

# A Path to Life with Less Pain

Intellis<sup>™</sup> Spinal Cord Stimulation Guide

## **Medtronic**

Welcome to a new day in pain relief, and thanks for making the decision to receive a Medtronic Intellis™ spinal cord stimulation (SCS) system. We're grateful to have the opportunity to support your chronic pain needs.

This guide offers information to help you use your Medtronic Intellis™ SCS device. If you have questions or concerns, please see the list of resources we have available for you to connect with us.



## Contents

Postoperative Tips
Take Charge of Pain Relief
Your Medtronic Patient Identification Card
Your Therapy System
Recharging System
AdaptiveStim <sup>™</sup> Technology1
Getting an MRI Scan1

## Resources

### Talk with Your Doctor First

Your doctor should be your first resource in case of medical concerns. If you have questions or experience any pain or discomfort with your device, contact your doctor.

### **Patient Services**

The Medtronic Patient Services team is able to help you with:

- Programmer troubleshooting
- Finding a new physician if you are traveling or moving

#### Visit medtronic.com/SCSHelp

Or call 1-800-510-6735 Monday-Friday, 8 a.m. to 5 p.m. Central time.

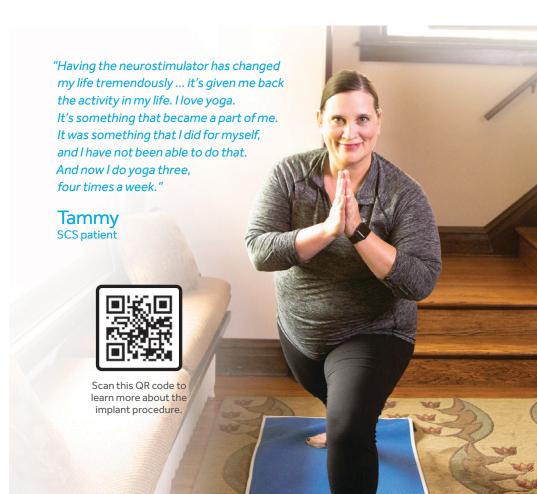
#### Ask a Nurse

Speak with a registered nurse who is experienced in Medtronic chronic pain therapies. They can help answer your questions about ongoing SCS therapy. This Nurse is a paid consultant of Medtronic.

#### Visit medtronic.com/nurse

Or call 1-888-430-PAIN (7246) to schedule an appointment.

For additional SCS resources and support, visit medtronic.com/info



# Postoperative **Tips**

## What to Expect

- Follow your physician's post-surgery recovery instructions and keep all follow-up appointments.
- If you feel some discomfort at the incision sites after surgery, your doctor may recommend restricting daily activity.
- (Neurostimulation will not relieve new incisional pain.)
- Positions may affect intensity of the stimulation.
- Several stimulation settings are available. Follow up with your doctor to ensure your SCS system is working correctly and relieving your pain.



#### Dos

- Talk with your doctor about which activities you can do.
- Follow up with your doctor for assistance if you:
- 1. Have medical concerns
- Experience additional or unusual pain
- 3. Notice changes in the effect your therapy is having on your pain
- Need to discuss managing your therapy
- If you're having a problem with your neurostimulator, turn off the system and contact your doctor's office



#### Don'ts

- Activities you may need to avoid immediately following surgery:
- 1. Sudden bending or twisting
- 2. Lifting more than 5 pounds (a gallon of milk)
- 3. Reaching over your head (no reaching up, over, across, down)
- Do not drive while the neurostimulator is on
- Do not get the programmer wet

# Take Charge of Pain Relief



## Long Battery Life, Rapid Recharge:

Battery capacity can last up to nine years and recharging takes approximately an hour.



## Full Body MRI Access:

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 gives you access to MRI anywhere on your body.\* Just like a person without an implanted device.



#### Personalized Pain Relief:

A therapy setting your clinician may choose to use is called AdaptiveStim<sup>TM</sup> technology, which personalizes pain relief by sensing changes in your body position. Whether you're standing, lying on your side, or in any of seven unique body positions, AdaptiveStim<sup>TM</sup> technology automatically tailors stimulation to manage pain. This technology is only available on Medtronic devices.



