Protege™

Implantable Pulse Generator

Clinician's Manual

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

For a listing of patents for St. Jude Medical neuromodulation products, visit http://patent.sjmneuro.com.

Clinician's Manual

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

This rechargeable 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 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

This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

⚠ Warnings

The following warnings apply to the use of this neurostimulation system.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

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.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted neurostimulation system. Contact between an active electrode and an implanted IPG, lead, or extension can cause severe injury to the patient. If use of electrocautery is necessary, first turn off the neurostimulation system.

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) verify that the neurostimulation system is not interfering with the functions of the implanted cardiac system and (2) avoid programming either device in a unipolar mode (using the device's can as an anode).

Magnetic resonance imaging (MRI). Patients with implanted neurostimulation systems should not be subjected to MRI. The electromagnetic field generated by an MRI may forcefully dislodge implanted components, damage the device electronics, and induce voltage through the lead that could jolt or shock the patient.

Device components. The use of non-St. Jude Medical components with this system may result in damage to the system and increased risk to the patient.

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 (see "Disposing of Explanted Components"). IPGs contain lithium ion 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 the use of this neurostimulation system.

General Precautions

Physician 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 two systems. If two systems are implanted, ensure that at least 20 cm (8 in) separates the implanted IPGs to minimize the possibility of interference during programming.

Implant heating. While recharging an IPG, patients may perceive an increase in temperature. In patients who have areas of increased sensitivity to heat, consider placing the implant where the patient has normal sensation.

Theft detectors and metal screening devices. Certain types of antitheft devices, such as those used at entrances or exits of department stores, libraries, and other public establishments, and airport security screening devices may 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 has been described by some patients as uncomfortable or jolting. Patients should use caution when approaching such a device and should request assistance to bypass the device. If they must proceed through the device, patients should turn off the IPG and proceed with caution, being sure to move through the detector quickly.

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

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 because of the risk of infection and device malfunction.

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. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to St. Jude Medical for evaluation.

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.

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.

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.

External defibrillators. The safety of discharge of an external defibrillator on patients with implanted neurostimulation systems has not been established.

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.

Home and Occupational Environments

Electromagnetic interference (EMI). Certain commercial electrical equipment (for example, arc welders, induction furnaces, and resistance welders), communication equipment (for example, microwave transmitters, linear power amplifiers, and high power amateur transmitters), and high voltage

power lines may generate sufficient EMI to interfere with the operation of the neurostimulation system if approached too closely.

Adverse Effects

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

- Unpleasant sensations or motor disturbances, including involuntary movement, caused by stimulation at high outputs (If either occurs, turn off your IPG immediately.)
- Stimulation in unwanted places
- Paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
- Persistent pain at the IPG site
- Seroma (mass or swelling) at the IPG site
- Allergic or rejection response to implant materials
- Implant migration or skin erosion around the implant

- Battery failure

Product Description

The Protege™ IPG is a rechargeable, electronic device designed to be connected to one or more extensions or leads 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 (called MultiStim™ programs). New features can be introduced to the Protege system via software updates allowing for upgraded technology to be used. A St. Jude Medical external programmer may be needed for certain types of software updates to this product.

NOTE: For more information about the neurostimulation system, see the clinician's programming and reference manual for this system.

Contents of Package

In addition to the product documentation, the Protege™ IPG kit (Model 3789) contains the following items:

- 1 IPG
- 1 pocket sizer
- 1 torque wrench (Model 1101)
- 2 port plugs (Model 1111)
- 1 tunneling tool (Model 1112)

Identifying the IPG

Using standard X-ray procedures, you can view the code that identifies the manufacturer and model number of the IPG in the header of the IPG. For the Protege™ IPG, the code is SJM Z*NN*, where Z designates Model 3789 and *NN* designates the last two digits of the year of manufacture. For example, SJM Z14 designates a Protege IPG (Model 3789) manufactured in 2014.

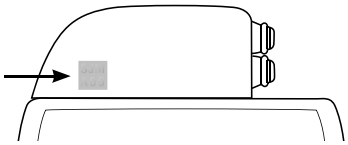


Figure 1: Location of IPG code

Directions for Use

Read this section for 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: Well in advance of the surgical procedure, authorize the programmer to the IPG while the IPG is in its sterile packaging to ensure that it is functional.

