

Medtronic

Welcome to a new day in pain relief

Spinal Cord Stimulation (SCS) trial guide
for less pain, more life



Test drive your treatment

Our spinal cord stimulation (SCS) trial system can help you determine whether the treatment is right for you – without having the SCS device implanted.

How does the temporary device work?

The temporary wireless device is small and fits comfortably under clothing.

Mild electrical pulses from the external neurostimulator (A) travel through the temporary leads (B) to the nerves along your spinal cord. The wireless programmer (C) lets you adjust the stimulation levels.



Connect with us

Talk with a patient pain ambassador

Connect with someone who received Medtronic SCS treatment. They can answer common questions, including:

- What was the procedure like?
- How did you know SCS was the right option for you?
- How has your life been impacted?

Visit [medtronic.com/painambassador](https://www.medtronic.com/painambassador)

Or, call 888-430-PAIN (7246) to schedule an appointment.

Pain ambassadors are not medical experts or employees.

Ask a nurse

Speak with a registered nurse (at no cost to you) who is experienced in Medtronic chronic pain treatments. They can help with answers on what to expect before, during, and after the SCS trial and implant procedure.

Visit [medtronic.com/nurse-scs](https://www.medtronic.com/nurse-scs)

Or, call 888-430-PAIN (7246) to schedule an appointment.

Our registered nurses are paid consultants of Medtronic.

Get the CareGuidePro™ app

You're starting your journey to pain relief with Medtronic spinal cord stimulation. Take along the CareGuidePro™ app – a free app that's like a roadmap and toolbox all in one. Scan the QR code to download the app onto your mobile phone or tablet.



Android



Apple iOS

What is SCS?

SCS is a proven, opioid-free, FDA-approved way to manage chronic pain. 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 your spine.

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



Scan this QR code
to learn more.
[medtronic.com/chronicpain](https://www.medtronic.com/chronicpain)

