

USING YOUR IMPLANTED SPINAL CORD STIMULATION SYSTEM



OUT OF PAIN.
INTO RELIEF.

Medtronic
Further. Together

USING THIS GUIDE

This guide provides basic information to help you use your Medtronic spinal cord stimulation system. It also describes other Medtronic resources available to help you as you begin living with your implanted spinal cord stimulation system.

For additional information, you may also refer to the *MyStim™ Patient Programmer User Manual* and the *Charging System Patient User Manual*.

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YOUR MEDTRONIC PATIENT IDENTIFICATION CARD

Your Medtronic Patient Identification (ID) Card contains important information about your medical device and includes your physician's phone number in case you have a medical question or emergency. 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 case of an emergency.
- includes a toll-free number to contact Medtronic.
- helps Medtronic maintain current and accurate information for your records.

Your ID card allows you to notify security personnel and health professionals that you have an implanted medical device. Present your ID card when you have any 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

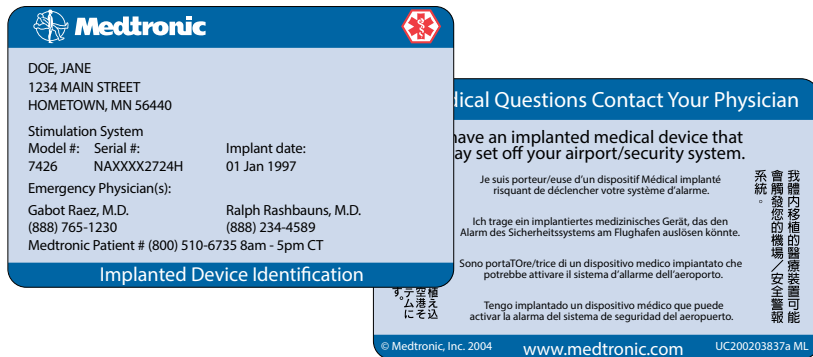
You should have received a temporary ID card at the time of your implant procedure. You will automatically receive a permanent plastic ID card from Medtronic, 3-4 weeks after the procedure. There is no fee for the card. Contact Patient Registration at the number below if you do not receive a permanent ID card in 4-6 weeks.

We recommend that you carry your ID card with you at all times. If you move or change physicians, or if any of the other information on the card changes, contact Patient Registration to update your information and request a new card. You may also update your card online at www.medtronic.com by selecting the **Patients** tab, then clicking on **Manage ID Card** under the **Tools** heading.

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

Patient Registration Contact Information:

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



PROGRAMMER BASICS

PROGRAMMER KEYS

- 1. Decrease**
Decreases a parameter.
- 2. Increase**
Increases a parameter.
- 3. Power**
Turns programmer on and off.
Holding the key down turns the screen backlight on or off.
- 4. Navigator Key**
Press up and down arrows to move selection box to desired row.
Press left and right arrows to see additional options in a desired row (if enabled by your doctor).



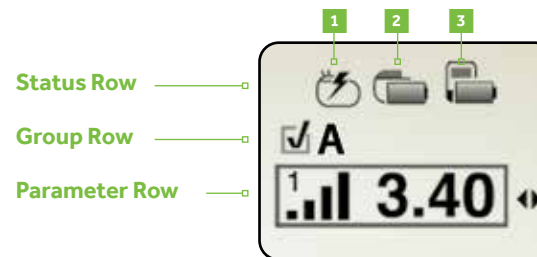
Front View



Side View

- 5. Neurostimulator On**
Turns neurostimulator on.
- 6. Neurostimulator Off**
Turns neurostimulator off.
- 7. Sync**
Communicates with the neurostimulator.
Press at the beginning of each session or to activate a new group.

THERAPY SCREEN OVERVIEW



Status Row





- 1.** Neurostimulator on/off (lightning bolt = on).
- 2.** Implantable neurostimulator battery level.
- 3.** Programmer battery level.

Group Row

- Shows current group name (indicated by a letter, an icon, or text).
- Checkmark ✓ indicates the group is active.
- The Options icon ◀▶ will appear if other groups are available.

