

BRING THE FOLLOWING ITEMS TO YOUR MRI APPOINTMENT:

- Abbott Patient ID Card
- Patient Controller
- Patient Eligibility Form (recommended, but not required)

CE marking does not necessarily indicate regulatory approval status for all markets. Please refer to the instructions for use for a full listing of indications, contraindications, warnings and precautions

Abbott

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St. Jude Medical is now Abbott.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain. **Contraindications:** Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation. **Warnings/Precautions:** Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted. **Adverse Effects:** Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). User's Guide must be reviewed for detailed disclosure.

™ Indicates a trademark of the Abbott group of companies.

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Item approved for global use./A4.



BEFORE AND AFTER YOUR

MRI SCAN

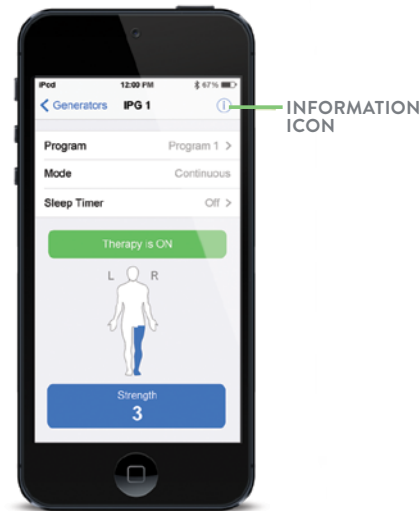
For Patients with the Proclaim™ Elite Recharge-Free SCS System for Chronic Pain



PREPARING FOR YOUR MRI

Help your clinician and radiologist determine your eligibility by following these guidelines:

- Tell the doctor who prescribed your MRI scan that you have an implanted Proclaim Elite™ recharge-free spinal cord stimulation (SCS) system.
- Contact your pain specialist to discuss whether you can safely undergo the type of MRI scan prescribed. Your pain specialist may provide you or your radiologist with a copy of the **Patient Eligibility Form**.
- Schedule your MRI appointment. When scheduling:
 - Provide the model numbers and locations of your implanted neurostimulation system parts and your pain specialist's contact information. This information is located on your Abbott ID card and on the **Patient Eligibility Form**.
 - Inform the radiologist of all implanted medical devices (including abandoned devices).
- Fully charge your patient controller before your procedure. For charging instructions, refer to your user guide.



ST. JUDE MEDICAL™ PATIENT CONTROLLER

PLACING YOUR PROCLAIM™ ELITE SCS SYSTEM IN MRI MODE

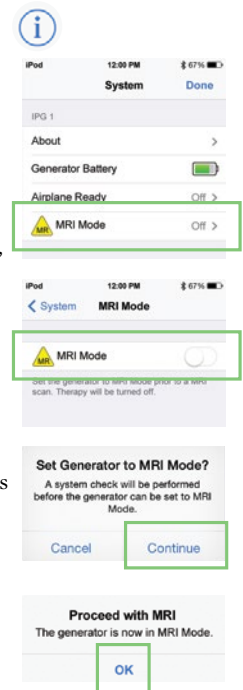
Place your implanted neurostimulator in MRI mode up to 24 hours before your MRI scan. Activating MRI mode turns off your stimulation.

MRI mode should be activated before you enter the room where your MRI will be performed. Otherwise the potential for uncomfortable, unintended stimulation or damage to the neurostimulator is increased. Refer to your user guide for additional detail.

Caution: Do not bring your controller into the room where your MRI will be performed. Your neurostimulator may be MR Conditional, but your controller is not. Exposing it to the MRI magnet can present a projectile hazard.

To activate MRI mode

- 1 From the Therapy screen, tap the **information icon**:
- 2 From the System screen, tap **MRI Mode**.
- 3 From the MRI Mode screen, tap the **MRI Mode switch**.
- 4 When the “Set Generator to MRI Mode?” message appears, tap **Continue**. Stimulation stops, and the patient controller app checks the system for any issues.
- 5 If the checks are successful, the “Proceed with MRI” message appears and MRI mode is turned on. Tap **OK**.



To disable MRI mode

- 1 Launch the patient controller app and connect with your generator. The “Generator is in MRI Mode” message appears.
- 2 Tap **Exit MRI Mode** to disable MRI mode.
- 3 The Therapy screen appears, showing that stimulation therapy is off.
- 4 Tap **Therapy is OFF** to start stimulation.

