SPRINT®
PNS SYSTEM

# Clinician Instructions for Use

2018-5-XX

Kommentar [MW1]: Will require to be updated prior to final release



Information on patents can be found at:
www.sprtherapeutics.com/patents

The SPRINT® PNS System is manufactured by:

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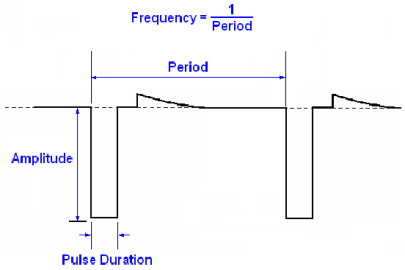
# Glossary

**Amplitude** – the level of current flowing during the stimulus pulse. The Amplitude is measured in milliamperes (mA). See Figure G.1




*G.1: Stimulus waveform; Two stimulus pulses are shown*

**Burst** – the portion of a stimulation cycle during which stimulus pulses are delivered at the maximum programmed amplitude and pulse duration (Figure G.2).

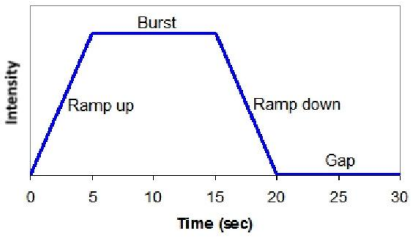



Figure G.2 One cycle of stimulation, composed of four periods:
ramp up, burst, ramp down, and gap.

**Charge** – The total magnitude of electrical charge delivered by the rectangular stimulus pulse. The per pulse charge of a stimulus pulse in nanoCoulombs (nC) is equal to the product of Amplitude and Pulse Duration (nC =mA x µs).

**Cycle** – the period of time for the ramp up, burst, ramp down, and gap periods of stimulation to each occur once (Figure G.2).

**Duty Cycle** – the percent of time full stimulus pulses are being delivered during one cycle of stimulation. (ramps are counted at half the actual time)

**Electrode** – a conductor in electrical contact with tissue to transfer electric current from a stimulator to the body of a patient. The distal exposed metal portion of the Sprint MicroLead is the electrode.

**Frequency** – the number of stimulus pulses delivered per second on the (or each) channel / Lead. Measured in Hertz (Hz). See Figure G.1.

**Gap** – the portion of a stimulation cycle during which stimulus pulses are not delivered (Figure G.2). (Not applicable when duty cycle is set to 100%; i.e., when the pulse train continues at set value until stimulation is stopped.)

**Intensity** - the strength of the stimulation delivered on a scale of 1.0 (minimum) to 100.0 (maximum). The Intensity value (1 – 100) is mapped into clinically useful per pulse stimulus charges that allows convenient control of the strength of stimulation.

**Pulse Duration** – the length of time one stimulus pulse lasts. Measured in microseconds (μsec). See Figure G.1.

**Ramp Down** – the period of time during the stimulus cycle when stimulus pulse Amplitude is decreasing from its maximum value to zero (Figure G.2). (Not applicable when duty cycle is 100%; i.e., when the pulse train continues at set value until stimulation is stopped.)

**Ramp Up** – the period of time during the stimulus cycle when is increasing from zero to its maximum value (Figure G.2). (Not applicable when duty cycle is 100%; i.e., when the pulse train continues at set value until stimulation is stopped.)

# 1 Introduction

## 1.1) Indications for Use

The SPRINT® Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days in the back and/or extremities for:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The SPRINT® PNS System is not intended to treat pain in the craniofacial region.

A randomized controlled trial failed to show that the SPRINT® PNS System was effective for post-stroke shoulder pain.

## 1.2) Contraindications

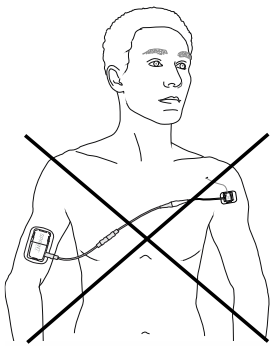
- Use of the SPRINT® PNS System is contraindicated for:
  - Patients who have a Deep Brain Stimulation (DBS) system.
  - Patients who have an implanted active cardiac implant (e.g. pacemaker or defibrillator).
  - Patients who have any other implantable neuro-stimulator whose stimulus current pathway may overlap with that of the SPRINT System.
  - Patients who require Magnetic Resonance Imaging (MRI). The SPRINT® MicroLead and other SPRINT components must be removed from the body before an MRI.
  - Patients who have a tape or adhesive allergy.

