

# PREPARING FOR YOUR PROCEDURE OR MRI SCAN

## If you are going to undergo a surgical procedure or have an MRI scan, follow these steps:

1. Tell the physician who prescribed your MRI scan or is performing your surgery that you have an implanted Proclaim™ neurostimulation system.
2. Contact your pain specialist to:
  - Determine whether you can safely undergo the type of MRI scan prescribed (if applicable).
  - Discuss your upcoming procedure or scan and the possible effects it may have on your implanted device.
3. Schedule your procedure or scan. 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 Patient ID Card.
  - For MRI scans, inform the radiologist of all implanted medical devices (including abandoned devices).
4. Fully charge your patient controller before the procedure.

## BRING THE FOLLOWING ITEMS TO YOUR MRI APPOINTMENT:

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

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St. Jude Medical is now Abbott.

**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.

**Spinal Cord Stimulation 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.

**Dorsal Root Ganglion Stimulation Indications for Use:** This neurostimulation system is indicated for spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable\* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.\*\*

\*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

\*\*Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively.

**Contraindications:** US: Patients who are unable to operate the system, who are poor surgical risks, or who have failed to receive effective pain relief during trial stimulation. **CE MARK and Australia:** Patients who have an active implantable medical device including but not limited to cardiac pacemakers and cardiac defibrillators, are unable to operate the system, and are poor surgical risks. **Warnings/Precautions:** Diathermy therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrosurgery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, pediatric use, pregnancy, and case damage. **Adverse Effects:** Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). Implant Manual must be reviewed for detailed disclosure. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

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## UNDERSTANDING IMPORTANT FEATURES ON YOUR

# ST. JUDE MEDICAL™ PATIENT CONTROLLER

Things to Know before and after an MRI or Surgical Procedure When You Have an Abbott Proclaim™ Neurostimulation System for Chronic Pain



# INTRODUCTION TO SURGERY MODE AND MRI MODE

Implantable neurostimulation systems are active electronic devices designed to help manage your condition. These devices can be receptive to external factors sometimes seen during surgical procedures or MRI scans.

To help reduce the possibility of negative device interaction during these procedures,\* your system has two different features that can be activated:

- Surgery Mode — for use during surgical procedures
- MRI Mode — for use during MRI scans

These modes can be activated directly from your Patient Controller.

## USING THIS GUIDE

This guide is intended to help you activate and deactivate these modes. If you feel uncomfortable completing the steps, contact your Abbott representative before your procedure or scan. Contact your physician before your procedure to learn about any risks. This guide should be used in addition to the Instructions for Use for your device.

\*These features do not completely eliminate the possibility of the neurostimulator being affected during surgery or MRI scans.



INFORMATION ICON

# PLACING YOUR SYSTEM INTO SURGERY MODE

Place your device into Surgery Mode before your procedure. Activating Surgery Mode turns off your stimulation.

## To turn on Surgery Mode

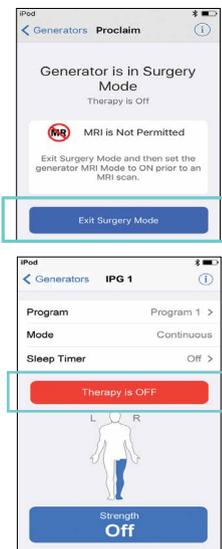
- 1 From the Therapy screen, tap the **information icon**. Make sure your application version is higher than version 3.3
- 2 From the Therapy screen, tap **Mode** to display to the Mode screen.
- 3 Tap **Surgery Mode** to view the Surgery Mode screen.



- 4 Tap the **Surgery Mode** toggle button.

## To turn off Surgery Mode

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

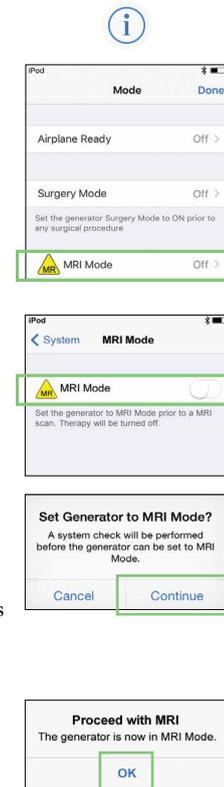


# PLACING YOUR SYSTEM INTO MRI MODE

Place your device into MRI Mode up to 24 hours before your MRI scan. Activating MRI Mode turns off your stimulation.

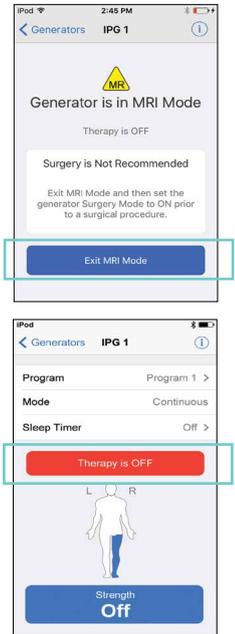
## To turn on MRI Mode

- 1 From the Therapy screen, tap **Mode** to display to the Mode screen.
- 2 Tap **MRI Mode** to view the MRI Mode screen.
- 3 Tap the **MRI Mode** toggle button.
- 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 turn off 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 turn off MRI Mode.
- 3 The Therapy screen appears, showing that stimulation therapy is off.
- 4 Tap **Therapy is OFF** to start stimulation.



## IMPORTANT ITEMS TO REMEMBER

Surgery Mode or MRI Mode should be turned on before you enter the room where your procedure or MRI scan will be performed. Otherwise, the potential for uncomfortable, unintended stimulation or damage to the neurostimulator is increased. Refer to your user guide for more information.

### FOR SURGERY MODE

Turning off Surgery Mode before the completion of your procedure may cause unintended effects like unintended stimulation or damage to your neurostimulation system. Refer to your user guide for more information.

### FOR MRI MODE

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.