

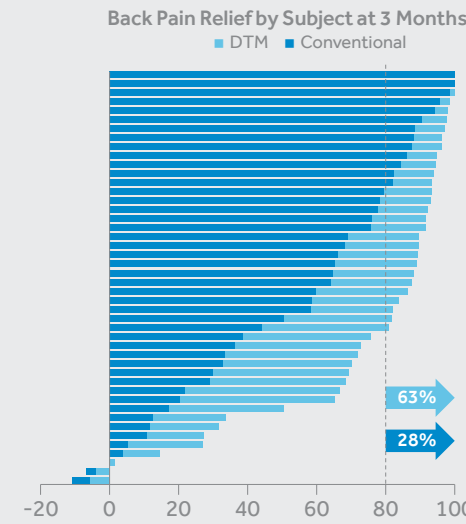
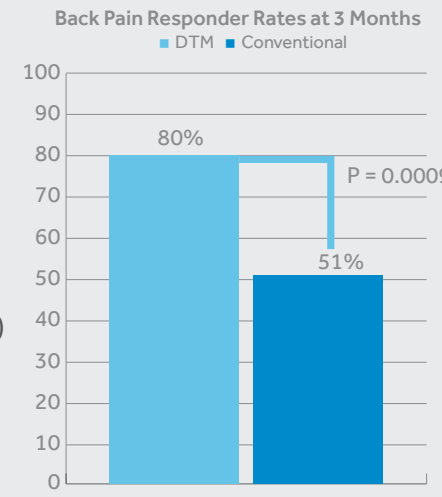
# THE DTM SCS THERAPY IS PROVEN ONLY ON THE INTELLIS PLATFORM

WITH SUPERIOR BACK PAIN RELIEF<sup>1</sup> COMPARED WITH CONVENTIONAL STIMULATION AT 3 MONTHS (N = 94)

Post market, multi-center, randomized control trial (RCT) comparing the efficacy of DTM™ SCS for back pain compared to conventional SCS.

**80%**  
Back Pain Responder Rate

with DTM™ SCS (≥ 50% improvement)

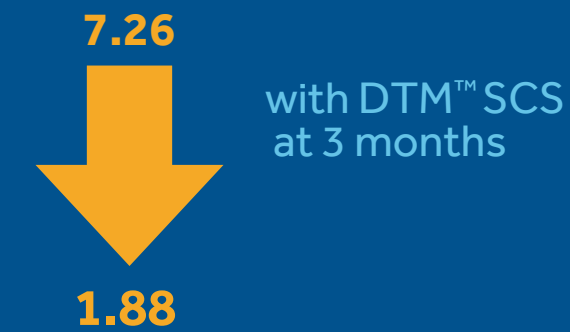


**63%**

of patients reported profound pain relief of 80% or more with DTM™ SCS, compared with 28% with conventional SCS.

**74%**

Mean reduction in back pain VAS (0-10)



**72%**

Mean reduction in leg pain VAS (0-10)



\*For more information on our 9-year INS limited warranty, contact [rs.rtgwarranty@medtronic.com](mailto:rs.rtgwarranty@medtronic.com)

For more details, go to [Medtronic.com/DTM](https://www.Medtronic.com/DTM)