## 1.3) Warnings

Refer to the warnings below before using the system. Additional warnings specific to home use are included in the *Patient Instructions for Use* (Section 2: Important Safeguards).

**SPRINT PNS System placement**

- The Sprint PNS System is for use in the back and/or extremities.
- The Sprint PNS System is not intended to treat pain in the craniofacial region.
- Do not place the SPRINT Mounting Pad on the head or on the front of the throat. Stimulation in these areas may cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the chest; introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.



⚠ **Stimulating Probe or MicroLead placement near vital structures (i.e. major arteries, visceral organs, pleural cavity, etc.)** – Use imaging (e.g., ultrasound) to guide placement of the Stimulating Probe and MicroLead when placing near an artery or organ to decrease the risk of puncture.

⚠ **Pregnancy** – Safety for use during pregnancy has not been established.

⚠ **Pediatric Use** – Safety and effectiveness have not been established for pediatric use (i.e., in a patient 21 years of age or younger).

⚠ **Infection Control** – Follow all applicable infection control procedures. Standard aseptic technique should be followed. Failure to follow infection control procedures could lead to an increased risk of infection.

⚠ **Explosive or Flammable Gases** – To avoid ignition, do not use the SPRINT® PNS System in the presence of flammable anesthetic mixtures with air or with oxygen.

⚠ **Diathermy** – Patients with a SPRINT MicroLead CANNOT undergo therapy using any shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy anywhere on their body. Energy from diathermy can heat the Lead and cause severe injury.

⚠ **Electrocautery** – Simultaneous connection the SPRINT System and high frequency surgical equipment (electrocautery) to a patient may result in burns at the site of the electrode at the tip (barb) of the MicroLead and/or at the Mounting Pad.

⚠ **Do not reuse the SPRINT PNS System** – the SPRINT PNS System is a single patient device. Use of the system, or any component thereof except the Clinical Programmer, by more than one person may result in infection, damage to the system, or failure of the System to operate. This does NOT include the Clinical Programmer Tablet or Clinical Programmer Charger, which are non-sterile, reusable system components for use by medical professionals only and should not be allowed to come into contact with patients.

⚠ **Clotting disorders** – Do not place the Stimulating Probe or MicroLead in any patient who has a bleeding or clotting disorder. Bleeding risk should also be considered in patients taking anticoagulant therapy.

⚠ **Anesthetic Block** - Use caution when placing a Stimulating Probe or MicroLead in patients who have recently received an anesthetic block in the area of the targeted PNS therapy. These patients may have an altered response to stimulation.

⚠ **Modifying the SPRINT System** – Do not take apart or modify any component of the Sprint System. Doing so may result in injury to the patient or damage to the System.

⚠ **Do not use any component of the SPRINT System with a component that is not part of the SPRINT System.** Doing so may result in injury or damage to the System. This is also true of the AC Power Adapters supplied; a replacement device must have the same specifications and safety Certifications.

## 1.4) Precautions

Refer to the precautions below before using the system. Additional precautions specific to home use are included in the *Patient Instructions for Use*.

**Painful stimulation** – If stimulation feels painful to the patient, decrease the intensity or turn it off. If it is not possible to turn stimulation off, remove the Pulse Generator from the Mounting Pad (this will force the stimulation to turn off).

**Use during surgery and delivering stimulation near a surgical incision** - If a Lead is to be placed prior to a surgical procedure, then the lead should be placed away from the expected surgical incision as well as other areas that may be impacted by supplies used during the surgical procedure (e.g., tourniquet). The SPRINT Pulse Generator, Mounting Pad, and cables should be removed prior to any surgery, and the MicroLead and MicroLead Connector should be secured beneath sterile bandages. Use caution when delivering stimulation near an unhealed surgical incision. Doing so could cause a surgical incision to re-open or fail to heal properly.