#### Sleek and Small Device:

Intellis™ SCS is designed with your comfort in mind. Its thin size may give you enhanced comfort and may remain undetected under clothing.





\*\*Under specific conditions. Refer to product labeling for full list of conditions. Patients with non-Medtronic leads and an EMBSNV2O adaptor extension are not eliable for an MRI.

# Your Medtronic Patient Identification Card

Keep your ID card with you at all times, and ensure the information on it is accurate.

#### Your ID Card:

- Identifies you as having an implanted device in an emergency
- Includes a toll-free number to contact Medtronic
- Helps Medtronic maintain current and accurate information for your records
- Allows you to notify security personnel and health professionals that you have an implanted medical device

Present your ID card when you have medical or dental procedures, or when you must pass through a security screening system (such as airport security) where your device may set off an alarm.



## Getting an Identification Card

You should have received a temporary ID card at the time of your implant procedure. You will automatically receive a permanent ID card from Medtronic about two weeks after the procedure. There's no fee for the card.

If you move or change physicians, or edit other information on your card, contact Patient Registration at the number below.

You may also update your card by going to medtronic.com/IDRegistration.

Contact Patient Registration at the number below if you do not receive a permanent ID card in four to six weeks.

If your ID card is lost or stolen, Patient Registration can issue a replacement card and can also issue an extra card for your spouse.



Scan QR code to request an ID Card

## Patient Registration Contact Information

Call 1-800-551-5544 Monday-Friday, 7 a.m. to 6 p.m. Central time.

# Your Therapy System



## **Charging Port**

- Connects to the recharger cord
- Used to recharge the programmer
- Used to recharge the neurostimulator

Note: To perform most functions on the programmer, you must first press the Increase/Decrease key to wake up the programmer.

# Therapy Screen Overview

### **Battery Status Button**

- Press to check battery status.
- Left icon on this button displays the programmer battery status.
- Right icon displays the neurostimulator battery status.

#### Lock Button

Press to lock programmer.

#### Menu Button

Press to access Menu screen.

## **Group Button**

- Press to show group name (indicated by A, B, and C.
- Green highlighting indicates the group is active.

Note: The Group button will be gray when stimulation is off. An orange message will appear, alerting you that stimulation is off.

### **Program Buttons**

- Home screen displays up to four programs, indicated by numbered boxes (1-4).
- After pressing the Program button on the Home screen, available settings for that program may appear.



#### Intensity

Controls the strength of the stimulation



#### Stimulation

Turns stimulation on or off



#### Rate

Sets the speed of the stimulation pulses



#### **AdaptiveStim**™

Turns AdaptiveStim<sup>™</sup> on or off

(This feature is only available with the Intellis™ with AdaptiveStim™ technology implanted neurostimulator.)



#### Pulse width

- **†** 

Sets the length of the stimulation pulse

(pulse width affects the strength and coverage area of the stimulation)

Δ

 $\nabla$ 



#### Cycling

Turns stimulation on and off at regular intervals, as programmed by your clinician



#### **Up/Down buttons**

Press to view additional parameter and stimulation settings for a program

(These buttons may not appear, depending on how your clinician has programmed your neurostimulator.)

## Basic Programmer Functions

### **Unlocking Your Programmer**

- When the Increase/Decrease key is pressed to wake up the programmer, the Unlock screen appears.
  - When the programmer is locked, you can press the Stimulation On/Off key to bypass the Unlock screen and to turn stimulation on or off.
- 2. Press and hold the Lock (1) button on the Unlock screen.
  - As the Lock button is held, bars appear on the screen and move toward the Lock button.
  - When the screen changes to a circle of dots, release the Lock button.
     The dots indicate that the programmer is searching for your neurostimulator.



## Turning Stimulation On or Off for All Programs within a Group

- 1. Press the Stimulation On/Off key, which is located on the top of your programmer, to turn the stimulation on or off.
  - Press the Go To Unlock button if you wish to access the Home screen instead.
- 2. The Home screen will appear to confirm whether stimulation is on.