Note: The Group Row only appears if you have more than one group, or if Scheduled Therapy is enabled.

Parameter Row

- Shows icons and settings for program parameters you can change.
- The Options icon ◀▶ will appear if other parameters are available.
- Parameters which may appear in the Parameter row include:
 -  **Amplitude** – Changes how strong the stimulation feels or the spread of the stimulation area.
 -  **Pulse Width** – Changes how strong the stimulation feels or the spread of the stimulation area.
 -  **Rate** – Changes how smooth the stimulation feels. Rate feels like a tapping sensation.
 -  **Amplitude Group Adjust** – Simultaneously changes all program amplitudes for the active group.


BASIC PROGRAMMER FUNCTIONS

Turning Stimulation On or Off

1. While holding the programmer (or external antenna) over the neurostimulator, with the programmer screen facing outward, press the **Neurostimulator On** or **Neurostimulator Off** key.




Note: The Therapy screen will display a lightning bolt in the upper left corner when stimulation is turned on.

Adjusting Stimulation


1. Hold the programmer over the neurostimulator, with the programmer screen facing outward, and press the **Sync** key .
2. Press the up or down arrow on the **Navigator** key to select the **Parameter** row.
3. Press the left or right arrow on the **Navigator** key to select a parameter to adjust.
4. Hold the programmer over the neurostimulator and press the **Increase (+)** key or the **Decrease (-)** key.

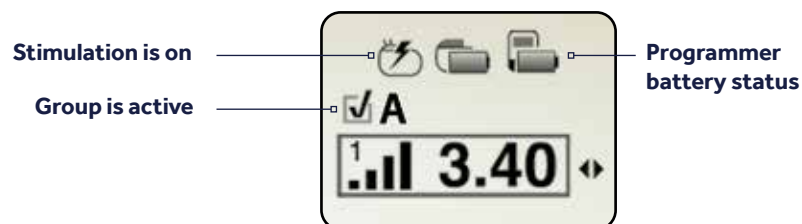
Note: Decrease amplitude before adjusting pulse width or rate to avoid potential discomfort.

Changing a Group

1. Hold the programmer over the neurostimulator, with the programmer screen facing outward, and press the **Sync** key .
2. Press the up or down arrow on the **Navigator** key to select the **Group** row.
3. Press the left or right arrow on the **Navigator** key to select a group.
4. Hold the programmer over the neurostimulator, with the programmer screen facing outward, and press the **Sync** key .
5. Verify that the group is active .

Checking Programmer Battery Level

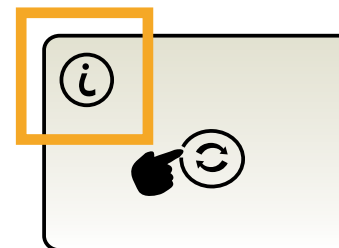
1. Hold the programmer over the neurostimulator, with the programmer screen facing outward, and press the **Sync** key .
2. Examine the programmer battery status icon in the **Status** row.



INFORMATION AND WARNING SCREENS

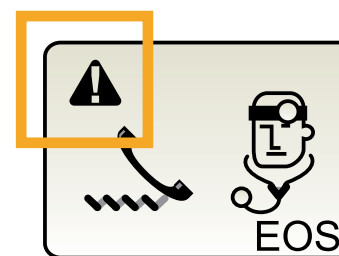
Information screens provide information about therapy settings, error conditions, and battery levels.

Information screens display a lowercase “i” in a circle, in the upper-left corner of the screen.



Warning screens indicate a problem with the programmer, the antenna, or the neurostimulator.

Warning screens display an exclamation mark in a triangle, in the upper-left corner of the screen.

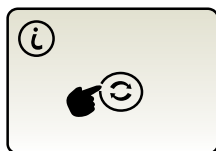


Refer to Table 1 on page 8 for a description of common Information and Warning screens.