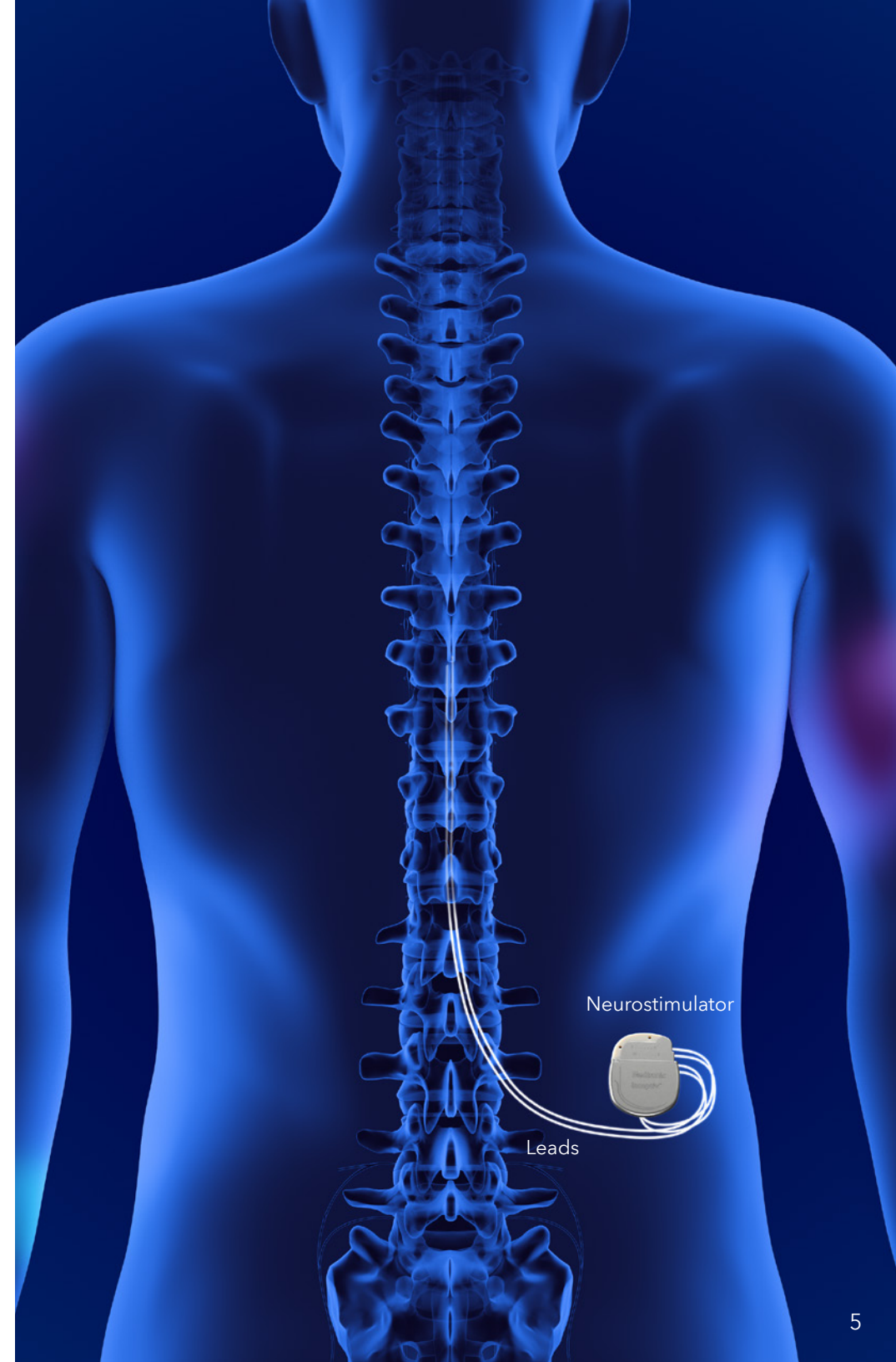
Potential benefits of SCS

- Proven, long-term treatment for managing chronic pain^{1,2}
- Improved ability to function³
- More effective than repeat surgeries for pain⁴
- May be able to reduce oral opioid consumption^{5,6,7}
- Profound pain relief of 80 percent or more⁸

Potential risks

Risks include infection, lead movement, pain at the implant site, and loss of treatment effectiveness. Please discuss them in detail with your doctor. Not everyone responds to SCS in the same way, and your experience may vary.

Review the Spinal Cord Stimulation Brief Summary at the back of this brochure for additional risk and safety information, and discuss it with your doctor.



Why Medtronic SCS?

As a global leader in medical technology with over 50 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 doctor resources and support throughout your journey to pain relief.

There are a number of choices when deciding which SCS system is right for you. You'll want to select the SCS system that you and your doctor feel will have the features that benefit you most. Medtronic offers you these important features:

430,000+

people with chronic pain worldwide have been helped by Medtronic SCS pain treatment.⁹

Medtronic SCS pain treatment is now approved to help treat diabetic foot pain.



Test drive

The trial system lets you temporarily "test drive" SCS and decide if you want to move forward with receiving the device.



High-performance battery options

Rechargeable and recharge-free device options suit your needs and lifestyle.



Small and discreet

Medtronic SCS devices are designed with your comfort in mind. Their thin size may give you enhanced comfort and may remain undetected under clothing.



Personalized pain relief

The Medtronic SCS system offers multiple settings to meet your personal pain relief needs.

If you choose the Inceptiv™ rechargeable device with closed-loop programming, your treatment instantly adjusts stimulation to maintain a balanced treatment dose during all activities. Inceptiv™ SCS can be paired with a variety of programming options based on your personal needs.¹⁰

If you choose recharge-free treatment, Vanta™ SCS can be paired with unique Medtronic programming offering meaningful pain relief, satisfaction, and quality-of-life improvements.¹¹



Full-body MRI scans

Some systems limit which parts of the body can be scanned. You may not be able to get an MRI of your spine, knee, abdomen, or shoulder, for example. The Medtronic SCS system lets you have scans anywhere on your body^{†‡} - just like a person without an implant device.

