Medtronic

Clinical Summary

# NOVA RCT: DTM™ Spinal Cord Stimulation (SCS) Randomized Controlled Trial

12-Month results from the on-label, prospective, multicenter, randomized controlled trial comparing DTM™ SCS to conventional SCS for chronic back pain patients not eligible for spine surgery.

## Overview

On-label, prospective, multicenter, Randomized controlled trial comparing DTM™ Spinal Cord Stimulation (SCS) to conventional SCS with the Medtronic Intellis™ SCS system in patients with chronic back pain ineligible for spine surgery with degenerative disc disease (DDD), herniated disc (HD), or radicular pain syndrome (RPS).

Evaluating patients with chronic intractable back pain (VAS ≥ 6 cm), with or without leg pain, who were not a candidate for spine surgery, who were diagnosed with degenerative disc disease, herniated disc, or radicular pain syndrome at 20 sites across the United States. Sample size:

- 105 subjects randomized
- 77 subjects implanted
- 74 subjects with 3-month follow-up
- 67 subjects with 12-month follow-up

## Primary endpoint

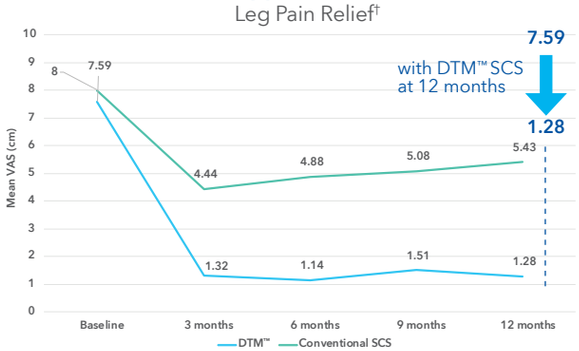
Back pain responder rate, defined as percentage of subjects with a decrease of at least 50% in back pain VAS relative to baseline, at 3 months with DTM™ SCS compared to conventional SCS.

## Secondary objectives

- To compare back pain responder rate in DTM™ SCS versus conventional SCS study arms
- To compare back and leg pain relief as measured by VAS and responder rate from baseline to 3 and 12 months for both study arms
- To report outcomes on quality of life (EQ-5D), Oswestry Disability Index (ODI), Patient Global Impression of Change (PGIC), and therapy satisfaction
- To characterize adverse events at all follow-up periods

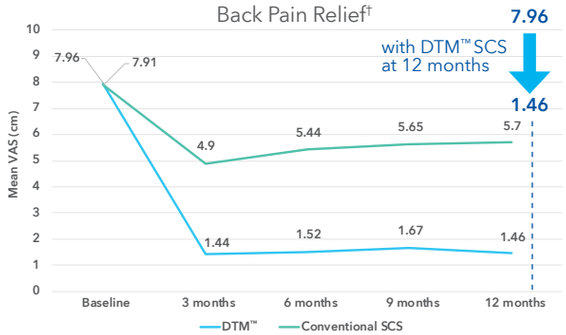
## DTM™ SCS therapy outcomes

Leg Pain Relief†




Sustained leg pain relief with a mean VAS score of 1.28 cm at 12 months with DTM™ SCS.

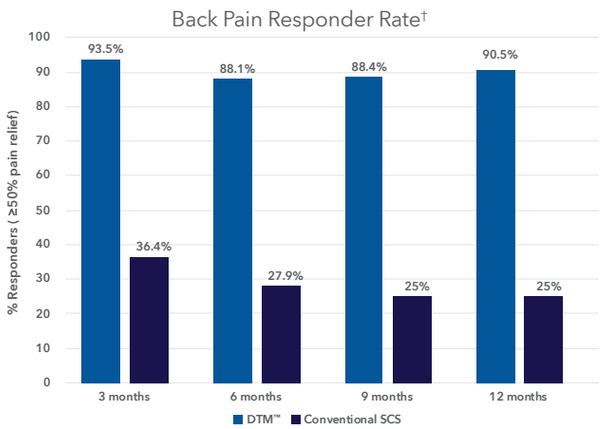
Back Pain Relief†




DTM™ SCS provided sustained back pain relief with a mean VAS score of 1.46 cm at 12 months.

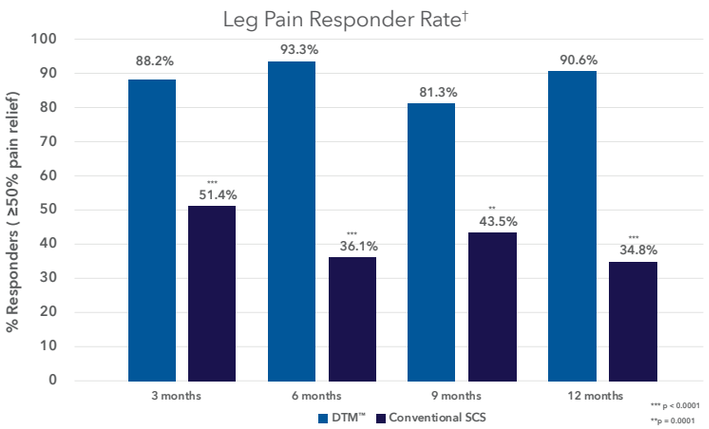
## DTM™ SCS therapy outcomes
## Superior pain relief compared to conventional stimulation†

Back Pain Responder Rate†




90.5% - Back pain responder rate with DTM™ SCS at 12 months (≥50% improvement)

Leg Pain Responder Rate†




90.6% - DTM™ SCS leg pain responder rate reported at 12 months. (≥50% improvement).