Instructional videos explaining basic programmer functions and the meaning of common Information and Warning screens may be viewed at the following website: [medtronic.com/programming](https://www.medtronic.com/programming)

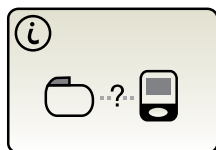
Table 1. Common Information and Warning Screens

SYNCHRONIZE



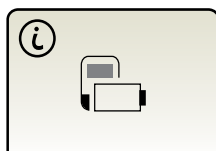
When the programmer is turned on, the **Synchronize** screen will display. This screen means the programmer is on, but it must be synchronized with the neurostimulator before therapy settings can be viewed or changed.

POOR COMMUNICATION

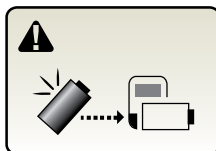


If the **Poor Communication** screen appears, it means the programmer and neurostimulator did not establish communication. To correct this problem, reposition the programmer or antenna directly over your neurostimulator and press the **Sync** key (⌘) again. If you are using the external antenna, make sure the antenna is properly plugged into the antenna jack on the programmer.

PROGRAMMER BATTERIES NEED REPLACEMENT



If either of these screens appear, it means the programmer batteries need replacement.



To replace the batteries, open the battery compartment, remove the old batteries, and replace them with new AAA alkaline batteries.

CALL YOUR DOCTOR

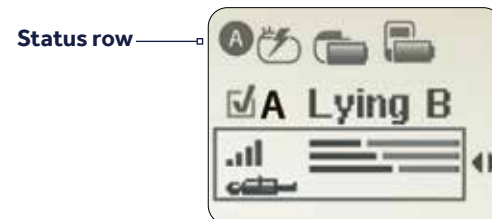


If the **Call Your Doctor** screen appears, you should write down the code that appears in the lower-right corner (e.g., EOS) and call your doctor right away.

ADAPTIVESTIM™

USING ADAPTIVESTIM

If you have a RestoreSensor™ neurostimulator and your clinician has programmed AdaptiveStim, and AdaptiveStim is turned on, the **AdaptiveStim On** icon (A) will appear in the **Status** row on the **Therapy** screen.



- If AdaptiveStim is on and your therapy is on, your amplitude settings will change automatically in response to your body position changes.
- If AdaptiveStim is turned off, only the **Neurostimulator On** icon (⚡) or **Neurostimulator Off** icon (⊖) will display in the upper left corner of the **Status** row.
- AdaptiveStim must be turned on in order to view AdaptiveStim information on the **Therapy** screen.

Making adjustments to AdaptiveStim


If you make an adjustment to your stimulation with AdaptiveStim on and want to have that adjustment remembered for a certain position, make the adjustment and stay in that position for **at least three minutes**.

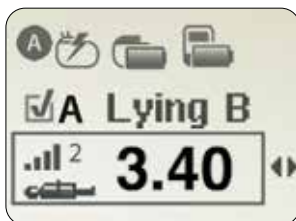
Note: If you change position while increasing or decreasing your stimulation amplitude, the AdaptiveStim icon or text will blink, indicating the MyStim™ programmer has updated to the current AdaptiveStim position.



Use the definitions listed in Table 2 on page 11 to understand the AdaptiveStim position names and icons on the Therapy screen.

TURNING ADAPTIVESTIM™ ON AND OFF

Complete the following steps to turn AdaptiveStim on or off.


1. Synchronize the MyStim™ programmer and neurostimulator.
 - Hold the MyStim programmer directly over your neurostimulator with the screen facing outward.
 - Press the **Sync** key . The **Therapy** screen appears.



2. Press the up  arrow on the **Navigator** key to move the selection box to the **Status** row.
3. Press the right  arrow on the **Navigator** key to move the selection box to the **AdaptiveStim** preference.

The preference screen displays the AdaptiveStim state that you will change to. For example, if AdaptiveStim is currently turned on, the **AdaptiveStim Off** icon will be displayed on the **Preference** screen.