**Mounting Pad Placement** – Mounting Pads should only be placed on clean healthy skin. Placement on unhealthy skin (i.e. irritated or injured skin, rashes or wounds) may further irritate the area and cause stimulation to feel different or be uncomfortable. It is acceptable to apply the Mounting Pad to a birthmark and hair baring areas. If the patient experiences sensitivity or poor adhesion, move the Mounting Pad to another location.

**MicroLead Connector and Mounting Cradle Placement** – To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.

**Electronic medical equipment** – The System may interfere with patient monitoring equipment or other physiological instruments. Always turn off and disconnect the stimulator before any unrelated medical tests or procedures.

**Broken or disconnected MicroLead or cable** – Avoid pulling on the MicroLead or anything connected to it, which may cause the MicroLead to be pulled out. If the MicroLead or any cable breaks or becomes disconnected, stop stimulation and replace the broken component or reconnect the components, as applicable. A broken or disconnected MicroLead or cable may deliver a safe, but uncomfortable stimulation lasting a few seconds.

**Portable and mobile Radio Frequency (RF) communications** – Portable and mobile Radio Frequency (RF) communications equipment can interfere with the stimulator. Do not use such equipment while using the System. For additional information on RF communications, contact SPR Therapeutics.

- ***System interference from other radio frequency devices:*** In the presence of other radio frequency devices (including but not limited to cell phones, two-way handheld radios, and other Bluetooth devices), it is possible that the Clinical Programmer will have difficulty communicating with the Pulse Generator over its Bluetooth wireless link. This may result in delay or pauses between issuing a command and a response from and change in the operation of the Pulse Generator.

**Electromagnetic Interference (EMI)** – The SPRINT® PNS System is not likely to cause any interference in nearby electronic equipment through Electromagnetic Interference (EMI) other than Bluetooth interactions (complies with CISPR 11, Type B).

- ***System interference with nearby devices:*** As with most medical electronic equipment, operation of the SPRINT® PNS System has the potential to interfere with the operation of nearby radio frequency devices (for example, radios, televisions, wireless phones, headsets,

and digital appliances). The System incorporates Bluetooth wireless communications features in the Pulse Generator and the Hand-Held Remote. Although commonly used with many personal digital appliances, too many Bluetooth equipped devices in use at the same time within a few feet of each other can disrupts the operation of one or more of those devices.

  - If moving away from another device reduces or eliminates the problem, it is likely that the System is interfering with the other device. Similarly, if the problem is only observed while you are using the Hand-Held Remote to monitor or control the Pulse Generator, it is likely that the System is interfering with the other device. You should move or orient yourself such that the SPRINT® PNS System is not interfering with the other device.

- ***Nearby device interference with the System:*** As with most medical electronic equipment, operation of the SPRINT® PNS System has the potential to be disrupted by the operation of other nearby radio frequency devices (for example, cellular telephones, handheld two-way radios used by emergency or utility service personnel, broadcast radio and television transmitters, and amateur radio transmitters).
  - Such a disruption is most likely to cause either an inability to use (or a pause or delay in using) the Hand-Held Remote to control the Pulse Generator **OR** to cause a temporary change to stimulation being delivered (for example missing pulses for a short period of time) or turning the stimulation OFF.
  - Portable RF communications equipment (especially cell phones but including antennas and antenna cables) should not be used closer than 30cm (12 inches) to the Pulse Generator, the Hand-Held Remote, or the Clinical Programmer. If disruption occurs, the SPRINT system will not be damaged and there is no risk of injury to the patient.
  - In all cases, stimulation can be turned OFF by pressing the button on the Pulse Generator, or by removing the Pulse Generator from the Mounting Pad or unplugging the cables to the Pulse Generator. If the cause of the interference is suspected, you should physically separate yourself from the source of the interference or avoid using the interfering device at the same time as the SPRINT® PNS System.
- ***FCC Compliance:*** This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
  - Changes or modifications made to the system or system components not expressly approved by SPR Therapeutics will void the authority to operate the system.
  - The FCC ID of the Hand-held Remote (2AO2X-9620) is displayed on the initial splash screen after being unlocked. The FCC ID of the Pulse Generator (2AO2X-9620) is located on the label on the back the device.
- For more details on Electromagnetic Interference contact SPR Therapeutics (see *Appendix C: Contacting SPR Therapeutics*).

