Medtronic

# Take a step forward in how you treat chronic diabetic pain

## Spinal cord stimulation (SCS) for moderate to severe diabetic peripheral neuropathy (DPN) pain

# Help your patients control the debilitating pain in their feet and legs.

There's new hope for those who suffer from diabetic peripheral neuropathy (DPN) and anyone who treats them. Spinal cord stimulation (SCS) therapy from Medtronic, long used to safely and effectively treat chronic pain, is now approved for use with patients suffering from moderate to severe DPN.

That's good news for your patients. Two industry-independent RCTs have shown that patients with moderate to severe DPN achieved significant pain relief when treated with SCS compared to conventional treatments alone. Together the studies indicated a 70 percent treatment success in patients receiving SCS therapy versus six percent in the control group[1]. A long term follow-up study showed that 80 percent of those patients with a permanent implant were still using their device five years after beginning SCS therapy[4].

The approval of SCS for pain in patients with moderate to severe DPN is also good news for you. SCS therapy typically involves a standard care path and provides your patient access to an alternative therapy for managing their pain.

By referring your patient to an SCS implant specialist, you are helping them take a step forward in their relief from DPN pain, and you can continue the important work of focusing on their routine care.

Scan this QR code to learn more.

# What's inside



For patients who experience chronic pain due to DPN and have not been satisfied by the levels of relief provided by oral pain medication, creams or ointments, or other pain treatments, spinal cord stimulation can provide a new approach. Medtronic can help you bring this therapy to patients looking for solutions.

# What is spinal cord stimulation (SCS)?

Spinal cord stimulation is a proven, non-opioid, FDA-approved way to manage chronic pain that may be caused by DPN. SCS works by disrupting the pain signals traveling between the spinal cord and the brain.

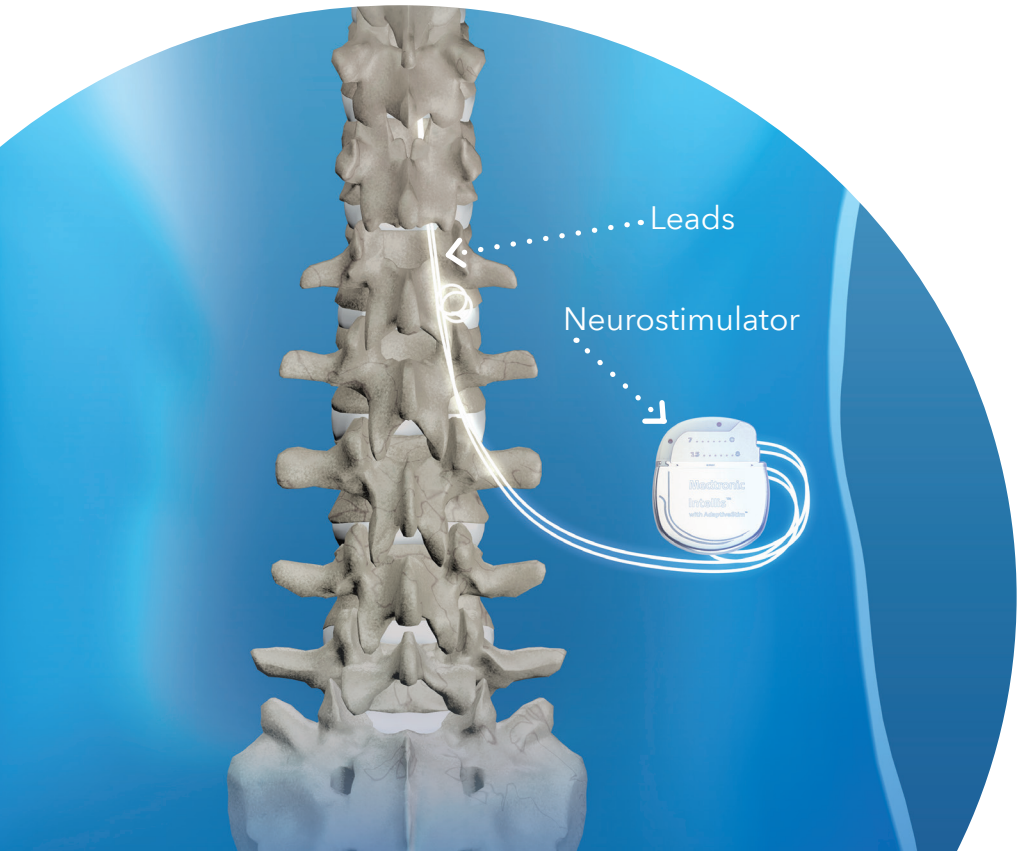
## How SCS works

Stimulation is delivered by a neurostimulator, a device similar to a pacemaker, implanted under the skin.