Up to 98%

of SCS implanted patients will likely need at least one MRI within 10 years of implant¹²



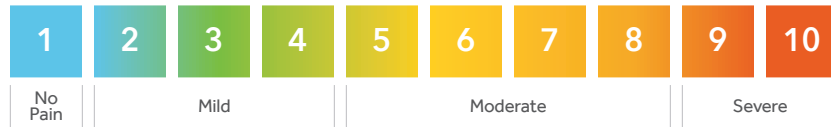
[†]Under specific conditions. Refer to product labeling for full list of conditions.

[‡]Patients with non-Medtronic leads and an EMBSNV20 adaptor extension are not eligible for an MRI.

Before your test drive

Record your pain score

Use the scale below to keep track of your pain and progress before and during the trial to assess your response to spinal cord stimulation.



Set reasonable goals

Work with your doctor to list up to five lifestyle and activity goals you would like to achieve if your pain were managed better.

Rank them in order, with #1 being the highest.

Activities	Goals
Walking	Walk to the back of the grocery store without resting
Reclining	Watch a movie while sitting comfortably on the couch
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____

Your personal guide

CareGuidePro™ app

When you're starting your journey to pain relief with Medtronic SCS, take along the CareGuidePro™ app – a free app that's like a roadmap and toolbox all in one.

- Track your appointments and receive important reminders.
- Keep your health care team updated with your daily progress through in-app surveys.
- Access educational resources and FAQ.
- Be informed throughout your SCS trial and procedure, so you can spend less time worrying about your pain and more time doing the things you love.



Install the CareGuidePro™ app

The free CareGuidePro™ app can be downloaded on your mobile phone or tablet and is available on iOS and Android operating systems. Scan the QR code to download CareGuidePro™.

To scan:

1. Open your phone's camera app.
2. Hover over QR code.
3. Complete the steps on your tablet or mobile phone to download.



Android



Apple iOS

For CareGuidePro™ technical support, please contact Higgs Boson at **866.704.4447** or by email at support@higgsbosonhealth.com

During your test drive

What to expect

The trial period can vary depending on your response to treatment and can last up to 10 days. With your trialing system in place, try to live as normally as possible. Consider doing some of the things you normally can't do because of your pain – like walking up stairs, standing in one place, or getting ready in the morning. It may take a few days to see the potential benefits of the trial.

During the trial, follow your doctor's recovery and care instructions.

- Keep in mind that neurostimulation will not relieve incisional pain (postprocedural pain).
- Do not get the external stimulator or programmer wet.
- Do not drive while the neurostimulator is on.
- Avoid sudden bending or twisting, and avoid lifting more than 5 lbs (a gallon of milk).
- Be aware that sudden, excessive, or repetitive motions, such as reaching up, down, over your head, and across could impact your treatment by moving trial components.

Contact your doctor with any questions you may have following your procedure.

Pain relief can vary. If you don't feel like you're receiving adequate pain relief, your doctor may be able to adjust your stimulation to better manage your unique pain relief needs.

Visit [medtronic.com/scstrial](https://www.medtronic.com/scstrial) for more information on the trial.

Every patient experience is unique. Not everyone responds to SCS in the same way, and your experience may vary.

"Having the stimulator has relieved the burden from my mind of constantly having to worry about my pain."

Bryan
SCS patient



Note: A technical user guide to assist you with programming needs during your trial is provided at the back of the brochure.

During your test drive

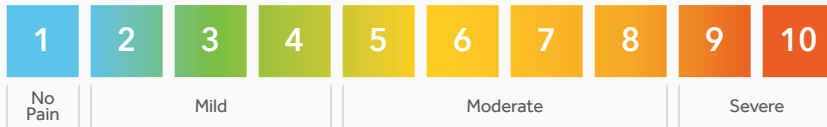
Track your goals

Track your top two function and activity goals electronically through the CareGuidePro™ app or written in the Pain Diary provided below, then share with your doctor. For each of your goals, please answer the following:

- Have you tried to reach one of your goals?
Example: "Yes, I was able to walk farther than I used to."
- How is that going? (List below.)