**Handle the SPRINT® PNS System with care** – Rough handling, including dropping on the ground or being crushed, can damage the SPRINT System.

**MicroLead Movement** – Do not apply force to the SPRINT MicroLead. Pulling on the MicroLead will cause it to move or dislodge. A change in sensation (including intensity or location), response (including location of response), or stimulus intensity required to foster pain relief may indicate that the MicroLead has moved. If the MicroLead has moved and the desired response is no longer attained after testing the full range of stimulus parameters available, MicroLead replacement may be necessary.

**Kommentar [MW2]:** Required statement per 47 CFR 15.21

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**Kommentar [MW3]:** Required per 47 CFR 2.935

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**Not water proof** – Do not submerge any components of the SPRINT System in water, alcohol, other fluids, or dust. Exposure to fluids or dust could damage the System and cause it to stop operating. Adding a drop of water to the pad before its use to improve adhesion is acceptable.

**Battery Care** – The batteries may become unsafe if disassembled, shorted (when battery connections contact metal), or exposed to high temperature or fire. The materials within the battery can discolor skin and are not safe to ingest. Do not leave the SPRINT System in a closed car or truck in hot summer temperatures.

**Long Term Effects** – The long-term effects of electrical stimulation are unknown. The use of this system is intended for up to 60 days.

## 1.5) MRI Safety Information

**The SPRINT® PNS System is MR Unsafe** - All MRI procedures, no matter the anatomic site, are contraindicated for patients with the SPRINT® PNS System. Exposure can cause tissue heating and injury or unwanted stimulation. Remove the lead and all other system components from the patient before an MRI examination is performed.


In the case of a lead fracture beneath the skin that results in a retained lead fragment, an MRI examination is safe to perform under the conditions described in the **MR Conditional** statement below.

**A Retained Lead Fragment ONLY is MR conditional**
Non-clinical testing demonstrated that a retained lead fragment entirely beneath the skin is conditionally MR-safe. A patient with a retained lead fragment can be safely scanned in an MR system under the following conditions:


- Static magnetic field of 1.5 Tesla
- Maximum spatial gradient magnetic field of 1,000 Gauss/cm (10 T/m)
- Maximum MR system-reported whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (Normal Operating Mode)

Under these scan conditions, the fragment is expected to produce a maximum temperature rise of less than 3.3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a fragment extends approximately 7 mm from the fragment when imaged using a gradient echo pulse sequence and a 1.5 Tesla MR system.

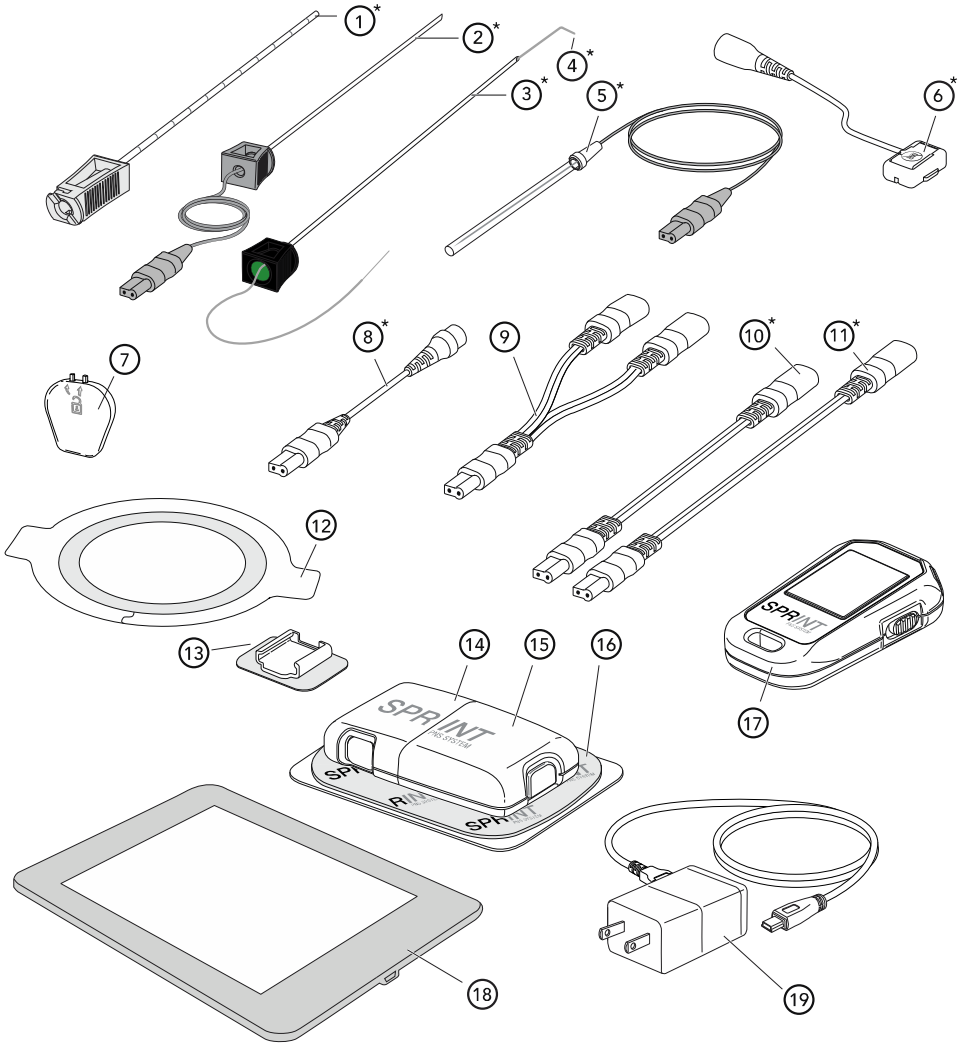
✎ NOTE: There should be no section of lead visible above the skin.