The impulses travel from the device to the spine over thin insulated wires called leads. The leads deliver mild electrical impulses to an area near the spine.

By interrupting pain signals between your patient's spinal cord and their brain, the stimulator may help your patient get back to doing the everyday things they love most.

Scan this QR code to learn more.




## Potential benefits of SCS

- Patients living with DPN are 17 times more likely to experience significant pain relief if treated with SCS compared to conventional treatment.[1,2,3]
- 86% of patients experienced treatment success after receiving SCS therapy for 1-year.*[4]
- Proven long-term therapy for managing chronic pain. The majority of patients experiencing meaningful pain relief through 5 years of treatment with SCS.[4]
- An average reduction in pain of 53% at 6 months[1]

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

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

**5yrs** of meaningful pain relief [4]

*Success rates in a population of patients treated with SCS in two studies and followed for 5 years.

## Understand the risks

Risks include infection, lead movement, pain at the implant site, and loss of therapy effectiveness. Not everyone responds to SCS in the same way, and your patients' experiences may vary. Risk of infection and severity of complications may be greater in diabetic patients.

Consider a preoperative risk assessment to determine if patients are healthy enough for surgery.

Monitor patients glucose levels.

*Review the Important Safety Information at the back of this booklet for additional risk and safety information.*

# Why Medtronic SCS for moderate to severe DPN pain?

As a global leader in medical technology, with over 40 years of SCS experience, Medtronic paved the way in pain relief and continues to innovate and provide options that reduce pain and restore function. Medtronic offers you and your patient resources and support throughout your journey to pain relief.

There are a number of SCS system choices and therapy options that can benefit your patient. Rest assured that Medtronic can provide you and your patient with each of these important features:


## Small and sleek devices with unrivaled performance

Intellis™ rechargeable offers 95% capacity at 9 years and Vanta™ recharge-free neurostimulator offers ~2x more longevity than competitive PC devices at comparable settings*.

## Test drive

Short screening trial allows you and your patients to assess their response to SCS prior to device implantation.

## Unrestricted, full-body MRI access

Medtronic offers full-body MRI access on all SCS devices*. Your Medtronic SCS system will never hold your patient back from getting a scan anywhere on their body if they need it.

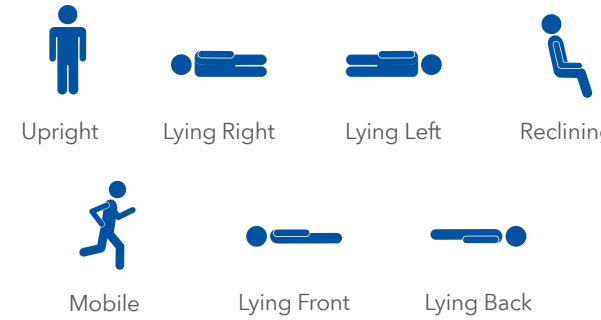
MR *Under specific conditions. Refer to product labeling for a full list of conditions.*

**Settings used from Abbott Proclaim™ XR clinician manual. Nominal settings 12 hours per day: 50-Hz frequency, 225-µs pulse width, and 5-mA amplitude at 500-ohms impedance. Compared to flagship model 3660. Settings from Boston Scientific's Alpha™ IFU. Programmed at 4.1mA, 280us, 40 Hz, 1 area, 730 Ohms, 2 contacts.*



## Personalized pain relief

Your patient's therapy can be customized to help them manage their pain. One therapy setting your clinician may choose to use is called AdaptiveStim™ technology which personalizes pain relief by sensing changes in their body position. Whether your patient is standing, lying on their side or in any of seven unique body positions, AdaptiveStim™ technology automatically tailors stimulation to manage pain. Only available on Medtronic devices.