4. Press the **Sync** key  to send the change to your neurostimulator and return to the **Therapy** screen.

Note: With the AdaptiveStim off, you will not see the AdaptiveStim On icon, position name next to the Group, or position icon:

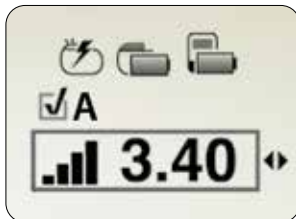
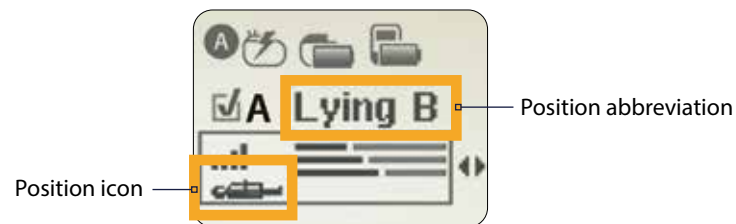


Table 2. AdaptiveStim™ groups and positions

Your clinician can program specific amplitudes for each of the following six positions:

Position Icon	Position Description	Position Abbreviation
	Standing or sitting upright	Upright
	Lying on your back	Lying B
	Lying on your front	Lying F
	Lying on your right side	Lying R
	Lying on your left side	Lying L
	Mobile while upright	Mobile

AdaptiveStim position abbreviations are displayed on the **Group** row of the **Therapy** screen. AdaptiveStim position icons are displayed on the **Parameter** row.



Note: If you change positions after synchronizing, re-synchronize in order to view updated positions and settings.

RECHARGING SYSTEM

If you have a rechargeable neurostimulator, this section explains how to recharge both your neurostimulator and the recharger.

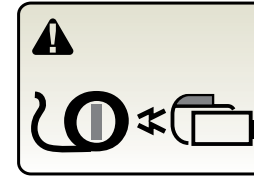
The Recharging System includes the following components:

- The **Recharger** charges your implanted neurostimulator.
- The **Antenna** establishes communication between the neurostimulator and the recharger, when charging the neurostimulator.
- The **Belt** can be used to keep the antenna positioned directly over the neurostimulator during a charging session.
- The **AC Power Supply** charges the recharger using AC power. Plug one end into a wall outlet and the other end into the recharger.



CHARGING YOUR NEUROSTIMULATOR

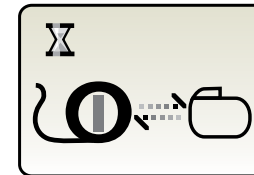
If the **Charge Neurostimulator Battery** screen appears, you need to charge your implanted neurostimulator.



Charge Neurostimulator Battery screen

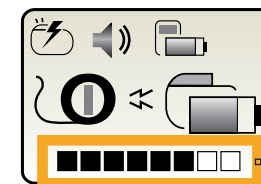
To charge your neurostimulator:

1. **Position the antenna.** Press your skin where your neurostimulator is located to determine the best place for the antenna. Depending on the location of your implanted neurostimulator, you may use the belt to ensure the antenna is correctly positioned for charging.
2. **Press the green Start Charge key** on the recharger, after the antenna is in place.
3. The **Recharger Wait** screen will display on the recharger, indicating that the neurostimulator and recharger are trying to communicate with each other. Note: Every time you move the recharger, you will need to press the green **Start Charge** key again.



Recharger Wait screen

4. When charging begins, the **Neurostimulator Recharging** screen will appear. The bottom row of boxes on this screen will indicate the strength of the charging signal.



Charging signal strength

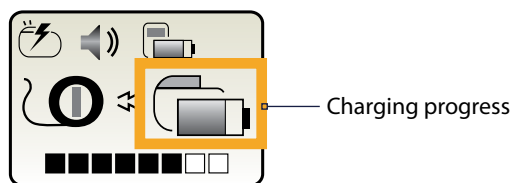
Neurostimulator Recharging screen

If all eight boxes are solid black, the charging signal is as strong as possible, and the charging session will be as short as possible.

If you see fewer than eight solid black boxes on the screen, you may be able to increase the strength of the charge (as described in step 5 below).

Note: These black boxes are only an indicator of the charging signal strength and do not indicate how much the battery has been charged.