  Note: When stimulation is on, the active Group will be highlighted in green.

### **Adjusting Stimulation**

- Press a Program button on the Home screen. The available setting for that program will display.
- Use the Increase/Decrease keys to adjust desired program settings.

Note: Some settings may not be available, depending on what your clinician has programmed for your neurostimulator.

## Changing a Group

- From the Home screen, select the group on the left side of the screen to access the other groups available, then select the circle next to the desired group. Only one group can be selected at a time.
- 2. Up to three groups may be available. Groups are viewed by letters A, B and C.
- 3. Press the OK button. The Home screen will display the selected group.

## **Checking Programmer Battery Level**

- 1. From the Home screen, press the Battery status button. Two battery figures appear.
- 2. Press the Exit (☒) button at the top right corner of the touchscreen to exit.



Neurostimulator



Intensity

## **Recharging System**

This section explains how to recharge both your neurostimulator and the programmer.

The Recharging System includes the following components:

- The recharger (attached to the programmer) charges your implanted neurostimulator.
- 2. The belt can be used to keep the antenna positioned directly over the implanted neurostimulator during a charging session.
- The programmer battery pack is the rechargeable power source for the patient programmer.
- 4. The AC power supply charges the programmer using AC power.

  Plug one end into a wall outlet and the other end into the programmer.



## Recharging your implanted neurostimulator

If the Low Battery screen appears, you need to recharge your implanted neurostimulator.

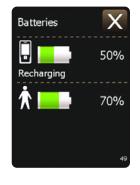
- 1. If desired, place the recharger head into the opening on the belt.
- 2. Plug the recharger into the programmer charging port.
- If necessary, press and hold the Lock (1) button on the Unlock screen. The Position screen will be displayed.
- Press your skin where your neurostimulator is located to determine the best place to position the recharger.
- Position the recharger over your neurostimulator and press the Continue button. A series of screens will appear on the programmer screen describing the recharging activity.

Note: To perform most functions on the programmer, you must first press the Increase/Decrease key to wake up the programmer.



The recharging temperature and speed can only be adjusted while the neurostimulator is being actively recharged. The higher the number, the quicker and warmer recharging will be. The default recharging temperature and speed is 4.

- 1. If necessary, press and hold the Lock (1) button on the Unlock screen.
- 2. Press the Exit (X) button on the Batteries screen.
- 3. Press the Menu ( ) button on the Home screen.
- 4. Drag the slider bar, or use the Increase/Decrease key to view additional preferences on the Menu screen.
- 5. Select the Recharging button. The Recharging screen is shown to the right.
- 6. Using the touchscreen or the Increase/Decrease key, select the circle next to the desired recharging temperature and speed.
  - The more bars you select, and the higher the number, the faster the recharging speed and the warmer the recharger will feel while you are recharging.
  - It is normal to feel some heat under the recharger while recharging. If it is uncomfortable, reduce the recharging speed.
  - The recharging temperature and speed that you select will stay the same until you change the setting again.
- 7. Press the OK button to exit.
- 8. Press the Exit (☒) button to return to the Home screen.
- Press the Battery status ( button to view the Batteries screen.
   Or press the Lock ( button to lock the programmer.



Recharging

Set the temperature and

speed.

OK

### Recharging the programmer battery pack

The power supply cannot be used to recharge AA batteries.

- 1. Plug the power supply into an electrical outlet.
- Plug the connector end of the power supply into the charging port of the programmer.
- 3. Press and hold the Lock ( ) button on the Unlock screen. If recharging is successful, the word "Recharging" will begin to flash on the Batteries screen.

Note: The recharging light above the touchscreen will flash green while your programmer battery pack is recharging. When the programmer battery pack is completely charged, the recharging light above the touchscreen will be steady green and no longer flashing. The Batteries screen will display Finished.

- 4. Press the Exit (☒) button to view the Home screen.
- 5. Press the Lock ( ) button to lock the programmer while recharging.
- To complete recharging the programmer battery pack, unplug the power supply from the programmer charging port.