CareGuidePro™



Day 1	Pain Score:
Goal 1	
Goal 2	

Day 2	Pain Score:
Goal 1	
Goal 2	

Day 3	Pain Score:
Goal 1	
Goal 2	

Day 4	Pain Score:
Goal 1	
Goal 2	

Day 5	Pain Score:
Goal 1	
Goal 2	

Day 6	Pain Score:
Goal 1	
Goal 2	

Day 7	Pain Score:
Goal 1	
Goal 2	

Day 8	Pain Score:
Goal 1	
Goal 2	

Day 9	Pain Score:
Goal 1	
Goal 2	

Day 10	Pain Score:
Goal 1	
Goal 2	

Patient programmer basics

To view and adjust your treatment, you must connect to your neurostimulator using the MyStim™ trial app:

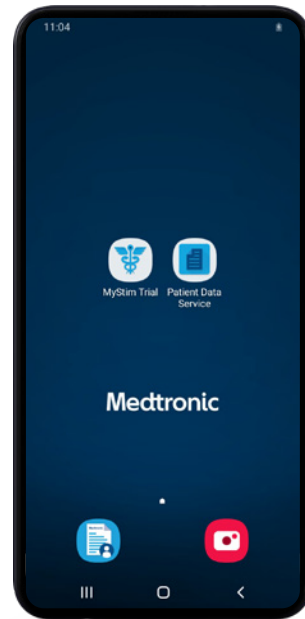
- **Patient programmer handset** – with the MyStim™ trial app
- **Communicator**

1. Turn on the handset and check that it is charged. If needed, refer to the handset quick start guide.

2. Tap the **MyStim™** trial app icon on the handset.



3. Tap the Connect button on the handset. Ensure handset is within 3 feet of your neurostimulator.



After the app connects to your neurostimulator, you will see the home screen.

Therapy screen overview

Menu button

Therapy toggle

Tap to turn treatment on or off

Change group button

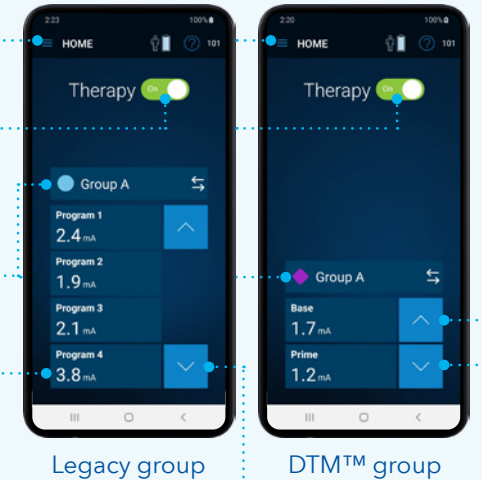
Tap to select a different group

Program buttons

Tap to view program status and adjust treatment settings

Adjust buttons

Tap to adjust intensity for all programs in active group



Adjusting therapy settings

Depending on the patient controls defined by your clinician, you may be able to adjust one or more treatment settings. There are three settings that control stimulation:

Intensity

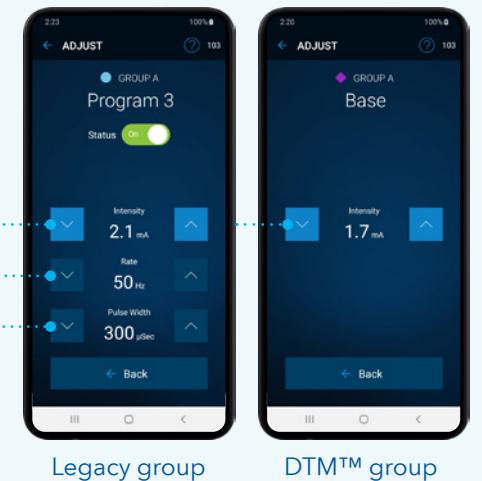
Controls the strength of the stimulation

Rate

Affects the number of electrical pulses delivered each second

Pulse width

Affects the length or duration of an electrical pulse



After your test drive

Evaluating your experience

As part of the conversation with your doctor about spinal cord stimulation, review your CareGuidePro™ surveys, look back on your Pain Diary pages, and compare your ability to do things before and during the trial.