✎ NOTE: If a lead is placed in an individual with an existing retained lead fragment, the new lead should not be placed in a location where it could touch the original lead fragment. During MRI, two lead fragments touching each other can result in an increase in temperature of the lead fragments and surrounding tissue where they touch.

# 2 System Overview

## 2.1) System Components

The SPRINT® PNS System is made up of sterile and non-sterile components.




* Indicates that two (2) of each component will be included for a dual lead system.

✎ NOTE: Components not shown to scale.

## Sterile Components

1. **Percutaneous Sleeve:** Part of the MicroLead™ OnePass Introducer™ System, the Percutaneous Sleeve is used for testing stimulation and placing the MicroLead.

2. **Stimulating Probe:** Part of the MicroLead™ OnePass Introducer™ System, the Stimulating Probe is used to test stimulation prior to placing the MicroLead.

3. **MicroLead Introducer:** Part of the MicroLead™ OnePass Introducer™ System, the MicroLead Introducer is used to insert the MicroLead.

4. **MicroLead:** The MicroLead is a fine wire with anchoring tip and electrode contact suitable for placement through the skin into tissue in proximity to a target nerve.

5. **Stimulating Needle:** Utilized as an alternative to the MicroLead™ OnePass Introducer™ System, the Stimulating Needle is a small gauge needle with a stimulating electrode tip used as an option to identify the optimal site for MicroLead placement.

6. **MicroLead Connector (Light Gray & Dark Gray):** The connecting piece that creates an efficient electrical connection between the MicroLead and the Pulse Generator. (Dual-Lead Systems come with two MicroLead Connectors, one with a light gray cable connector (Light Gray) and the other with a dark gray cable connector (Dark Gray).)

7. **MicroLead Connector Key:** The key that unlocks the MicroLead Connector when re-connection by the clinician is desired.

8. **Magnetic Coupler (Light Gray & Dark Gray)** Breakaway system between the MicroLead Connector and the Pulse Generator intended to separate and minimize the potential for MicroLead dislodgement. (Dual-Lead Systems come with two Magnetic Couplers, one with a light gray cable connector (Light Gray) and the other with a dark gray cable connector (Dark Gray).)

9. **Dual-Lead Adapter:** In a Dual-Lead configuration, this allows two MicroLead connectors to attach to one port on the Pulse Generator. (Only included in Dual-Lead SPRINT *extensa™* System)

10. **Short Extension:** Allows for 15 cm of extra length between the Magnetic Coupler and the Pulse Generator. (Not necessary for use)

11. **Long Extension:** Allows for 36 cm of extra length between the Magnetic Coupler and the Pulse Generator. (Not necessary for use)

## Non-Sterile Components

12. **Waterproof Bandage:** Intended to keep the lead exit site clean and dry and to minimize the risk for lead dislodgement.