#### References:

1. Fishman M, Cordner H, Justiz R, et al. Randomized Controlled Clinical Trial to Study the Effects of DTM-SCS in Treating Intractable Chronic Low Back Pain: 3 Month Results. Presentation at NANS 2020, Las Vegas, Nevada.
2. Vallejo R, Tilley DM, Vogel L, Benyamin R. The role of glia and the immune system in the development and maintenance of neuropathic pain. *Pain Pract.* 2010 May-Jun;10(3):167-84.
3. Milligan ED, Watkins LR. Pathological and protective roles of glia in chronic pain. *Nat Rev Neurosci.* 2009 Jan;10(1):23-36.
4. De Leo JA, Tawfik VL, LaCroix-Fralish ML. The tetrapartite synapse: Path to CNS centralization and chronic pain. *Pain.* 2006;122:17-21.
5. Sato KL, Johaneck LM, Sanada LS, Sluka KA. Spinal cord stimulation reduces mechanical hyperalgesia and glial cell activation in animals with neuropathic pain. *Anesth Analg.* 2014 Feb;118(2):464-72.
6. Ruiz-Sauri A, Orduña-Valls JM, Blasco-Serra A, et al. Glia to neuron ratio in the posterior aspect of the human spinal cord at thoracic segments relevant to spinal cord stimulation. *Journal of Anatomy.* 2019;235(5):997-1006.
7. Cedeno DL, Cass CL, Kelley CA, et al. Pre-clinical comparison of differential-target multiplexed scstm with low and high rate SCS. *Neuromodulation.* 2019;22(3):E185-.
8. Cedeno DL, Kelley CA, Cass CL, et al. Pre-clinical Comparison of Differential-Target Multiplexed SCS with Low and High Rate SCS. Presentation at ASRA 2018, San Antonio, Texas.
9. Vallejo R, Kelley C, Smith WJ, et al. Cell-specific targeting in neural tissue using Differential Target Multiplexed (DTM) SCS. Poster Presentation at the American Society for Regional Anesthesiology (ASRA) Conference, November 2019.
10. Cedeno DL, Smith WL, Kelley C, et al. Neuron-glia inflammatory enhanced reversal by DTM-SCS relative to high rate and low rate SCS in a neuropathic pain model. Poster Presentation at the American Society for Regional Anesthesiology (ASRA) Conference, November 2019.
11. Vallejo R, Kelley CA, Gupta A, Smith WJ, Vallejo A, Cedeno DL. Modulation of Neuroglial Interactions Using Differential Target Multiplexed Spinal Cord Stimulation in an Animal Model of Neuropathic Pain. *Molecular Pain.* 2020. Accepted for publication.

**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. **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. Refer to [www.medtronic.com](http://www.medtronic.com) for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0119

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# SUPERIOR PAIN RELIEF. PROVEN.

DTM™ Spinal Cord Stimulation Therapy on the Intellis™ Platform



**Medtronic**  
Further, Together



# BEYOND THE NEURON

Glial cells are active contributors to neural processing and various disease states, including chronic pain. In a pain state, glial cells are known to release factors that can sensitize neurons and cause pro-inflammatory responses, indicating they play a crucial role in the chronic pain process.<sup>2-4</sup>

Furthermore, decades of basic science research have discovered glial cells outnumber neurons 12:1 in the spinal cord.<sup>6</sup> Pre-clinical evidence suggests glial cells can be modulated with electrical stimuli, resulting in the release of neurotransmitters, impacting cell-to-cell communication.<sup>2</sup>