If successful, spinal cord stimulation may help you manage certain types of chronic pain that have not responded to other treatments and improve your ability to participate in your usual daily activities.^{1,2} Many people experience improvements in their pain symptoms and quality of life after receiving Medtronic SCS.

"I am able to sleep, hike, bike, and walk my dog. I couldn't live a normal life without my neurostimulation system."

Jaclyn
SCS patient



Warnings, alerts, and notifications

Warning screens indicate a problem with the programmer or neurostimulator.




See the Patient Therapy Guide for more about warnings.

Alert screens indicate a pairing or other connection problem between the programmer or neurostimulator.

See the Patient User Guide for more about alerts.

Notification screens provide information about stimulation settings, error conditions, and battery levels.

See Patient User Guide for more about notifications.

Icon	Description	Screen type
	Red triangle with an exclamation point	Warning screen
	Orange triangle with an exclamation point	Alert screen
	Blue circle with the letter "i"	Notification screen

Talk with your doctor

While a nurse is available before your trial to provide general educational information about Medtronic devices and spinal cord stimulation treatment, you should always talk with your doctor about your unique medical condition and treatment management.

Your Medtronic representative is

Our Medtronic representatives are not medical professionals and cannot give medical advice. In the case of medical concerns or questions, you should always talk with your doctor about your unique medical condition and treatment management.

References

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2. Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. Effect of spinal cord stimulation for chronic complex regional pain syndrome type 1: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg*. 2008;108(2):292-298.
3. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain*. 2007;132(1-2):179-188.
4. North RB, Kidd D, Shipley J, Taylor RS. Spinal cord stimulation versus reoperation for failed back surgery syndrome: a cost effectiveness and cost utility analysis based on a randomized, controlled trial. *Neurosurgery*. 2007;61(2):361-368. Discussion:368-369.
5. Gee L, Smith HC, Ghulam-Jelani Z, et al. Spinal cord stimulation for the treatment of chronic pain reduces opioid use and results in superior clinical outcomes when used without opioids. *Neurosurgery*. 2018;84(1):217-226. A non-randomized prospective cohort study of SCS patients between September 2012 and August 2015 (N = 86 [n = 53 on opioids]).
6. Sharan AD, Riley J, Falowski S, et al. Association of opioid usage with spinal cord stimulation outcomes. *Pain Med*. 2018;19(4):699-707. A non-randomized analysis of Truven Health Marketscan databases from January 2010 to December 2014 based on the first occurrence of an SCS implant (N = 5,476).
7. Pollard EM, Lamer TJ, Moeschler SM, et al. The effect of spinal cord stimulation on pain medication reduction in intractable spine and limb pain: a systematic review of randomized controlled trials and meta-analysis. *J Pain Res*. 2019;12 1311-1324. A research review summarising SCS studies with respect to opioid use and a further meta-analysis of comparative SCS RCTs of 1 year or greater duration (N = 489).
8. Fishman M, Cordero H, Justiz R, et al. 12-month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. *Pain Pract*. 2021;21(8):912-923.
9. Based on analysis of Medtronic internal GCH sales monitoring from 1982 through March 2023.
10. Fishman M, Cordero H, Justiz R, Provenzano, D, Merrell, C, Shah, B, et al. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. *Pain Pract*. 2021; 21: 912- 923.
11. Peacock, Provenzano, Fishman, et al. Long-Term Clinical Outcomes of a Low-Energy Derivative Study of Differential Target Multiplexed™ Spinal Cord Stimulation. Poster presented at: North American Neuromodulation Society (NANS) 26th Annual Meeting; Jan 12-15, 2023; Las Vegas, NV.
12. Desai MJ, Hargens LM, Breitenfeldt MD, et al. The rate of magnetic resonance imaging in patients with spinal cord stimulation. *Spine*. 2015;40(9):E531-537.

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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