Proclaim™ DRG Implantable Pulse Generator

Model 3664

Clinician's Manual

St. Jude Medical

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This neurostimulation system is designed to deliver low-intensity electrical impulses to nerve structures. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use

This neurostimulation system is indicated for the management of chronic, intractable pain.

Contraindications

This system is contraindicated for patients who are

- Unable to operate the system
- Poor surgical risks
- Pregnant
- Under the age of 18

MRI Safety Information

Some models of this system are Magnetic Resonance (MR) Conditional, and patients with these devices may be scanned safely with magnetic resonance imaging (MRI) when the conditions for safe scanning are met. For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at **manuals.sjm.com**). For more information about MR Conditional products, visit the St. Jude Medical product information page at sjmprofessional.com/MRI.

Warnings

The following warnings apply to this neurostimulation system.

Pregnancy and nursing. Safe and effectiveness of neurostimulation for use during pregnancy and nursing have not been established.

Pediatric use. Use of neurostimulation has not been approved specifically for patients under 18 years of age.

External defibrillators. Safety for use of external defibrillator discharges on a patient receiving neurostimulation has not been established.

Magnetic resonance imaging (MRI). Some patients may be implanted with the components that make up a Magnetic Resonance (MR) Conditional system, which allows them to receive an MRI scan if all the requirements for the implanted components and for scanning are met. A physician can help determine if a patient is eligible to receive an MRI scan by following the requirements provided by St. Jude Medical. Physicians should also discuss any risks of MRI with patients.

Patients without an MR Conditional neurostimulation system should not be subjected to MRI because the electromagnetic field generated by an MRI may damage the device electronics, cause heating at the lead tip that could result in tissue damage, and induce voltage through the lead that could jolt or shock the patient.

Computerized tomography (CT). If the patient requires a CT scan, all stimulation should be turned off before the procedure. If stimulation is not turned off, the patient may experience a momentary increase in stimulation, which may be uncomfortable. After the procedure, stimulation should be turned back on and the system should be checked for proper function.

Diathermy therapy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy is further prohibited because it may also damage the neurostimulation system components. This damage could result in loss of therapy, requiring additional surgery for system implantation and replacement. Injury or damage can occur during diathermy treatment whether the neurostimulation system is turned on or off. Advise patients to inform their healthcare professional that they should not be exposed to diathermy treatment.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation system. Contact between an active IPG, lead, or extension and the electrosurgical pencil can cause direct stimulation of the contacted nerve and severe injury to the patient. Electrosurgery devices may also damage the IPG, lead, or extension and cause a loss of stimulation.

Implanted cardiac systems. Physicians need to be aware of the risk and possible interaction between a neurostimulation system and an implanted cardiac system, such as a pacemaker or defibrillator. Electrical pulses from a neurostimulation system may interact with the sensing operation of an implanted cardiac system, causing the cardiac system to respond inappropriately. To minimize or prevent the implanted cardiac system from sensing the output of the neurostimulation system, (1) maximize the distance between the implanted systems; (2) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system; and (3) avoid programming either device in a unipolar mode (using the device's can as an anode) or using neurostimulation system settings that interfere with the function of the implantable cardiac system.

Emergency procedures. Instruct patients to designate a representative (family member or close friend) to notify any emergency medical personnel of their implanted neurostimulation system if emergency care is required. Patients will receive an identification card to carry with them that will inform emergency medical personnel of their implanted system. Advise patients to use caution when undergoing any procedure that could include radiofrequency (RF) or microwave ablation, defibrillation, or cardioversion.

Routine medical procedures. Advise patients to avoid dental procedures, diathermy, electrolysis, diagnostic ultrasound, static field therapeutic magnets, diagnostic X rays, and high-output ultrasonic lithotripsy. These procedures may cause interference that can affect the operation of the neurostimulator or damage components of the system, causing patient harm. If patients with a neurostimulator receive any medical treatment in which an electrical current is passed through their body from an external source, either the device should first be deactivated or care should be taken to monitor the functioning of the neurostimulator during the initial stages of treatment.