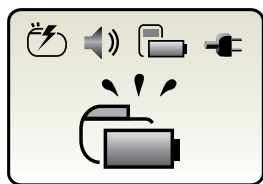
- 5. Adjust signal strength.** Signal strength can be improved by ensuring that the antenna is not placed over bulky clothing. You can also increase the charging signal strength by adjusting the dial on the antenna or by repositioning the belt. To adjust the dial, turn it a quarter turn in either direction. Then press the **Start Charge** key again.
- 6.** Once communication begins, the **Neurostimulator Recharging** screen shows the progress of the charging session on the battery icon.



Neurostimulator Recharging screen

This progress indicator is updated throughout the charging session and the battery icon will fill in from left to right (in one-quarter increments) as your neurostimulator is charged. Charging sessions can last as little as a few minutes to more than 12 hours, depending on the charging signal strength, the current battery level, how often you charge, and your therapy settings.

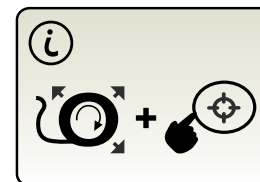
- 7.** When your neurostimulator battery is almost full, the **Neurostimulator Charge Sufficient** screen will appear.



Neurostimulator Charge Sufficient screen

Neurostimulator charging tips:

- You can turn stimulation on and off during a charging session, but you cannot adjust stimulation during this time.
- If the recharger loses its connection to your neurostimulator, you will hear three beeps and the **Reposition Antenna** screen will appear.



Reposition Antenna screen

To reestablish the connection, reposition the antenna over your neurostimulator and press the green **Start Charge** key again.

- If you need to interrupt your charging session, press the **Stop Charge** key on the recharger. To resume the charging session, press the **Start Charge** key again.

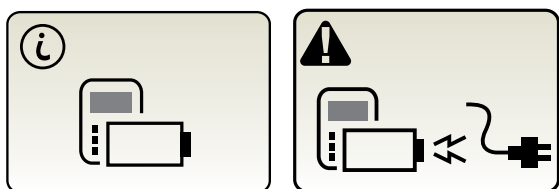
Instructional videos explaining how to charge your implanted neurostimulator and your recharger may be viewed at the following website: [medtronic.com/recharging](https://www.medtronic.com/recharging)

CHARGING THE RECHARGER

- 1. Check recharger battery level.** With the recharger off, you can check its battery level by pressing the **Audio Control** key.
 - If the recharger battery is full, the **Battery Status** icon will look like this:

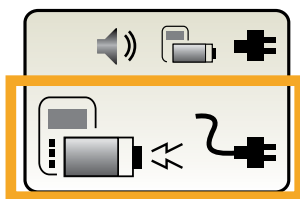


- 2. Low battery.** If you see either of these screens, it means the recharger battery is low and you need to charge the recharger soon:



- 3. To charge the recharger:**
 - Plug the AC power supply into an electrical outlet. The green light on the AC power supply indicates the power supply has power.
 - Connect the recharger to the AC power supply, aligning the two white arrows. The recharger automatically starts charging when connected to the power supply.

The icons in the lower half of this screen indicate that the recharger is properly connected and is being charged:



The recharging session could last several hours, depending on the battery level.

BEFORE YOUR MRI

Depending on the type of neurostimulation system you have, you may be eligible for either a full-body or head-only MRI scan. You can help your clinician and radiologist determine which type of scan you are eligible for by following these guidelines.

Note: *If you do not have a Medtronic SureScan™ MRI neurostimulation system, you may still be eligible for a head-only scan. Your pain specialist and radiologist can refer to Medtronic's MRI Guidelines to make that determination.*

- 1. Tell the doctor who prescribed your MRI scan that you have an implanted Medtronic neurostimulation system.** An MRI scan could be prescribed by a variety of doctors, including a general practitioner, orthopedist, oncologist, or your pain specialist.

- 2. Contact your pain specialist to discuss your upcoming MRI scan.** Your pain specialist should tell you if you can safely undergo the type of MRI scan prescribed.

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.