13. **Mounting Cradle:** Adhesive pad that holds the MicroLead Connector in place near the MicroLead exit site to minimize the potential for lead dislodgement.

14. **Rechargeable Battery:** The power source used to run the Pulse Generator.

15. **Pulse Generator:** The device that produces the electrical pulses used to deliver stimulation therapy.

16. **Mounting Pad:** Connects the Pulse Generator to the skin. One side of the Pad has an adhesive gel, exposed by removing the clear liner. The non-sticky side of the Pad has two snaps that connect to the Pulse Generator.

17. **Hand-Held Remote:** The tool that allows patients and clinicians to communicate to the Pulse Generator via Bluetooth® allowing the clinician to program the Pulse Generator and the patient to make safe, clinician-prescribed adjustments to their therapy at home.

18. **Clinical Programmer Tablet:** Touch screen tablet provides an alternative to the Hand-held Remote while providing access to advanced programing functions. Not intended for patient use.

19. **Clinical Programmer Charger:** USB cord and AC adapter plug used to recharge the Clinical Programmer.

20. **Patient Case:** Includes Recharging Base and Power Supply (recharges the Rechargeable Batteries for the Pulse Generator), extra Rechargeable Battery, Waterproof Bandages, Mounting Cradles, Mounting Pads, and Patient Instructions for Use and Quick Start Guide documents.

21. **Patient Disposable Supplies:** Extra Waterproof Bandages, Mounting Cradles, and Mounting Pads are supplied in addition to what is included inside the Patient Case.

## 2.2) Programming Tools Overview

Initial programming of the Pulse Generator may be performed using either the Hand-Held Remote or the Clinical Programmer (both provided non-sterile). Both the Hand-Held remote and the Clinical Programmer communicate wirelessly with the Pulse Generator.

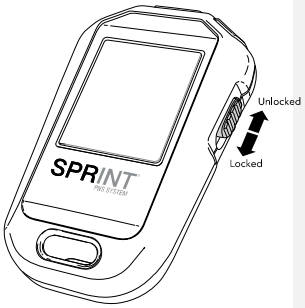
### 2.2.1) Hand-Held Remote

The Hand-Held remote is pre-paired to connect only with the packaged Pulse Generator. The Hand-Held remote is operated using the buttons positioned at the top of the device. The variable functions of the buttons on the top of the remote correlate with the symbols or messages displayed on the screen below each respective button.

**The Hand-Held Remote may be used in two modes:**

- By the clinician during MicroLead placement procedure.
- By the patient during home use.

The Hand-Held Remote is not able to access some programming features that are available via the Clinical Programmer.




To unlock the Hand-Held Remote:
Move the Lock/Unlock Switch to the up position.

To lock the Hand-Held Remote:
Move the Lock/Unlock Switch to the down position.

To wake up the Hand-Held Remote:
The Hand-Held Remote will automatically go to sleep after a period of inactivity. To wake up the remote, press any button or toggle the Lock/Unlock Switch to the Up/Unlocked position.

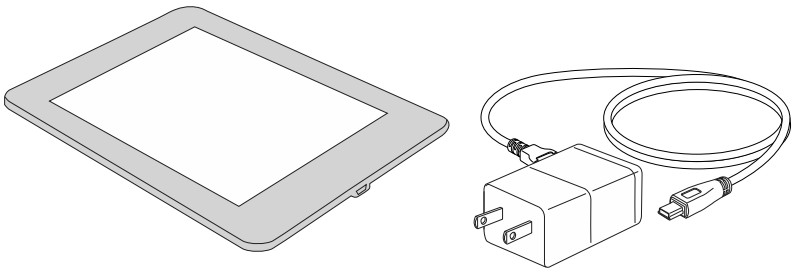

The startup screen will show for a few seconds while the remote is connecting to the Pulse Generator.

✎ NOTE: The Hand-Held Remote is shipped with a thin plastic tab in the battery compartment which prevents the Remote battery from draining during storage and shipment. Prior to use of the Hand-Held Remote, this tab must be removed by pulling on it. If not removed, the Hand-Held Remote will not operate.