## Key takeaways for pain relief outcomes

- DTM™ SCS was proven effective at treating chronic back pain patients with DDD, HD, or RPS who are ineligible for spine surgery
- Outcomes at the 12-month follow-up (n = 40 subjects) included:
  - 90.5% back pain responder rate with DTM™ SCS
  - 90.6% of leg pain responder rate with DTM™ SCS
  - Sustained back pain relief with a mean VAS reduction of 6.4 cm from baseline
  - Sustained leg pain relief with a mean VAS reduction of 6.2 cm from baseline

- DTM™ SCS provided a 65.5% higher back pain responder rate and 55.8% higher leg pain responder rate than conventional SCS at 12 months ($p < 0.0001$)
- The primary endpoint was met with DTM™ SCS providing a 57.1% higher back pain responder rate than conventional SCS at 3 months ($p < 0.0001$)
- DTM™ SCS back pain responder rate was 3.6x higher than conventional SCS at 12 months ($p < 0.0001$)

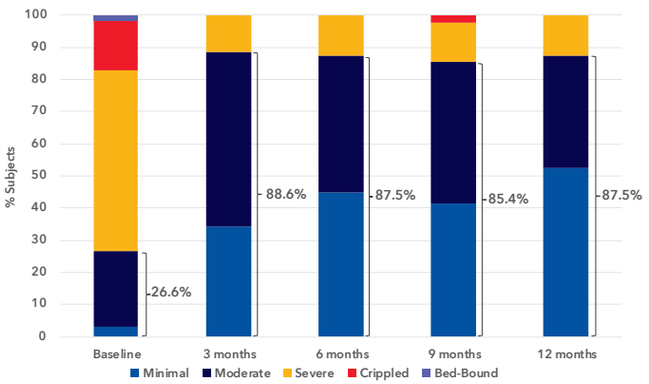
## Safety outcomes

- The incidence of device-related adverse events and serious adverse events were consistent with other SCS studies.

†mITT analysis = all successfully randomized subjects who completed the Trial Phase
‡Leg pain (n): DTM™ (37), conventional SCS (44)
‡Back Pain (n): DTM™ (51), conventional SCS (54)

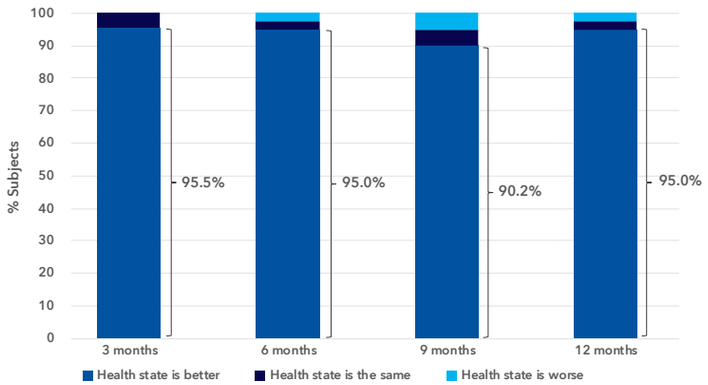
## Secondary outcomes

Effect on Disability (ODI)†



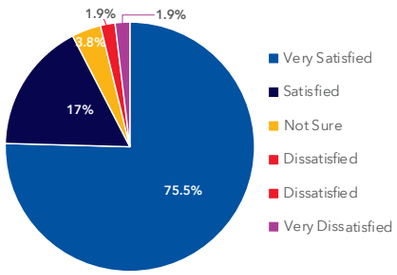

Clinically significant reduction in disability: In the DTM™ SCS arm, subjects with moderate to minimal disability increased from 26.6% at baseline (n = 64) to 87.5% at 12 months (n = 40) with moderate to minimal disability at baseline (n = 64) to 87.5% at 12 months (n = 40).

Effect on Quality of Life (EQ-5D Pain/Discomfort)†



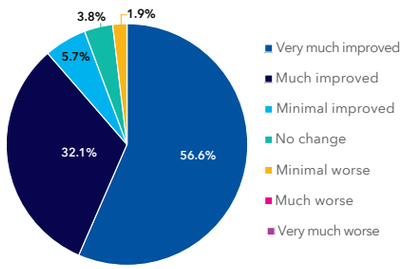

Significant improvement in quality of life: 95.0% of subjects reported being in a better health state with DTM™ SCS at 12 months (n = 40).

DTM™ SCS Subject Satisfaction‡




93.2% of patients were satisfied or very satisfied with DTM™ SCS at 12 month follow-up visit (n = 53).

DTM™ SCS Patient Global Impression of Change‡




88.7% of subjects reported feeling much improved or very much improved at 12 months with DTM™ SCS (n = 53).

## Key takeaways for quality of life outcomes

- DTM™ SCS provided sustained improvements in degree of disability and quality of life at 12-month follow-up.
- SCS therapy improved subject ODI scores: 87.5% of subjects reported minimal to moderate disability with DTM™ SCS at 12 months versus 26.6% at baseline.
- The majority of subjects were very satisfied with DTM™ SCS therapy: 92.5% of subjects were satisfied or very satisfied with DTM™ SCS at 12 months
- EQ-5D scores improved with SCS: 95.0% of subjects reported being in a better health state with DTM™ SCS at 12 months.

Medtronic SCS Publications Webpage see NOVA RCT poster

†mITT analysis = all successfully randomized subjects who completed the Trial Phase
‡Per protocol analysis
1. White, T, Justiz, R, Almonte W, et al. DTM™ SCS for Indicated Chronic Back Pain Patients Non-Eligible for Spine Surgery: US RCT Outcomes. ASRA Annual Meeting. November 10-11, 2023. New Orleans, LA.

**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

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