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: The IPG should be located in an area that the patient can easily reach with the programming wand. Common sites for 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 2.25 cm (0.9 in) because the patient programmer and charger may not communicate efficiently with the IPG and the charger may not charge efficiently.

2. Create the pocket so that the IPG is parallel to the skin surface and no deeper than 2.25 cm (0.9 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.

Tunneling to the Pocket

Tunneling is usually done from the lead anchor site directly to the IPG pocket. However, when an extension is used or the IPG pocket is in the abdominal region, tunneling is done from the lead anchor site to a midpoint (where an incision and appropriate dissection have been performed) and then continued to the IPG pocket site.

The following steps outline the suggested procedure to tunnel from the lead anchor site to the IPG pocket:

> ⚠ **CAUTION:** Use extreme care so as not to damage a lead with the sharp point of the tunneling tool.

NOTE: The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.

1. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the lead anchor site and the IPG pocket.

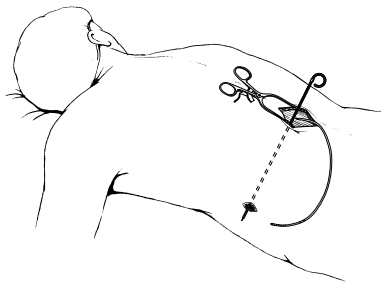
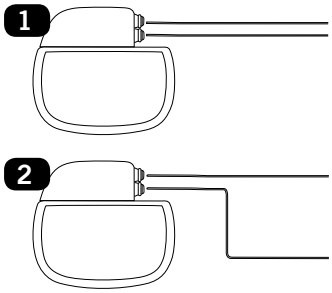


Figure 2: Suggested tunnel to the IPG pocket

2. Withdraw the tunneling tool from the cannula sleeve, leaving the cannula sleeve in the subcutaneous tunnel.

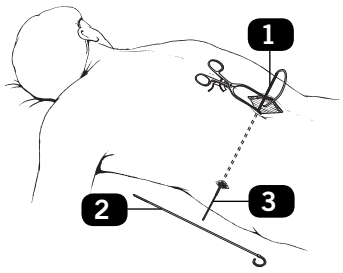
CAUTION: Multiple leads must be routed adjacent to one another. Patients with nonadjacent leads may experience changes in perceived stimulation from theft detectors and metal screening devices.

The correct way to route multiple leads is as follows:



Legend:
1. Correct
2. Incorrect

3. Carefully pass the end of the lead or leads through the cannula sleeve from the anchor site to the IPG pocket; or, if a two-step tunneling procedure is used, pass the lead or leads from the anchor site to the midway incision site and then to the IPG pocket. Multiple leads may be placed in the same tunnel.



Legend:
1. Leave cannula sleeve in place
2. Remove tunneling tool
3. Pull lead through cannula sleeve to IPG pocket

Figure 3: Sequence of tunneling steps for SCS

4. Withdraw the cannula sleeve from the subcutaneous tunnel by passing it over the lead or leads, taking care not to cause traction on them.

Connecting a Lead or Extension to the IPG

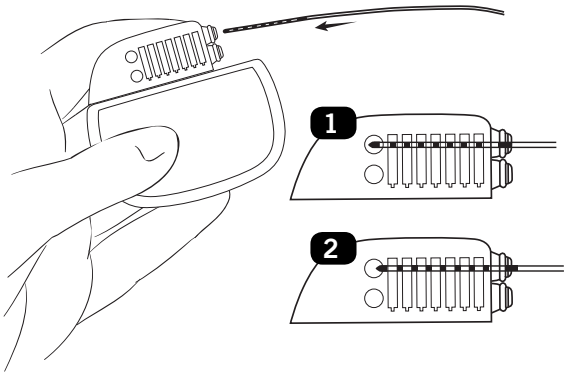
The following steps outline the suggested guidelines to connect a lead or extension to the IPG:

> ⚠ **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 lead or extension into the IPG header until all of the contact bands are fully inside the connector assembly and hidden from view.