Ultrasonic scanning equipment. The use of ultrasonic scanning equipment may cause mechanical damage to an implanted neurostimulation system if used directly over the implanted system.

Therapeutic radiation. Therapeutic radiation may damage the electronic circuitry of an implanted neurostimulation system, although no testing has been done and no definite

information on radiation effects is available. Sources of therapeutic radiation include therapeutic X rays, cobalt machines, and linear accelerators. If radiation therapy is required, the area over the implanted IPG should be shielded with lead. Damage to the system may not be immediately detectable.

Restricted areas. Warn patients to seek medical guidance before entering environments that could adversely affect the operation of the implanted device, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.

Component manipulation by patients. The patient must be instructed to not rub or exert pressure on implanted components through the skin as this may cause lead dislodgement leading to stimulation at the implant site, IPG inversion leading to the inability to communicate with the device, or skin erosion that can lead to another surgical procedure or possible infection.

Lead movement. Patients should be instructed to avoid bending, twisting, and stretching; entering hyperbaric chambers above 1.5 atmospheres; operating the neurostimulator while driving; or lifting objects over 2 kg (5 lb) for at least six weeks after implantation. These activities may cause lead movement, resulting in understimulation or overstimulation for the patient. Excessive lead migration may require reoperation to replace the leads.

Operation of machines, equipment, and vehicles. In the clinical experience with this device, patients have experienced few effects when moving from lying down to sitting up. Therefore, it is unlikely patients will need to adjust stimulation when changing positions or moving. However, advise patients who feel uncomfortable paresthesia during postural changes that they should not operate potentially dangerous equipment such as power tools, automobiles, or other motor vehicles. These patients should not climb ladders or participate in activities where postural changes or abrupt movements could alter the perception of stimulation intensity and cause patients to fall or lose control of equipment or vehicles or injure others.

Explosive and flammable gases. Do not use a clinician programmer or patient controller in an environment where explosive or flammable gas fumes or vapors are present. The operation of these devices could cause them to ignite, causing severe burns, injury, or death.

Device components. The use of components not approved for use by St. Jude Medical with this system may result in damage to the system and increased risk to the patient.

Application modificiation. To prevent unintended stimulation, do not modify the operating system in any way. Do not use the application if the operating system is compromised (i.e., jailbroken).

Case damage. Do not handle the IPG if the case is pierced or ruptured because severe burns could result from exposure to battery chemicals.

IPG disposal. Return all explanted IPGs to St. Jude Medical for safe disposal. IPGs contain batteries as well as other potentially hazardous materials. Do not crush, puncture, or burn the IPG because explosion or fire may result.

Product materials. Neurostimulation systems have materials that come in contact or may come in contact with tissue. A physician should determine whether or not a patient may have an allergic reaction to these materials before the system is implanted.

Precautions

The following precautions apply to this neurostimulation system.

General Precautions

Clinician training. Implanting physicians should be experienced in the diagnosis and treatment of chronic pain syndromes and have undergone surgical and device implantation training.

Patient selection. It is extremely important to select patients appropriately for neurostimulation. Thorough psychiatric screening should be performed. Patients should not be dependent on drugs and should be able to operate the neurostimulation system.

Infection. Follow proper infection control procedures. Infections related to system implantation might require that the device be explanted.

Implantation of multiple leads. If multiple leads or extensions are implanted, the leads and extensions should be routed in close proximity. Nonadjacent leads and extensions have the possibility of creating a conduit for stray electromagnetic energy that could cause the patient unwanted stimulation.

High stimulation outputs. Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the patient controller. If unpleasant sensations occur, the device should be turned off immediately.