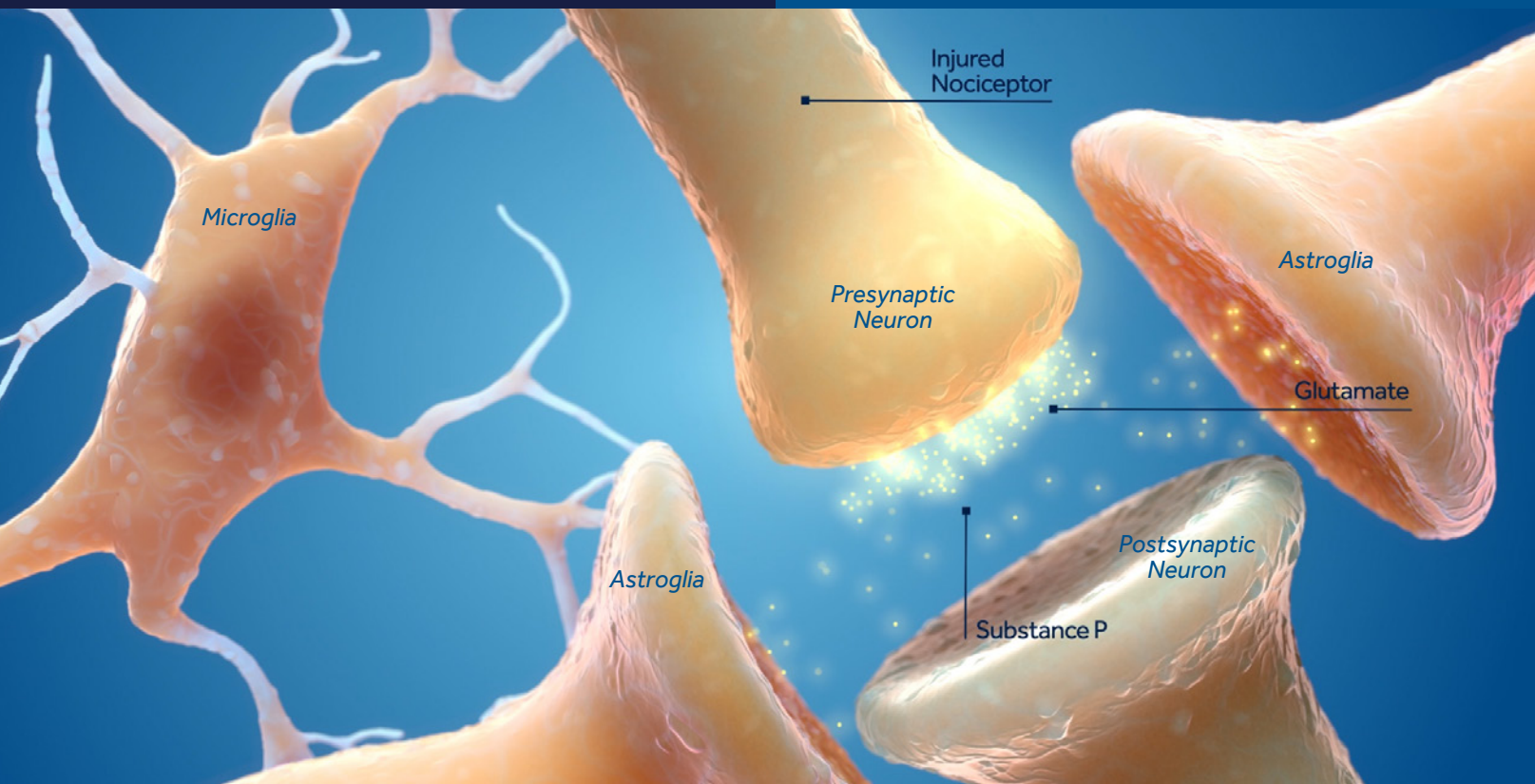
## BEHIND THE SCIENCE

Glial cells<sup>3</sup>:

- Are key contributors to chronic pain mechanisms
- Respond to neuronal signaling molecules
- Release signaling molecules (that can be protective or pathological)
- Release inflammatory signals in chronic pain states
- Respond to electrical stimuli<sup>5</sup>



## THE SYNAPTIC MICRO-ENVIRONMENT

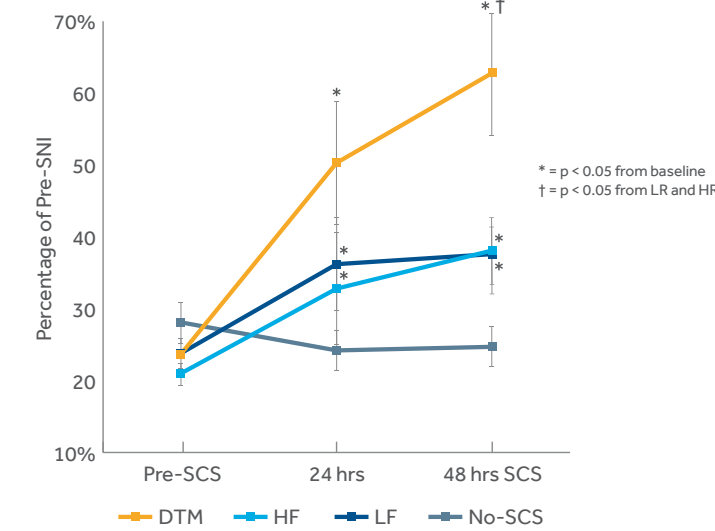


# TOWARD A NEW THEORY

**Hypothesis:** Do glial and neuronal cells have varied responses to different waveforms?

**Conclusion:** In pre-clinical studies, the DTM™ waveform best modulates glial and neuronal gene expression back toward the non-pain state.<sup>8-11</sup>

