BRING THE FOLLOWING **ITEMS TO YOUR MRI APPOINTMENT:**

• Abbott Patient ID Card

- Patient Controller

Abbott

One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000 Neuromodulation.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.

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BEFORE AND AFTER YOUR MRI SCAN

For Patients with the Proclaim[™] XR **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[™] XR 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.

PLACING YOUR PROCLAIM[™] XR 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 details.

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

Before completing the steps below, ensure that your patient controller app has the latest software version, vA3.8.

(i)

Program

Mode

Airplane Ready

Surgery Mode

MRI Mode

MRI Mode

Therapy will be turned of

Cance

< Mode

Set the generator Surgery Mode to ON prior to any surgical procedure

MRI Mode

Set Generator to MRI Mode? A system check will be performed before the generator can be set to MRI Mode.

Continue

tor MRI Mode to ON prior to an

Cenerators Proclain

Continuous

Done

Off

Off

Off)

To check the software version, click the **information icon**.

If you require a software upgrade, contact your Abbott representative before your scan.

2 From the Therapy screen, tap **Mode** to display the Mode screen.

3 Tap **MRI Mode** to view the MRI Mode screen.

- 4 From the MRI Mode screen, tap the **MRI Mode switch**.
 - When the "Set Generator to MRI Mode?" message appears, tap **Continue**. Stimulation stops, and the patient controller app checks the system for any issues.

. • /	If the checks are successful	
	the "Proceed with MRI"	Proceed with M The generator is now in f
	message appears and MRI	OK
	mode is turned on. Tap OK .	OK
Го	disable MRI mode	
1	Launch the patient	iPod 🕈 14:08
	controller app and connect	Cenerators Proclaim
	with your generator. The	<u> </u>
	"Generator is in MRI Mode"	Generator Is in MR
	message appears.	Therapy is OFF
		Surgery Is Not Recomm
	Tap Exit MRI Mode to	Exit MRI Mode and then s
	disable MRI mode.	generator Surgery Mode to to a surgical procedu
		Evit MRI Mode
	The Therapy screen	
	appears, showing that	
	stimulation therapy is off.	Therapy is OFF
		LUR
	Tap Therapy is OFF	2()
	to start stimulation	
	to start stimulation.	
	to start stimulation.	Strength
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