4. Prepare your neurostimulation system for an MRI Scan.


If your neurostimulation system does not have SureScan™ MRI technology:

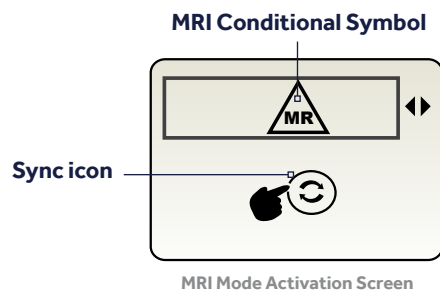
- You must turn off stimulation (as described in the *Turning Stimulation On and Off* section on page 6), before you enter the MRI scanner (magnet) room.


If you have a Medtronic SureScan MRI neurostimulation system:

- Your implanted neurostimulation system must be placed in MRI Mode before you enter the MRI scanner (magnet) room. Activating MRI Mode turns off your stimulation. You or your pain specialist can activate MRI Mode using your patient programmer. If the patient programmer is not available, your clinician can also activate MRI Mode using the clinician programmer.

To activate MRI Mode:

- Synchronize the patient programmer and the neurostimulator. Hold the patient programmer directly over your neurostimulator with the screen facing outward. Press the **Sync** key . The **Therapy** screen will appear.
- Press the up arrow on the **Navigator** key to move the selection box to the **Status** row on the **Therapy** screen.
- Press the left or right arrows on the **Navigator** key to move the selection box until the **MRI Mode Activation** screen appears.



- Hold the patient programmer directly over your neurostimulator with the screen facing outward and press the **Sync** key . MRI Mode is now activated and your stimulation is turned off. The **MRI Scan Eligibility** screen will display one of the sets of icons shown in Table 3 on page 19, indicating your MRI scan eligibility. Do not press any other keys once MRI Mode is activated.

MRI Mode should be activated before you enter the MRI scanner (magnet) room. Do not turn stimulation back on before your MRI scan.




Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.

You should not have an MRI if you have a fever. A rise in body temperature (even just two degrees) can significantly increase chances of injury.

- Attend your MRI appointment.** Inform the radiologist and MRI technologist of all implanted medical devices (including abandoned devices). You should also inform them if you have (or suspect you have) a fever. You may not be able to have an MRI if you have a fever.

- You must bring your Medtronic MyStim™ Patient Programmer with you to all MRI appointments.** Note: Do not bring the patient programmer into the MRI scanner (magnet) room.
- It is recommended that you also bring the following items with you to every MRI appointment:**
 - Medtronic Patient ID Card
 - MRI Patient Eligibility Form (if provided by your pain specialist)

Table 3. MRI Scan Eligibility Icons


Icons	Explanation
	Full-body scan eligible The patient is eligible to have MRI scans on 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 patient is 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.
	MRI scan eligibility cannot be determined The MRI clinician must consult the MRI Guidelines to determine how to proceed, or contact Medtronic.

TURNING STIMULATION BACK ON AFTER YOUR MRI SCAN

If your neurostimulation system does not have SureScan™ MRI technology:

- You should turn on stimulation (as described in the *Turning Stimulation On or Off* section on page 6).

If you have a Medtronic SureScan MRI neurostimulation system:

- You should deactivate MRI Mode as follows:
 - Hold the patient programmer directly over your neurostimulator with the screen facing outward and press the **Sync** key .
 - Hold the patient programmer directly over your neurostimulator with the screen facing outward and press the **Neurostimulator On** key.
 - Verify that the **Neurostimulator On** icon is displayed on the **Status** row of the **Therapy** screen.

MORE RESOURCES

Call Patient Services at (800) 510-6735 Monday–Friday, 8 a.m. to 5 p.m. CT for assistance with:

- Programmer or recharger troubleshooting
- Finding a new physician if you are traveling or moving
- Your Medtronic Patient ID card

Follow up with your doctor for assistance with:

- Medical concerns
- Managing your therapy, including what stimulation level you should use and adjustments to the stimulation level, if needed



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. **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 for product manuals for complete indications, contraindications,

warnings, precautions and potential adverse events. Rx only. Rev 0119

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