## MECHANICAL SENSITIVITY<sup>8,9</sup>



Evaluated SCS modalities:

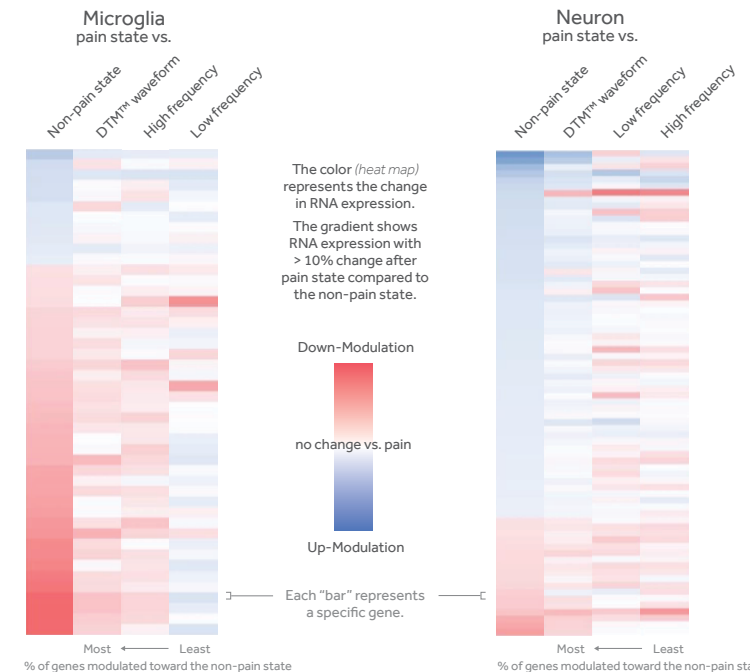
- DTM
- HF = 1,200 Hz and PW = 50 μs
- LF = 50 Hz and PW = 150 μs

## Study Description:

Behavioral studies were conducted in spared nerve injury (SNI) models of pain. Testing included paw withdrawal to a mechanical stimulus.

The DTM™ waveform has been studied in animal models, showing statistically significant reversal of pain behaviors compared to either low- or high-rate stimulation.<sup>7,8,11</sup>

## GENE EXPRESSION ANALYSIS



## Study Description:

Analysis of RNA expression comparing the pain state with non-pain state and SCS therapies.<sup>8-11</sup>

With the DTM™ waveform:

- Glial cells were modulated, in addition to neurons.
- The neuron and microglia modulation was closest to non-pain state.
- Genes related to biological functions, such as neuroinflammation, were modulated towards the non-pain state.<sup>11</sup>

# INSPIRED BY SCIENCE

How is DTM™ SCS applied to your patient? DTM™ SCS is a proprietary, multiplexed algorithm coordinating multiple signals at multiple anatomical targets. Therapy and settings are customized to your individual patient's needs.

## Patient selection<sup>1</sup>

- Patients diagnosed with back and leg pain, including unilateral pain (back/leg) (≥ 5 cm VAS in low back pain with moderate to severe leg pain)
- Diagnoses consistent with commercial labeling
- SCS naïve

DTM™ SCS proprietary algorithm includes:

3 + 4 + 6 + 6 = DTM™ SCS PROGRAMMING ALGORITHM

THERAPY OPTIONS    SIGNALS    ANATOMICAL TARGETS    PATIENT AMPLITUDES

Every DTM™ SCS therapy option coordinates multiple signals into one distinct therapy. The signals vary in frequency, pulse width, amplitude, and anatomical targets.

## DTM™ SCS Workflow

Step-by-Step Process of Implementing DTM™ SCS Therapy

- IF lead spans MID T8–MID T10, THEN consider the DTM™ SCS workflow.
- Patient flexion is recommended after lead placement and before the final fluoro shot.
- Use DTM™ SCS therapy, a programming algorithm based on the coordination of multiple signals at multiple targets.
- Conduct daily patient follow-up to assess for optimal programming.