- Delivers personalized stimulation based on 7 unique body positions
- Increases or decreases stimulation to provide personalized pain relief
- Tracks your patient's daily movement to help you assess their progress and, if needed, adjust their settings
- 88.7%*† of patients with spinal cord stimulation implants report better pain relief with AdaptiveStim™ technology vs. conventional stimulation[1,5]

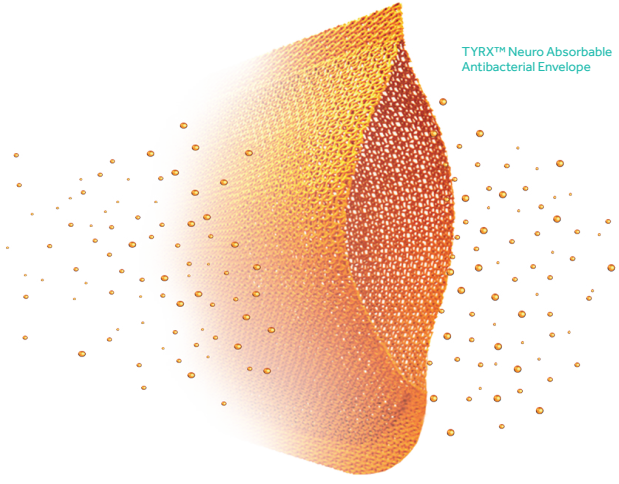
**88.7%*†**

of patients with SCS implants reported better pain relief, with AdaptiveStim™ technology[1,5]

*†Studies conducted on patients with chronic neuropathic pain, conducted prior to FDA approval of SCS for DPN.*

## TYRX™ Neuro Absorbable Antibacterial Envelope

The TYRX™ Neuro Absorbable Antibacterial Envelope is a fully absorbable antibacterial envelope for implantable neurostimulator (INS) devices like spinal cord stimulators. The surgical mesh envelope contains two powerful antibiotics – minocycline and rifampin. It is designed to stabilize the device and help reduce the risk of infection and infection-related costs.




## Objective outcome data

Real-time insights captured in Snapshot™ reporting help transform patient conversations from subjective to objective.

# Medtronic SCS devices



| Options to suit your patient's needs | Medtronic Intellis™ SCS | Medtronic Vanta™ SCS |
|---|---|---|
| Access to MRI anywhere on the body* | ● | ● |
| Personalized pain relief with AdaptiveStim™ technology | ● | ● |
| Designed for comfort | ● | ● |
| Access to network of Medtronic support | ● | ● |
| Industry-leading battery longevity | Up to 9 Years** | Up to 11 years variable, based on programming |
| Fast battery recharge | ● | n/a |
| Recharge-free convenience | n/a | ● |

MR *Under specific conditions. Refer to product labeling for a full list of conditions.*

***For more information on our 9-year warranty of the neurostimulator, contact rs.rtgwarranty@medtronic.com.*

# Try spinal cord stimulation (SCS) first:

## Trial procedure

A Medtronic SCS trial helps you and your patient assess how well an SCS device may relieve their pain.

The Medtronic SCS trial system lets you and your patient "test drive" how SCS therapy may improve their daily activities without requiring them to have the SCS device implanted.

1. The trial procedure allows your patient to test drive the therapy. This takes about 30 to 90 minutes and is usually done in a doctor's office or day surgery center.
2. A trial procedure is temporary and requires no commitment.
3. By using an external stimulator, the patient can try the therapy for up to 10 days without having to undergo the implant procedure first.

## What to expect

1. The doctor will place the temporary leads (thin, flexible wires) under the skin in an area near the patient's spine using a small insertion device. Local anesthetic numbs the area.
2. As stimulation is applied during the trial procedure, the doctor will ask the patient how they feel to help determine the ideal location for the leads.
3. The leads are connected to an external, battery-operated neurostimulator, which will be attached in an adhesive pouch or taped to the patient's back during the trial.

*These steps may vary depending on the doctor.*

## The Medtronic trial system

Mild electrical pulses from the external neurostimulator travel through the temporary leads to the area near the patient's spinal cord.

The handheld therapy manager allows your patient to adjust the stimulation during the trial. This lets them experience different therapy settings and adjust the therapy based on their pain relief (or experience different therapy settings and adjust the therapy to their satisfaction).