Postural changes. In the clinical experience with this device, patients have experienced few effects when moving from lying down to sitting up. Therefore, it is unlikely patients will need to adjust stimulation when changing positions or moving. However, some patients may experience a decrease or increase in the perceived level of stimulation. Perception of higher levels of stimulation has been described by some patients as uncomfortable, painful, or jolting. Advise patients who experience these types of stimulation changes to turn down the amplitude or turn off the IPG before making extreme posture changes or abrupt movements such as stretching, lifting their arms over their heads, or exercising. If unpleasant sensations occur, the IPG should be turned off immediately.

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or “use-before” date) is printed on the packaging. Do not use the system if the use-before date has expired.

Care and handling of components. Use extreme care when handling system components prior to implantation. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Before opening any sterile package, verify the kit model number, that the kit is within its expiration (use-before) date, and that the packaging has not been damaged or compromised in any way. If the packaging has been compromised, the device is beyond its expiration date, or the sterile package or device show signs of damage, do not use the device as it may be compromised and could cause harm to the patient. Return any suspect components to St. Jude Medical for evaluation.

Exposure to body fluids or saline. Prior to connection, exposure of the metal contacts, such as those on the connection end of a lead or extension, to body fluids or saline can lead to corrosion. If such exposure occurs, clean the affected parts with sterile, deionized water or sterile water for irrigation, and dry them completely prior to lead connection and implantation.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Device modification. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to St. Jude Medical for service.

Component disposal. Return all explanted components to St. Jude Medical for safe disposal.

Hospital and Medical Environments

High-output ultrasonics and lithotripsy. The use of high-output devices, such as an electrohydraulic lithotriptor, may cause damage to the electronic circuitry of an implanted IPG. If lithotripsy must be used, do not focus the energy near the IPG.

Home and Occupational Environments

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy), and some medical devices (such as bone growth stimulators, transcutaneous electrical nerve stimulation [TENS] devices, dental drills, and ultrasonic probes).

Wireless use restrictions. In some environments, the use of wireless functions (e.g., Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, in hospitals, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on. (Bluetooth® is a registered trademark of Bluetooth SIG, Inc.)

Security, antitheft, and radiofrequency identification (RFID) devices. Some antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect stimulation. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect stimulation. Patients who are implanted with nonadjacent multiple leads and patients who are sensitive to low stimulation thresholds may experience a momentary increase in their perceived stimulation, which some patients have described as uncomfortable or jolting. Patients should cautiously approach such devices and should request help to bypass them. If they must go through a gate or doorway containing this type of device, patients should turn off their IPG and proceed with caution, being sure to move through the device quickly.

Mobile phones. The effect of mobile phones on neurostimulation system is unknown; patients should avoid placing mobile phone directly over the system.

Adverse Effects

In addition to those risks commonly associated with surgery, the following risks are associated with implanting or using this neurostimulation system:

- Unpleasant sensations or motor disturbances, including involuntary movement, cause by stimulation at high outputs (if either occurs, turn off your IPG immediately.)
- Undesirable changes in stimulation, which may be related to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections, or lead failure
- Pain where the needle has been inserted and below the level of implant,
- Persistent pain at the electrode site or over the implantable neurostimulator site

- Escalating pain
- Bleeding where the needle has been inserted
- Headache
- Infection
- Localized collection of serous (clear) fluid at the injection site
- Discomfort during the treatment
- Allergic or rejection response to implant materials
- Contact pain at the lead site
- Stimulation in unwanted places (such as stimulation of the chest wall)
- Lead migration (movement) causing changes in stimulation or pain from understimulation
- Implant migration (movement), local skin breakage, or both
- Weakness, clumsiness, or numbness
- Cerebrospinal fluid (CSF) leakage
- Tissue damage or nerve damage
- Spinal cord compression or paralysis
- Epidural hemorrhage or hematoma
- Swelling
- Seroma at the IPG site
- Sensory loss
- Skin erosion around implanted components
- Battery failure, leakage, or both
- Lead breakage that requires replacement of the lead
- Hardware malfunction that requires replacement of the neurostimulator
- Pain from a noninjurious stimulus to the skin (allodynia)
- Exaggerated sense of pain (hyperesthesia)

Additional risks to the patients, as a result of the placement and stimulation of the lead in the area of the DRG, include potential tissue damage or pain due to setting the stimulation parameters too high. This may occur once the lead is in place and is connected to the neurostimulator and activated. The neurostimulator is controlled by a trained operator and the starting point for the stimulation will be set to the lowest available settings. Additionally, all patients will be awake and conversant during the procedure to minimize the likelihood of any nerve damage.

