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 St. Jude Medical™ Proclaim™ neurostimulation system.
2. Contact your pain specialist to:
   - Determine whether you can safely undergo the type of MRI scan prescribed (if applicable)
   - Discourage 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 St. Jude Medical 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.

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.

Spinal Cord Stimulation Indications for Use: Spinal cord stimulation is 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 that stimulation. Warnings/Precautions: Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, therapeutic radiation, operation of machinery and equipment, postural changes, or any 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). Your Guide must be reviewed for detailed disclosure.

Dural 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 adults 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 treatment from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.**

**Please note that in 2019, 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 that 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, MRI, therapeutic radiation, explosive or flammable gases, therapeutic radiation, operation of machinery and equipment, postural changes, or any 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). Your Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions, and potential adverse events.

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 St. Jude Medical™ 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 St. Jude Medical 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.
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 St. Jude Medical™ 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 St. Jude Medical 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.

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.

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 their stimulation. Warnings/Precautions: Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, thor exterior 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 allergies, 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.

Dural Root Ganglion Stimulation Indications for Use: This neurostimulation system is indicated for spinal column stimulation via epidural and intraspinal lead access to the dorsal root ganglia as an aid in the management of intractable sciatic nerve pain in adults 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 pharmacological treatments from at least 2 different drug classes and continued their pharmacological 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), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, thor exterior 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). User’s Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

USB: 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), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, thor exterior 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). User’s Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

SPINAL CORD STIMULATION

Spinal Cord Stimulation Indications for Use: This neurostimulation system is indicated for spinal column stimulation via epidural and intraspinal lead access to the dorsal root ganglia as an aid in the management of intractable sciatic nerve pain in adults 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 pharmacological treatments from at least 2 different drug classes and continued their pharmacological 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), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, thor exterior 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). User’s Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

USB: 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), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, thor exterior 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). User’s Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

ST. JUDE MEDICAL PATIENT CONTROLLER THINGS TO KNOW BEFORE AND AFTER AN MRI OR SURGICAL PROCEDURE WHEN YOU HAVE A ST. JUDE MEDICAL™ PROCLAIM™ NEUROSTIMULATION SYSTEM FOR CHRONIC PAIN

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 St. Jude Medical™ 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 St. Jude Medical 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.

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.

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 their stimulation. Warnings/Precautions: Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, thor exterior 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 allergies, 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.

Dural Root Ganglion Stimulation Indications for Use: This neurostimulation system is indicated for spinal column stimulation via epidural and intraspinal lead access to the dorsal root ganglia as an aid in the management of intractable sciatic nerve pain in adults 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 pharmacological treatments from at least 2 different drug classes and continued their pharmacological 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), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, thor exterior 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). User’s Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

USB: 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), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, thor exterior 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). User’s Guide must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

POWEROVERYOURPAIN.COM

For more information, please visit PowerOverYourPain.com.
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 St. Jude Medical™ 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 St. Jude Medical Patient ID Card.
   - For MRI scans, inform the radiologist of all your St. Jude Medical Patient ID Card.

4. Fully charge your patient controller before the procedure.

**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.

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

**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. *Adverse Effects: Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis).** Implanted Manual must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.
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 St. Jude Medical 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.

### 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.
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 St. Jude Medical 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.

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 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 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.
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 St. Jude Medical 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.

*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.

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 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.
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 St. Jude Medical 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.

To turn on MRI Mode

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

Tap MRI Mode to view the MRI Mode screen.

Tap the MRI Mode toggle button.

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” message appears and MRI Mode is turned on. Tap OK.

To turn off MRI Mode

Launch the patient controller app and connect with your generator. The “Generator is in MRI Mode” message appears.

Tap Exit MRI Mode to turn off MRI Mode.

The Therapy screen appears, showing that stimulation therapy is off.

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.
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 St. Jude Medical™ 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 St. Jude Medical 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.

**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.

**Precautions:** Do not use these devices on or near pregnant patients or patients with implanted cardiac devices unless authorized by the manufacturer.

**Spinal Cord Stimulation Indications for Use:** Spinal cord stimulation is indicated 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 hyperalgesia of the lower legs, and intractable facial pain. Contraindications: Patients who are unable to tolerate the system or who have failed to receive effective pain relief during trial stimulation. Warnings/Precautions: Quality therapy, implanted cardiac systems, magnetic resonance imaging (MRI), and other electronic devices, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and nerve damage. Patients who are poor surgical risks with multiple diseases or who have active infections should not be implanted.

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

*Studies subjects from the ACCLAIM 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.

**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 carotid stent devices, unable to operate the system, and are poor surgical risks. Warnings/Precautions: Quality therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, 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). Implanted Manual must be reviewed for detailed disclosure.

**ICD Only**

**MRI Only**

**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 hyperalgesia of the lower legs, and intractable facial pain. Contraindications: Patients who are unable to tolerate the system or who have failed to receive effective pain relief during trial stimulation. Warnings/Precautions: Quality therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and nerve damage. Patients who are poor surgical risks with multiple diseases or who have active 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.

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

*Studies subjects from the ACCLAIM 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.

**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 carotid stent devices, unable to operate the system, and are poor surgical risks. Warnings/Precautions: Quality therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrocautery devices, ultrasonic scanning equipment, therapeutic radiation, explosive or flammable gases, 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). Implanted Manual must be reviewed for detailed disclosure. Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.