### 2.2.2) Clinical Programmer

The Clinical Programmer is a tablet that allows the clinician to operate and program the Pulse Generator. The Clinical Programmer is not intended for use by patients and is non-sterile. If the clinician wishes to use the Clinical Programmer during the MicroLead placement procedure, it is recommended that an assistant be present to handle the Clinical Programmer while the clinician is in the sterile field.

Ensure that the Clinical Programmer is fully charged prior to the start of a programming session.
The Clinical Programmer should be cleaned in the same manner that any consumer electronic device is cleaned.



✎ NOTE: When stored for extended periods of time, the Clinical Programmer should be stored in a cool, dry location.

# 3 Procedure Preparation

## 3.1) Procedural Precautions

These instructions are intended to provide the clinician with considerations, but are not intended as definitive descriptions of the lead placement technique. The clinician, based on standard clinical practice, should determine lead placement decisions and technique.

**MicroLead Insertion Site Considerations:**

As necessary, the lead insertion site should be adjusted to meet these criteria:

- Leads are only intended to be placed in the back and/or extremities.
- The SPRINT System is not intended to treat pain in the craniofacial region.
- Consider where the MicroLead Connector and Pulse Generator will be situated in relation to the lead exit site(s). The locations of these components should assure that tension on the lead is minimized and that the Pulse Generator is in a location that is comfortable and easily accessible by the patient or caregiver.
- Consider if the MicroLead or the stimulation it delivers will be susceptible to postural changes, pressure from body weight, clothing, etc.
- Consider the cleanliness and ease of access to clean the insertion site.
- If a Lead is to be placed prior to a surgical procedure, then the lead should be placed away from the expected surgical incision as well as other areas that may be impacted by supplies used during the surgical procedure (e.g., tourniquet).

⚠ Explosive or Flammable Gases – To avoid ignition, do not use the SPRINT® PNS System in the presence of flammable anesthetic mixtures with air or with oxygen.

⚠ Infection Control – Follow all applicable infection control procedures. Standard aseptic technique should be followed. Failure to follow infection control procedures could lead to an increased risk of infection.

⚠ Do not use a component of SPRINT® PNS System when:

- The packaging has been pierced, damaged, or altered;
- The component shows signs of damage; or
- The “Use By” date has passed.

## 3.2) Gather Components

Inspect all packaging for any signs of damage and lay out the components for easy access.

**Components provided for MicroLead Placement**

- Pulse Generator with Rechargeable Battery (non-sterile)
- Mounting Pad (non-sterile)
- Hand-Held Remote (non-sterile)
- Clinical Programmer (non-sterile) (optional)
- MicroLead™ OnePass Introducer™ System
    - Percutaneous Sleeve
    - Stimulating Probe
    - MicroLead with MicroLead Introducer
- Stimulating Needle (optional)
- Connector Key
- Waterproof Bandage(s)
- Mounting Cradle(s) (non-sterile)
- Short and Long Extension(s)
- Dual Lead Adapter (for two lead configuration)
- MicroLead Connector(s)
- Magnetic Coupler(s)

## 3.3) Assemble Additional Supplies and Set up a Sterile Procedure Tray

- Sterile surgical towels (2 packs) or similar to provide an area for sterile components
- Sterile gloves
- Preferred patient drape
- Antiseptic (povidone-iodine or chlorhexidine) swabs (2 packs)
- Local anesthetic and syringe/needle
- Scissors
- Sterile probe cover (if using ultrasound guidance)
- Surgical marker pack with ruler (if using a Stimulating Needle instead of the MicroLead™ OnePass Introducer™ System)

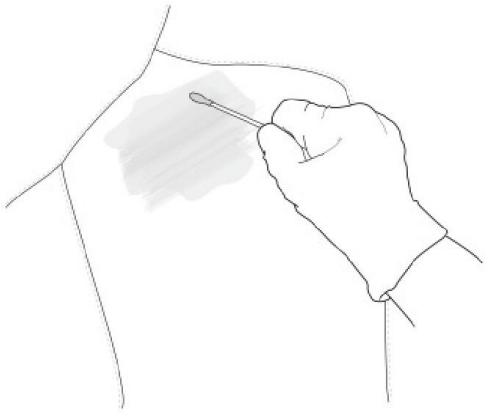
## 3.4) Prepare the Patient Case

**Ensure that the Patient Case is ready for patient use and includes all of the following:**

- Recharging Base and Power Supply
- Second Rechargeable Battery
- Waterproof Bandages
- Mounting Cradles
- Mounting Pads
- Patient Instructions for Use
- Patient Quick Start Guide