System Overview

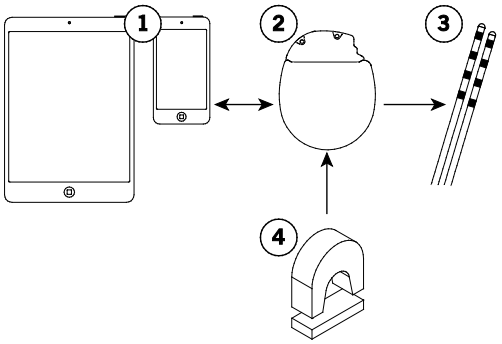
This neurostimulation system is designed to deliver electrical stimulation to nerve structures. The neurostimulation system includes the following main components:

- Implantable pulse generator (IPG)
- Leads
- Clinician programmer
- Patient controller
- Patient magnet

The IPG delivers electrical pulses through the leads to electrodes near selected nerve fibers in order to provide therapeutic stimulation. The patient magnet can turn the IPG on and off if the physician enabled this functionality. Physicians use the clinician programmer to create and modify programs for a patient. Patients use the patient controller to control their prescribed programs.

The following image shows how the major system components are intended to interact.

Figure 1. Interaction among main system components



1. Clinician programmer or patient controller
2. IPG
3. Leads
4. Patient magnet

NOTE: This manual provides instructions for implanting the IPG. For instructions for using other components, see the applicable manuals for those components.

Product Description

This implantable pulse generator (IPG) is an electronic device designed to be connected to one or more leads or extensions with up to 16 electrodes total. It is powered by a hermetically sealed battery within a titanium case and uses microelectronic circuitry to generate constant-current electrical stimulation. The IPG can deliver stimulation with a single program or with multiple programs. Each program can provide stimulation to a single anatomical area or to multiple areas. The IPG communicates wirelessly with system programmers and controllers. The IPG can receive software upgrades after implantation to provide patients with additional features as approved by the respective regulatory agencies. To upgrade features on the IPG, a system programmer is needed.

For more information about IPG features and specifications, see the appropriate appendix in this manual.

NOTE: In this document, the term "clinician programmer" refers to the St. Jude Medical™ Clinician Programmer device, "patient controller" refers to the St. Jude Medical Patient Controller device, "clinician programmer app" refers to the St. Jude Medical Clinician Programmer software application (app), and "patient controller app" refers to the St. Jude Medical Patient Controller app.

Package Contents

In addition to the product documentation, the IPG kit contains the following items:

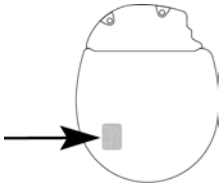
- 1 IPG (see the appendix in this manual for model numbers)
- 1 pocket sizer
- 1 torque wrench (Model 1101)
- 3 port plugs (Model 7108)

Identifying the IPG

Before implanting the IPG, you can view the model number engraved on the IPG. After implantation, you can identify the IPG using a radiopaque identification tag that you can view with standard X-ray procedures. The tag, which is located in the lower left corner of the IPG when the logo side of the IPG is facing toward you, contains a code in the following format: SJM*LN*. SJM designates St. Jude Medical as the manufacturer; *LN* is a letter and a number combination that identifies the model family (see the following figure).