## **Tips**

- Recharging can only be performed with the rechargeable battery pack installed in the programmer.
- The programmer battery pack should be charged before starting to recharge the neurostimulator battery.
- Charge the programmer battery pack and implanted neurostimulator even if you are not using them for an extended period of time.
- You cannot charge the programmer and neurostimulator at the same time.
- Your ability to locate your implanted neurostimulator and the depth of the neurostimulator determine the efficiency of the recharging session. With practice, you will find the best location on your skin for placing your recharger.
- After getting a good/excellent recharge quality it is suggested to allow the screen to "go to sleep" and monitor the blinking green light.

- The screen will display "Finished" if the charging session is stopped.
   Note: This does not mean your stimulator battery level is at 100%.
- If the stimulator battery depletes to the red warning level, the therapy/ stimulation will turn off and will require to be turned back on manually once the INS has a minimum of 15% (yellow).

WARNING: DO NOT use the recharger on an unhealed wound. The recharging system is not sterile, and contact with the wound can cause an infection.

- You can turn stimulation on and off during a charging session and also adjust stimulation during this time.
- If the recharger has a poor connection to your neurostimulator, the Reposition Antenna screen will appear. If repositioning the recharger does not complete the connection, select "Try Again."

Note: Your recharger may make clicking noises while it searches for the neurostimulator.

# Warnings, Alerts & Notifications

on warnings.

**Warning screens** indicate a problem with the programmer or neurostimulator. See the Patient Therapy Guide for more

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

See the Patient User Guide for more on alerts.

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

See the Patient User Guide for more explanation on notifications.

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

## AdaptiveStim<sup>™</sup>Technology

When AdaptiveStim<sup>™</sup> technology is turned on, the implanted neurostimulator can automatically sense your body position and adjust the stimulation based on your body position.

Note: AdaptiveStim<sup>™</sup> must be turned on to view or change AdaptiveStim<sup>™</sup> settings.

## Turning AdaptiveStim™ Technology On or Off

To turn the AdaptiveStim feature on or off, follow these steps:

- Press a Program icon on the Home screen for the program you want to adjust.
- 2. Press the AdaptiveStim™ (᠗) icon. The AdaptiveStim™ screen is shown at right.
- Press the On or Officon to turn AdaptiveStim™ on or off.
   Note: When you turn AdaptiveStim™ on or off for one program, it affects all programs the same way.
- 4. Press the Exit (☒) icon at the top right corner of the touchscreen to exit.

## Making Adjustments to AdaptiveStim™ Technology Settings

To change the intensity setting for a specific body position, follow these steps:

- To change AdaptiveStim™ intensity settings for a specific position, place your body in the desired position before making the adjustments.
- Use the Check Position feature to confirm that the neurostimulator recognizes your body position.
- 3. Make the appropriate adjustments to your intensity settings.
- 4. You may need to stay in your current position for up to five minutes before the new intensity settings are recorded. Your clinician can adjust this length of time. Confirm the length of time with your clinician.
- The next time you return to this position, the intensity settings will automatically change to the recorded settings.



## Getting an MRI

#### **Before Your MRI**

Your Intellis™ SCS system allows you to have an MRI scan anywhere on your body.\*

- Tell the doctor who prescribed your MRI scan that you have an implanted Medtronic neurostimulation system.
- 2. Contact your pain specialist to discuss your upcoming MRI scan. Your pain specialist may also provide you or your radiologist with a copy of the MRI Patient Eligibility Form. The information on this form can help the radiologist confirm your eligibility for the prescribed MRI scan.
- 3. Schedule your MRI appointment. When your MRI appointment is scheduled, provide them with the model number of your implanted neurostimulation system and the contact information for your pain specialist. This information is located on your Medtronic Patient ID Card and on the MRI Patient Eligibility Form (which may have been provided by your pain specialist).

If you have questions about your MRI Scan eligibility or how to prepare your neurostimulation system for an MRI scan, contact your pain specialist or Medtronic Patient Services at 1-800-510-6735.