Legend:
1. Fully inserted
2. Not fully inserted

Figure 4: Insert the lead fully into the IPG header

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

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

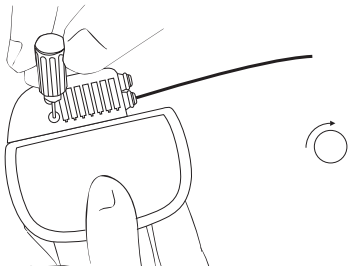


Figure 5: Tighten the setscrew clockwise

4. Remove the torque wrench and check the septum to ensure that it closed. If the septum did not close, gently reseat the septum flaps.

5. If implanting two leads, repeat the previous steps. If implanting a single lead only, insert the header port plug into the unused port, and use the torque wrench to tighten the setscrew until it clicks.

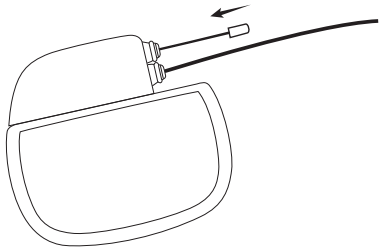


Figure 6: Insert the port plug

Implanting the IPG

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

> ⚠ **CAUTION:** Observe these cautions when performing the following step:
>
> - Do not implant the IPG face down. Implant it with the label facing toward the skin, or it may not communicate or recharge.
> - If using more than one IPG, implant them at least 20 cm (8 in) apart. Putting them too close together may interfere with the patient programmer's ability to communicate with each IPG separately.

1. Place the IPG into the IPG pocket, at a depth not to exceed 2.25 cm (0.9 in), with the label facing the skin surface.

Figure 7: Place the IPG in the pocket

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 a suture through the hole at the top of the IPG header and secure it to connective tissue.
4. Check the entire system by fluoroscopy prior to closing to ensure proper positioning of the lead or leads and that it is straight, with no sharp bends or kinks.
5. Connect the communication wand to the patient programmer, place the wand in a sterile bag, and position the wand over the IPG site.
6. Ensure that the patient programmer achieves effective communication with the IPG and that the system is operational.

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

CAUTION: Do not bring the suture needle in contact with an IPG, lead, or extension, or the component may be damaged.

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

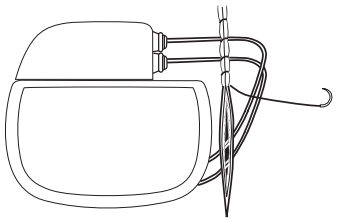


Figure 8: Close the pocket incision

Replacing the IPG

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

1. Turn off the IPG 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.

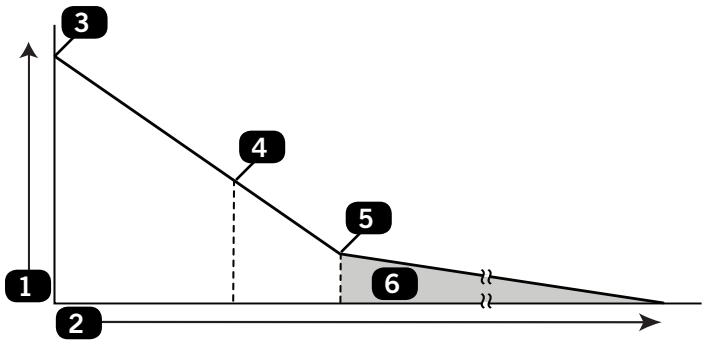
5. To complete the IPG replacement procedure, see the following sections: "Connecting a Lead or Extension to the IPG" and "Implanting the IPG."

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 Customer Service.

Maintaining the IPG Battery

The IPG contains a lithium ion battery. The time it takes to recharge a battery depends on these factors: age of the battery, daily usage time, stimulation settings, and length of time since the last recharge. The following graph shows how the rechargeable battery depletes over time.



Legend:
1. Battery capacity
2. Time
3. Battery fully charged
4. Recharge notice
5. Stimulation stops
6. Recharge within 30 to 90 days

Figure 9: IPG battery depletion over time

If the patient does not recharge the battery, stimulation will eventually stop, and the patient then must recharge the battery to prevent battery damage. A new battery can last up to 90 days before it must be recharged, while a ten-year-old battery should be recharged within 30 days. Frequent recharging can reduce charging session times and maximize the IPG's life.