For the Proclaim™ DRG IPG, the code is SJM A1. To determine the exact model IPG that is implanted, use the clinician programmer app to communicate with the IPG and view IPG information. See the clinician's manual for the clinician programmer for instructions.

Figure 2. Location of the IPG code on the IPG



Directions for Use

Read this section carefully for suggested directions for use related to the IPG. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

NOTE: Before the surgical procedure, set up communication between the clinician programmer and the IPG while the IPG is in its sterile packaging to ensure that it is functional. If the IPG has never established communication with a programmer, you must first activate the IPG for communication ("wake up" the IPG) by holding a magnet over the IPG for 8 seconds.

Creating an IPG Pocket

The following steps outline the suggested procedure to create an IPG pocket:

1. Determine the site for the IPG, ensuring that the lead is long enough to reach the pocket and provide a strain relief loop.

   NOTE: Common sites for IPG implantation are: along the midaxillary line, in the upper buttock along the posterior axillary line (taking care to avoid the belt line), and in the area over the abdomen just below the lowermost rib. To ensure a flat area is selected, you can mark a flat area prior to the surgical procedure while the patient is in a sitting position.

   CAUTION: Do not place the IPG deeper than 4.0 cm (1.57 in) because the clinician programmer may not communicate effectively with the IPG.

2. Create the pocket so that the IPG is parallel to the skin surface and no deeper than 4.0 cm (1.57 in) below the skin surface.

3. Insert and remove the pocket sizer to ensure that the pocket is large enough to accommodate the IPG, allowing enough extra room for a strain relief loop for each lead or extension.

Connecting a Lead or Extension to the IPG

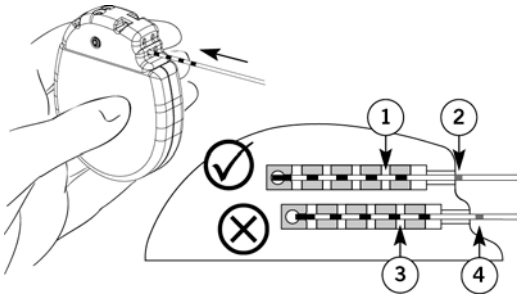
The following steps outline the suggested guidelines to connect a lead or extension to the IPG:

CAUTION: Do not connect a lead or extension with body fluid or saline residue on its contacts because corrosion can occur and cause failure of the system.

1. If any of the lead or extension contacts came in contact with body fluid or saline, thoroughly clean the contacts with sterile deionized water or sterile water for irrigation and dry them completely.

   CAUTION: Observe these cautions when performing the following step:
   - **Do not bend the lead sharply or it may be damaged.**
   - **Do not loosen the setscrew in the connector more than a quarter turn at a time while trying to insert the lead. Retracting the setscrew too far can cause the setscrew to come loose and make the connector assembly unusable.**
2. Using clean gloves, carefully slide the proximal end of the lead or extension into the IPG header until it stops. When the lead or extension is correctly inserted, the contact bands on the lead or extension are fully inside the connector assembly and the windows between each of the header contacts are clear. Additionally, the indicator band on the lead or extension aligns with the opening of the header port (see the following figure).

Figure 3. Insert the lead or extension fully into the IPG header



Fully inserted

1. Window between each header contact is clear
2. Indicator band aligns with opening of header port

Not fully inserted

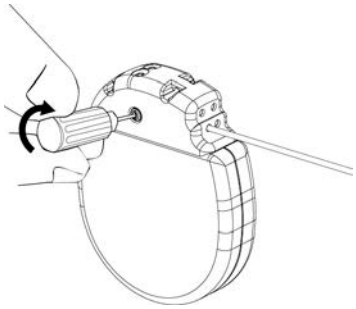
3. Window between each header contact is partially blocked by contact band
4. Indicator band is not aligned with opening of header port

CAUTION: Use only the torque wrench that is compatible with the IPG or the device may be damaged and rendered unusable.

