Medtronic

Engineering the extraordinary

Inceptiv[™] neurostimulator

MRI eligibility for spinal cord stimulation patients

Real-time MRI eligibility for the Inceptiv[™] neurostimulator

Pain specialist: Please complete this form to alert radiology staff about MRI eligibility for your implanted patient. Activate MRI Mode, using either the clinician or patient programmer, if appropriate.

Patient: Once your pain management specialist has completed this form, take the form and your patient programmer to your MRI appointment.

Radiology staff: Your MRI patient's pain specialist has completed this form to help confirm the patient's MRI scan eligibility. Visit medtronic.com/mri to access Medtronic manuals.

Contact information

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Eligibility information (Pain Specialist completes)

Patient name:	Date/time eligibility determined
Physician name:	
Physician phone number:	Neurostimulator model #
Clinic name:	
Clinic address:	Neurostimulator serial #
Today's date:	

EMBSNV20 Adaptor⁺ Yes No

Before your MRI

You may be eligible for an MRI scan* anywhere on your body or on just your head. This will depend on the type of neurostimulation system you have.⁺

- 1. 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.
- **3.** Your pain specialist may 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 MRI scan.
- 4. Schedule your MRI appointment. When your MRI appointment is scheduled, provide them with the model number of your neurostimulator 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 (if provided).
 - 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 800-510-6735.

Day of your MRI

- Bring your smart programmer, communicator, and charging cable to your appointment. You will need them to enter your device into MRI mode.
- Bring your Medtronic ID cards. Present your cards to the MRI clinician.

WARNING: Always inform the MRI clinician, before you enter the MRI scanner (magnet) room, that you have an implanted neurostimulation system. If you don't alert them, you risk getting an inappropriate MRI scan, which could cause you injury or cause damage to your implanted medical device. MRI clinicians need to be aware of all medical implants to determine the conditions for safely performing your MRI scan.

- * 📥 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.

5.

Using your programmer 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:

To activate MRI mode:

- **1.** Tap on the **Menu** icon (\equiv) on the Home screen.
- 2. Tap on MRI Mode (💬). The Enter MRI Mode screen appears.
- 3. Tap on Continue. When MRI mode is activated, your implanted neurostimulation system has been placed in MRI mode and stimulation is turned off. In addition, the In MRI Mode screen will appear and display your MRI scan eligibility.

Icon combination Explanation

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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.

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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.

MR unsafe

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

Share the MRI mode screen with MRI clinician

- 1. Provide your smart programmer to the MRI clinician.
- 2. MRI clinician can tap on 1 information icon.
- 3. MRI clinician can review details and tap Back to return to In MRI Mode screen.



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.

- 1. Tap the Exit MRI Mode button on the screen.
- 2. You will be presented with two choices:
 - To keep therapy off, select the box next to Keep Therapy Off.
 - To turn therapy on, select the box next to Turn Therapy ON for all programs in Group A.

Note: your group letter may be different.

3. Tap Continue. You will now be back on the Home screen.



SPINAL CORD STIMULATION BRIEF SUMMARY

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 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 inplant 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 precautions and potential adverse events. Rx only. Rev 0422

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