An MRI scan may be safely performed under certain specific conditions.\*† Not following the specific conditions can cause tissue damage and can result in serious patient injury.

Please have your healthcare professional contact Medtronic for the latest MRI guidelines for your neurostimulation system for chronic pain.

Contact information is found at the back of this manual, or the healthcare professional can go to medtronic.com/mri



Scan QR code to learn more about getting an MRI



\*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.

## Using Your Handset to Activate MRI Mode

Place your neurostimulation system in MRI mode before your MRI scan and outside of the MRI scanner (magnet) room. When you activate MRI mode with your programmer, stimulation is turned off and the In MRI Mode screen will appear. Show this screen to the MRI clinician.

## Activating MRI Mode:

Complete the following steps to activate MRI mode.

- 1. Press the Menu ( ) button on the Home screen.
- 2. Select the MRI Mode button. The Enter MRI Mode screen appears.
- 3. Press the Continue button to continue. When MRI mode is activated, your implanted neurostimulation system has been placed in MRI mode and stimulation is turned off. In addition, one of the In MRI Mode screens will appear, showing the MRI scan eligibility.



Full-body scan eligible



Head scan eligible



Eligibility cannot be determined



MR unsafe



### MRI scan eligibility icons

**WARNING:** You may be given an inappropriate MRI scan, which could cause you injury or could cause damage to your implanted medical device if you do not inform the MRI clinician before you enter the MRI scanner (magnet) room that you have an implanted neurostimulation system. The MRI clinician conducting your MRI scan needs to be aware of all medical implants in order to assess the conditions for safely performing your MRI scan.

#### Icon combination

#### **Explanation**







#### Full-body scan eligible

The implanted neurostimulation system allows the patient to be eligible to have MRI scans of any part of the body under specific conditions. The MRI clinician must consult the MRI guidelines for those conditions.







#### Head scan eligible with transmit/receive head coil

The implanted neurostimulation system allows the patient to be eligible for MRI scans of the head only using an RF transmit/receive head coil and under other specific conditions. The MRI clinician must consult the MRI guidelines for those conditions.





#### The neurostimulation system MRI scan eligibility cannot be determined

The MRI clinician must consult the MRI guidelines to determine how to proceed or contact Medtronic Technical Support.





#### MRI unsafe

You cannot have an MRI scan if your neurostimulation system contains any non-Medtronic component because safety in the MR environment is unknown.

- 1. Do not press any other keys or buttons. Note: The In MRI Mode screen on the programmer will display for 10 minutes.
- 2. Give your programmer to the MRI clinician with the In MRI Mode screen displayed.

Note: Do not take your programmer into the MRI scanner (magnet) room.



Caution: Do not turn stimulation back on before your MRI scan. Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.

## Turning Stimulation Back on After the MRI Scan

Complete the following steps to turn on your stimulation using the programmer.

- If necessary, unlock your programmer by pressing and holding the Lock (1) button on the Unlock screen.
- 2. Press the Exit MRI Mode button on the In MRI Mode screen. The Stimulation is off screen appears.
- 3. Press one of the available buttons from the Stimulation is off screen:
  - Press the OK button to keep stimulation off and to return to the Home screen.
  - Or press the Turn On button to turn on stimulation and return to the Home screen. Your stimulation settings will return to how they had been programmed before you entered MRI Mode.
- 4. If the Home screen is not shown after exiting MRI Mode, refer to the "Troubleshooting" section on page 161 of the controller (programmer) manual.





If you have questions about your MRI scan eligibility or how to prepare your neurostimulation system for an MRI scan, contact your pain specialist or Medtronic Patient Services at 1-800-510-6735.

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

If you're experiencing any pain or discomfort with your device, contact your physician.

### **Patient Services**

The Medtronic Patient Services team is able to help you with:

- Programmer troubleshooting
- · Finding a new physician if you are traveling or moving

Visit medtronic.com/SCSHelp

Or call 1-800-510-6735 Monday-Friday, 8 a.m. to 5 p.m. Central time.

## Medtronic

710 Medtronic Parkway Minneapolis, MN 55432-5604 USA