NOTE: The numbers and locations of each of the header ports are printed on the front of the IPG. The septa for port 1 (electrodes 1 to 4) and port 2 (electrodes 5 to 8) are located on the sides of the IPG header. The septa for port 3 (electrodes 9 to 12) and port 4 (13 to 16) are located on the top.

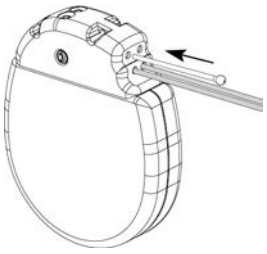
3. Insert the torque wrench through the septum on the IPG header and tighten the setscrew, turning it clockwise until the wrench clicks.

Figure 4. Tighten the setscrew clockwise



4. If implanting multiple leads, repeat the previous steps for each lead. If implanting fewer than the maximum number of leads, insert port plugs into any unused header ports, and use the torque wrench to tighten the setscrews until the wrench clicks.

Figure 5. Insert the port plug



Implanting the IPG

The following steps outline the suggested procedure to implant the IPG:

1. Place the IPG into the IPG pocket with the logo side facing the skin surface and at a depth not to exceed 4.0 cm (1.57 in).

   NOTE: By implanting the IPG with the logo side facing the skin surface, you enhance the IPG's ability to detect a magnet.

2. Carefully coil any excess lead or extension behind the IPG in loops no smaller than 2.5 cm (1 in) in diameter to provide strain relief for the lead or extension and IPG connection. **CAUTION: Do not bring the suture needle in contact with an IPG, lead, or extension, or the component may be damaged.**
3. To stabilize the IPG within the pocket, pass suture through the holes at the top of the IPG header and secure it to connective tissue.
4. Check the entire system by fluoroscopy before closing to ensure proper positioning of the lead or leads and that it is straight, with no sharp bends or kinks.

5. Use the clinician programmer app to communicate with the IPG and perform intraoperative testing to confirm that the system is operational. See the clinician's manual of the clinician programmer app for instructions.

   NOTE: IPG output may not be identical to that of the trial stimulator at the same settings.

6. Ensure that the IPG is away from the pocket incision suture line, close the pocket incision, and apply the appropriate dressings.

Replacing the IPG

The following steps outline the suggested procedure to replace an IPG:

1. Turn off stimulation or verify that it is turned off.
   CAUTION: Exercise care when using sharp instruments or electrocautery around leads or extensions, or they may be damaged.
2. Open the IPG implant site per normal surgical procedure.
3. Insert the torque wrench through the septum of the IPG header and loosen the setscrew by turning it counterclockwise.
   CAUTION: When performing the following step, do not bend the lead or extension sharply; or it may be damaged.
4. Gently remove the lead or extension from the IPG header; then clean and dry all connections, ensuring they are free of fluid and tissue.
5. To complete the IPG replacement procedure, see the following sections: “Connecting a Lead or Extension to the IPG” (page 9) and “Implanting the IPG” (page 10).

Disposing of Explanted Components

Explanted components should be returned to St. Jude Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your St. Jude Medical™ representative or Technical Support.

Checking the Status of the IPG Battery

The IPG contains a nonrechargeable battery. The amount of time that the battery will provide active stimulation depends on the patient’s stimulation settings and daily usage time. To check the status of the IPG battery, use the clinician programmer app or patient controller app. The clinician programmer app can also estimate how much time remains until the IPG battery can no longer support stimulation. For more information about these functions, refer to the clinician’s programming manual and the user’s guide for the patient controller app. For more information about the estimated longevity of the IPG battery, see the product specifications in the appropriate appendix in this manual.

NOTE: Measurements of the IPG battery’s remaining life are unavailable until 8 days after initial communication between the IPG and the clinician programmer app.

The following information provides general guidelines for the battery status:

- A battery status icon on the patient controller app shows a decreasing fill as the battery is used.
- A warning will appear on the clinician programmer app or patient controller app when the battery is almost depleted.
- Stimulation will automatically stop when the battery cannot support stimulation.

