-01
11. Saluda Evoke® SCS System MRI Guidelines For US. D102263 Rev 5.00. 25 Sep 2023.
12. 1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for the SENZA® Neuromodulation Systems. 11096 Rev M.
13. 1.5 Tesla and 3 Tesla Magnetic Resonance Imaging (MRI) Guidelines for Senza® HFX iQ™ System. 10001162 Rev B.
14. MRI Procedure Information Abbott Medical MR Conditional Spinal Cord Stimulation Systems Dorsal Root Ganglion Neurostimulation Systems | Abbott. ARTEN600132616 A. 2022-12.

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What makes Inceptiv™ the most advanced SCS system with closed-loop technology

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Inceptiv™ SCS
The **most advanced SCS system** with closed-loop technology

Automatic closed-loop
Senses ‡ and responds to deliver consistent therapy

Best 1.5T and 3T full-body MRI access†
With impedance independence

Smallest and Thinnest
Designed for comfort

Inceptiv™ continues to offer

Proprietary DTM™ SCS therapy

Proprietary battery technology with consistent charge time and recharge intervals over time.Ω

† Sensing signals may not be measurable in all cases.
‡ Under specific conditions. Refer to product labeling for full list of conditions.
§ For more information on our industry-leading 9-year INS limited warranty, contact rs.rtgwarranty@medtronic.com.

SPINAL CORD STIMULATION BRIEF SUMMARY

INDICATIONS Spinal cord stimulation (SCS) is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **CONTRAINDICATIONS** Diathermy - Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death. **WARNINGS** Sources of electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device. Patients with diabetes may have more frequent and severe complications with surgery. A preoperative assessment is advised for some patients with diabetes to confirm they are appropriate candidates for surgery. **PRECAUTIONS** Safety and effectiveness has not been established for pediatric use, pregnancy, unborn fetus, or delivery. Avoid activities that put stress on the implanted neurostimulation system components. Recharging a rechargeable neurostimulator may result in skin irritation or redness near the implant site. **ADVERSE EVENTS** May include: undesirable change in stimulation (uncomfortable, jolting or shocking); hematoma, epidural hemorrhage, paralysis, seroma, infection, erosion, device malfunction or migration, pain at implant site, loss of pain relief, and other surgical risks. Adverse events may result in fluctuations in blood glucose in patients with diabetes. Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0422