When the IPG is used at high stimulation parameters for tonic programs, battery usage studies demonstrate that the battery should allow at least ten years of practical recharging. In other words, a ten-year-old device will maintain at least 24 hours of continuous therapy between recharges.

Depending on the patient's stimulation parameters, the device will continue to operate for months to years. Patients may experience a significantly longer device life before recharging is determined to be impractical if they use lower stimulation parameters, a frequent recharging protocol, or both.

NOTE: The model used to predict device longevity was generated by fitting a mathematical model to three years of real-time cycling data, which was then used to extrapolate device battery capacity at the end of ten years.

Recharging the IPG Battery

For information about the charging system and how to recharge the IPG battery, see the user's guide for the charging system.

⚠ **WARNING:** Do not let an IPG battery remain depleted for an extended period of time. If a depleted battery is not recharged within 30 to 90 days of its full discharge, the charger may not be able to recharge it; and it will have to be surgically replaced to resume therapy.

Preserving the IPG When Not in Use

To preserve the IPG when discontinuing stimulation for an extended period of time, follow these steps:

1. Recharge the battery to its maximum capacity before turning off the IPG.
2. Recharge the battery to its maximum capacity every 3 months while it is not in use.

Customer Service Information

For help with a St. Jude Medical neuromodulation product, including technical service or repairs, contact Customer Service using the following information:

St. Jude Medical
6901 Preston Road
Plano, TX 75024
USA

800 727 7846
972 309 8000
972 309 8150 Fax

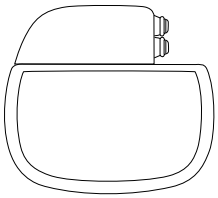
Appendix A: Product Specifications

Protege IPG

The Protege™ IPG (Model 3789) has the following physical specifications.

Table 1: IPG specifications

Height	4.8 cm (1.89 in)
Length	5.3 cm (2.09 in)
Thickness	0.95 to 1.1 cm (0.37 to 0.43 in)
Weight	29.0 g (1.0 oz)
Volume	17.7 cm^3 (1.08 in^3)
Power source	Rechargeable lithium ion cell
Storage temperature	-10°C–55°C (14°F–131°F)
Storage humidity	10%–90% (noncondensing)
Storage pressure	70–150 kPa (10.2–21.8 psi)
Connector strength	Exceeds EN45502-1 requirements



The Protege IPG has the following operating parameters.

Table 2: Operating parameters for the IPG

Parameter	Range	Steps
Pulse width	50–500 µs	Alternating 12 and 13 µs (starting with 12 µs)
Frequency	2–200 Hz	2 Hz
	200–500 Hz	10 Hz
	500–1200 Hz	20 Hz
Amplitude	0–25.5 mA (max 12 V)	0.1–1.0 mA

NOTE: The number of stim sets in use governs the maximum frequency (1200/number of stim sets).

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

Appendix B: Regulatory Statements

This section contains regulatory statements about your product.

Statement of FCC Compliance (FCC ID:PX 2001)

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.

Appendix C: Symbols and Definitions

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

Denotes that the user should pay special attention to avoid serious consequences. This document presents the symbol, the word WARNING or CAUTION, and a brief explanation of the seriousness of the situation.

A warning alerts the user to a situation which, if not avoided, could result in (1) death or serious injury, (2) serious or adverse reactions, or (3) safety hazards.

A caution alerts the user to a situation which, if not avoided, may result in (1) minor or moderate injury or (2) damage to the equipment or other property.

This symbol advises the reader to consult this document for important safety-related information.

 Denotes single use only

 Denotes expiration date

 Denotes date of manufacture

 Denotes temperature limits for storage conditions

 Denotes humidity limits

 Denotes pressure limits

 Denotes do not use if the product sterilization barrier or its packaging is compromised

 Denotes catalog number

 Denotes manufacturer

UNIT	Denotes content, the number of items contained in the package
PN	Denotes code that uniquely identifies an inventory item
SN	Denotes serial number
LOT	Denotes batch code
Rx only	Denotes for prescription use only
STERILE EO	Denotes ethylene oxide gas sterilization
EC REP	Denotes authorized European representative
CE	Denotes European conformity
0123	Denotes the EU notified body number for AIMD

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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