Technical Support

For technical questions and support for your St. Jude Medical™ neuromodulation product, use the following information:

- +1 972 309 8000
- +1 800 727 7846 (toll-free within North America)

For additional assistance, call your local St. Jude Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components according to the following conditions.

Table 1. Storage conditions for components

Temperature	-20°C–60°C (-4°F–140°F)

Product Materials

The following materials are intended to come into contact with tissue.

Table 2. Product materials for IPG kit

Component	Material
IPG	Titanium, silicone rubber, epoxy resin
Pocket sizer	Polybutylene terephthalate
Port plug	Polyether ether ketone, cobalt nickel chromium molybdenum alloy

IPG Specifications

The Proclaim™ DRG IPG has the following physical specifications.

Table 3. IPG specifications

Model	3664
Height	6.09 cm (2.40 in)
Length	4.95 cm (1.95 in)
Thickness	1.34 cm (0.53 in)
Weight	56.3 g (2.0 oz)
Volume	31.4 cm^3 (1.9 in^3)
Estimated battery longevity (nominal settings)*	4.5 years
Power source	Carbon monofluoride/silver vanadium oxide cell

Connector strength	Exceeds EN 45502-1 requirements
Program storage capacity	16 programs with 1 stim set per lead
Upgradeable features	Yes
MRI status	MR Conditional

* Battery longevity was estimated using the following nominal settings for a dual-lead system 24 hours per day: 20-Hz frequency, 300 µs pulse width, and 800-µA amplitude at 1600-ohms impedance. For information on how additional settings may impact the longevity of the device, please contact Technical Support.

The IPG has the following operating parameters.

Table 4. Operating parameters for the IPG

Parameter	Range	Steps
Pulse width	40–1000 µs	10 µs (40–500 µs range) 50 µs (500–1000 µs range)
Frequency	2–80 Hz	2 Hz
Amplitude	0–6.0 mA	0.025–0.4 mA

NOTE: The maximum current depends on the impedance, frequency, and pulse width settings.

Appendix B: System Components and Accessories

The Proclaim™ DRG neurostimulation system includes the following components.

NOTE: Not all models are available in all countries. Contact your local representative for more information.

IPGs

3664 Proclaim™ DRG IPG

IPG Accessories

1101 Torque wrench

7108 Port plug

Programmers and Controllers

3874 St. Jude Medical™ Clinician Programmer App

3875 St. Jude Medical™ Patient Controller App

Programmer and Controller Accessories

1210 Patient magnet

7884 DRG patient manual and magnet

Leads and Extensions

MN20450-series implant leads (standard and SlimTip™ leads)

MN20550-50	Lead extension kit, 50-cm

Lead and Extension Accessories

MN22050	Lead accessories kit
MN22150	Small curve delivery sheath kit, 22 cm
MN23650	Big curve delivery sheath kit, 22 cm
MN23850	Axium™ small curve delivery sheath, 22 cm
MN23950	Axium™ big curve delivery sheath, 22 cm
MN24000	14G curved delivery needle, 4.5 in
MN25000	Tunneling tool kit, 30 cm

Trial System

MN20100	Trial neurostimulator (TNS)

Trial System Accessories

MN20350-series trial leads (standard and SlimTip™ leads)

MN20700	Clinical programmer
MN20500-02	Patient programmer
MN21350	Connector cable kit

Appendix C: Regulatory Statements

This section contains regulatory statements about your product.

Disposal Guidelines for Battery-Powered Devices

This device contains a battery and a label is affixed to the device in accordance with European Council directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to St. Jude Medical at the end of its operating life.

Statement of FCC Compliance

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

Statement of Compliance With License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 5. Registration identification information

Identifier Type	Registration Identifier
FCC registration number	RIASJMRFC
Industry Canada (IC) registration number	IC: 8454A-M3660123

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth® Smart wireless technology as it is implemented in the device.

