Medtronic

Engineering the extraordinary

Personalized, long-lasting relief for diabetic foot pain

Spinal cord stimulation (SCS) delivers a non-opioid revolution in treatment for painful diabetic peripheral neuropathy (DPN), and has demonstrated statistically significant reduction in medication use after 6 months of treatment compared to conventional medical management.[1,2]

Potential benefits of SCS

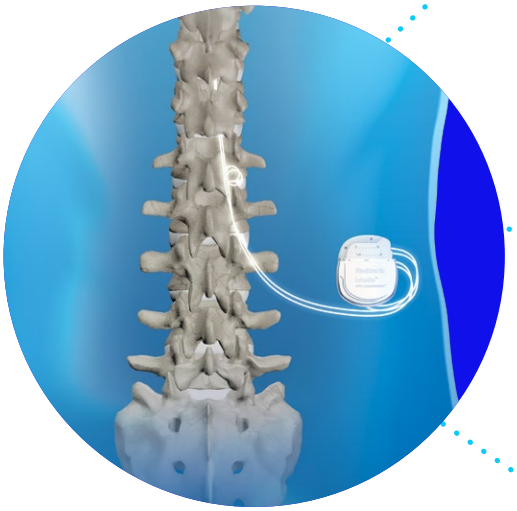
17x
more likely to experience pain relief [1,2,3]

86%
of patients experienced treatment success after receiving SCS therapy for 1 year[4†]

10yrs
of meaningful pain relief[5†]

How can SCS help?

For 50 years, SCS has been a proven, non-opioid, FDA-approved way to manage chronic pain. It works by disrupting pain signals traveling between the spinal cord and the brain. This therapy is now approved to help patients suffering from painful DPN in the legs and feet.



Medtronic SCS portfolio

SCS neurostimulators
Recharge, and Recharge-free device options. Small and sleek neurostimulators with unrivaled performance.

SureScan™ MRI technology‡
Unrestricted Full-Body MRI access.

TYRX™ neuro antibacterial envelope
Designed to stabilize the device and help reduce the risk[6] of infection and infection-related costs.[Ω]

† Success rates in a population of patients treated with SCS in two studies and followed for up to 10 years.

‡ MRI Under specific conditions. Refer to product labeling for a full list of conditions.

Ω Based on retrospective analyses of the TYRX™ Neuro Envelope with INSs and the randomized controlled global CIED trial – the TYRX WRAP-IT study.

DPN patient selection

- ✓ Diagnosed with painful diabetic peripheral neuropathy
- ✓ Refractory to conservative conventional medical management therapies
- ✓ Pain in legs and feet
- ✓ Appropriate candidate for SCS trial and implant procedure

Medtronic SCS indications

Medtronic is indicated for spinal cord stimulation 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 failed back surgery syndrome (FBSS) 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

Blue highlights SCS coverage for pain relief based on approved FDA indications

Scan to learn more about SCS and connect with a local representative

References:

1. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial. *Pain*. 2014;155(11):2426–2431. doi:10.1016/j.pain.2014.08.031
2. Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: A prospective two-center randomized controlled trial. *Diabetes Care*. 2014;37(11):3016–3024. doi:10.2337/dc14-0684
3. Medtronic Pain Therapy Clinical Summary M221494A016 Rev B. United States; 2022.
4. van Beek M, Geurts JW, Slangen R, et al. Severity of neuropathy is associated with long-term spinal cord stimulation outcome in painful diabetic peripheral neuropathy: Five-year follow-up of a prospective two-center clinical trial. *Diabetes Care*. 2018;41(1):32–38. doi:10.2337/dc17-0983
5. Zuidema X et al. Long-term Evaluation of Spinal Cord Stimulation in Patients With Painful Diabetic Polyneuropathy: An Eight-to-Ten-Year Prospective Cohort Study. *Neuromodulation*. 2022 Dec 30:S1094-7159(22)01403-9.
6. Tarakji KG, Mittal S, Kennergren C, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. *N Engl J Med*. 2019;380(20):1895-1905.

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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