Bluetooth™-enabled, wireless therapy programmer

External Neurostimulator


Temporary Leads

# If SCS is right for your patient:

## Implant procedure

If the patient had a successful trial, your patient and implanting doctor will decide if a long-term implant suits their needs. Similar to the trial procedure, leads will be placed near their spinal cord. The SCS device will be implanted under the skin. The procedure is most often performed in a hospital or surgery center on an outpatient basis and takes approximately 1 to 3 hours.

## Patient visits

A typical follow-up schedule is once every 6 months, although initially the SCS system may require more frequent visits to adjust their settings. The therapy manager device allows the patient to adjust their stimulation within pre-set parameters programmed by a doctor. This puts them in control of their pain management needs.

## Versatile therapy options

Medtronic SCS offers multiple device settings to meet your patient's unique pain needs.

Stimulation is often associated with a pleasant tingling, fluttering, or vibration sensation. This sensation can be adjusted for patient comfort, from strong intense perception to minimal or no sensation, depending on individual patient needs for pain relief and therapy preferences.

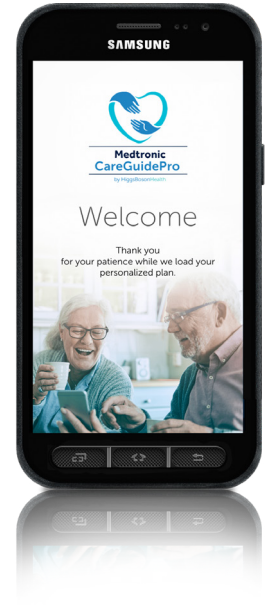


# Resources for your patient

Choosing treatment for moderate to severe DPN pain is a very important decision. Medtronic has resources available to help your patient make an informed choice that's best for them.

## Use CareGuidePro™ App

As your patient starts their journey to pain relief with Medtronic spinal cord stimulation, we offer them the CareGuidePro™ app – a free app that acts as both a roadmap and toolbox all in one. CareGuidePro™ app helps support patients during the process of spinal cord stimulation procedures, providing access to educational resources, appointment reminders, and progress tracking throughout the trial, implant, and post implant phases.



# Answers to common questions

## Helping your patient understand more about Medtronic SCS

### If the trial is successful, will an implanted system provide the same pain relief?

The SCS trial mimics therapy relief of the permanent implant, which can be adjusted so it delivers the best pain relief possible. Be sure to have your patient tell you about the way they feel, so changes can be made to optimize their therapy.

### What are the common risks?

There are general surgical risks that you should discuss with your patient. Review the important safety information in the back of this booklet for risks associated with this therapy.

### Will spinal cord stimulation therapy eliminate DPN?

Many people experience significant and sustained reduction in chronic pain. However, SCS does not eliminate the source of pain, so the amount of pain reduction varies from person to person.

### Will patients need to have another surgery to replace the SCS device?

The Intellis™ rechargeable device lasts up to 9 years . The Vanta™ recharge-free device offers variable longevity based on your programmed settings. Vanta™ SCS can last up to 11 years. The programmer will alert the patient when their device is nearing the end of its life span. At this point, Medtronic recommends your replace their device. Medtronic recommends that you replace your device.

### Can patients travel or move to another part of the country?

Intellis™ SCS, Vanta™ SCS, and therapy manager devices are safe to travel with and meet universal power requirements for recharging within the US and overseas. It is encouraged to fully charge devices before your patients travel.

If a patient moves to another part of the country, treatment-related information is conveniently stored on the device. Their doctor can access this information so that patients can be treated at any clinic that uses the Medtronic SCS platform. Whether traveling or moving, a patient can find a doctor who is an expert with Medtronic SCS. Scan this QR code to find a U.S.-based doctor.

Scan this QR code to find a U.S.-based doctor.



# References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2. 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
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5. Schultz D, Webster L, Kosek P, et al. Sensor-driven position-adaptive spinal cord stimulation for chronic pain. *Pain Physician*. 2012;15(1):1-12.


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## Important Safety Information

**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. Diabetic patients may have more frequent and severe complications with surgery. A preoperative assessment is advised for some diabetic patients 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 diabetic patients. Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0222