Table 6. Bluetooth Smart wireless technology information

Antenna type	Embedded patch antenna in header
Antenna dimensions	8.1 mm x 5.1 mm x 4.9 mm
Modulation	GFSK
Magnetic field strength (at 2 m distance)	16.3 µA/m
Electric field strength (at 2 m distance)	6.1 mV/m
Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
Range	1–2 m typical
Center frequency	2.44 GHz

Table 6. Bluetooth Smart wireless technology information

Channel	40 logical channels
Bandwidth	2 MHz per channel
Data flow	Bi-directional
Protocol	Bluetooth Smart wireless technology
*EIRP = Equivalent isotropically radiated power	

Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15dB): 2.398 to 2.4855 GHz
- Channel: 40 logical channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- Magnetic field strength (at 2 m distance): 16.3 µA/m
- Duty cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.

Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® Smart wireless technology enables communication between the generator and the clinician programmer or patient controller. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer or patient controller is paired with a generator, the Bluetooth wireless technology symbol is visible on the clinician programmer or patient controller in the upper right-hand corner of the screen. When the Bluetooth Smart wireless technology connection is not active, the symbol appears dimmed.

Other requirements include a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully. Each key press may transmit up to 8 data packets, depending on the number of packets that need to be transmitted (i.e., if there is only one packet to transmit, only one packet will be transmitted).

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The generator will encrypt its wireless communication.
- Only one patient controller may communicate with the generator at the same time.
- A unique key for each unit that is checked during each transmission.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth® Smart wireless technology, which includes an element of proximity.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to pair with the generator.

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the generator and the clinician programmer or patient controller, try the following:

- Decrease the distance between the devices
- Move the devices so they share line of sight
- Move the devices away from other devices that may be causing interference
- Wait a few minutes and try connecting again
- Do not operate other wireless devices (i.e., laptop, tablet, mobile phone, or cordless phone) at the same time

  NOTE: Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and tablets, can affect the device.

Appendix D: Symbols and Definitions

The following symbols may be used in this document and on some of the products and packaging:

Table 7. Symbols and definitions

Symbol	Definition
	Caution, consult accompanying documents
	Consult instructions for use
	Follow instructions for use on this website
	Device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device.
	Single use only
	Do not resterilize
	Expiration date
	Date of manufacture

	Manufacturing facility
	Temperature limits for storage conditions
	Do not use if the product sterilization barrier or its packaging is compromised
	Catalog number
	Manufacturer
	Contents quantity
	Pulse generator
	Accessories
	Serial number
	Batch code
	Prescription use only
	Ethylene oxide gas sterilization
	Authorized European representative
	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC and R&TTE directive 1999/5/EC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these directives.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Additional Symbols for Product Labels

The following table shows additional symbols that may appear on the product labels for parts related to this kit.

Table 8. Additional symbols for product labels

Symbol	Definition
Torque Wrench	Torque wrench
Port Plug	Port plug
Implantable Pulse Generator	Implantable pulse generator

Appendix E: CE Mark Date

The following table lists the year in which the CE mark was awarded from the applicable notified body by model number.

Table 9. Year in which CE mark was awarded

Model	Year	Notified Body
1101	1999	0123
3664, 7108	2016	0086

Manufacturer:
St. Jude Medical
6901 Preston Road
Plano, Texas 75024
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European Authorized Representative:
St. Jude Medical
Coordination Center BVBA
The Corporate Village
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1935 Zaventem
Belgium
+32 2 774 68 11

Australian Sponsor:
St. Jude Medical Australia Pty. Limited
17 Orion Road
Lane Cove NSW 2066
Australia

Manufacturing Site:
St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5
Santana Industrial Park
Arecibo, PR 00612
USA

Manufacturing Site:
St. Jude Medical Operations (M) Sdn. Bhd.
Plot 102, Lebuhraya Kampung Jawa,
Bayan Lepas Industrial Zone
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