## 3.5) Prepare the MicroLead Exit Site(s)

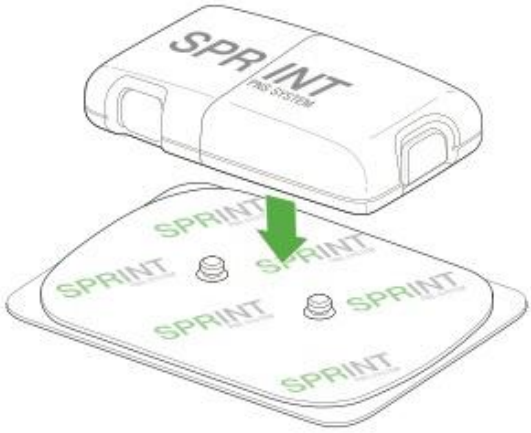
1. With the patient appropriately positioned, clean the skin following your institution's guidelines for aseptic technique. Clip (do not shave) hair as necessary.



2. If desired, administer local anesthetic around the planned insertion site(s) for the MicroLead. Local anesthesia may be provided at the discretion of the clinician. Anesthesia may be applied subcutaneously (e.g., lidocaine), topically (e.g., EMLA cream), or both.

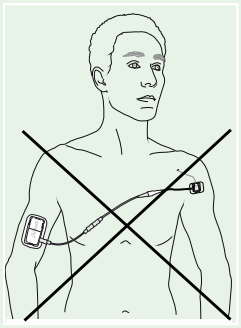
⚠ Do not administer the local anesthetic into deep tissues. Administering anesthetics close to the terminal position of the electrode could affect the response to stimulation.

3. Snap the Pulse Generator onto the Mounting Pad.



4. Remove Mounting Pad adhesive liner.


5. Attach the Mounting Pad with Pulse Generator onto clean skin outside of the sterile field, in an area away from motor points and away from the lead insertion site. Sensations of motor activity may occur beneath the Mounting Pad and Pulse Generator.



⚠ Do not cross the chest when placing the Mounting Pad to prevent passing current across the heart. The introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.

⚠ Do not place the Mounting Pad on the head or on the front of the throat. Stimulation in these areas may cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.

⚠ Mounting Pads should only be placed on clean healthy skin. Placement on unhealthy skin (i.e., irritated or injured skin, rashes or wounds) may further irritate the area and cause stimulation to feel different or be uncomfortable. It is acceptable to apply the Mounting Pad to a birthmark and hair baring areas. If the patient experiences sensitivity or poor adhesion, move the Mounting Pad to another location.

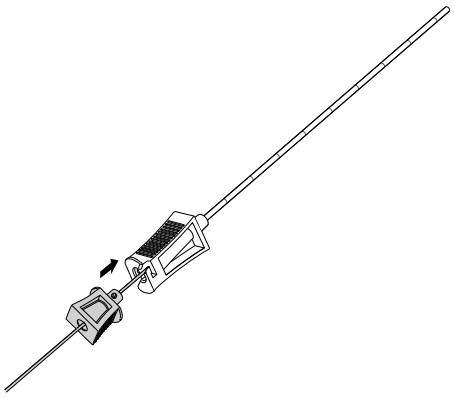
# 4 MicroLead Placement & System Set-up

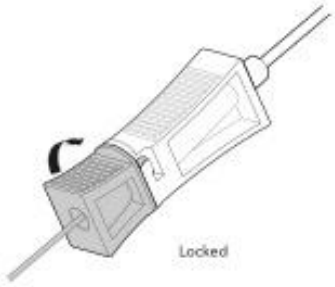
## 4.1) Identifying Lead Placement Target using the OnePass Introducer™ System

1. Locate the target peripheral nerve. (*see Appendix G: Lead Placement in Proximity to Peripheral Nerves* for example lead placements**)**

2. Insert the Stimulating Probe into the Percutaneous Sleeve. Align hub components and rotate the Stimulating Probe clockwise to lock components together prior to insertion into the body.

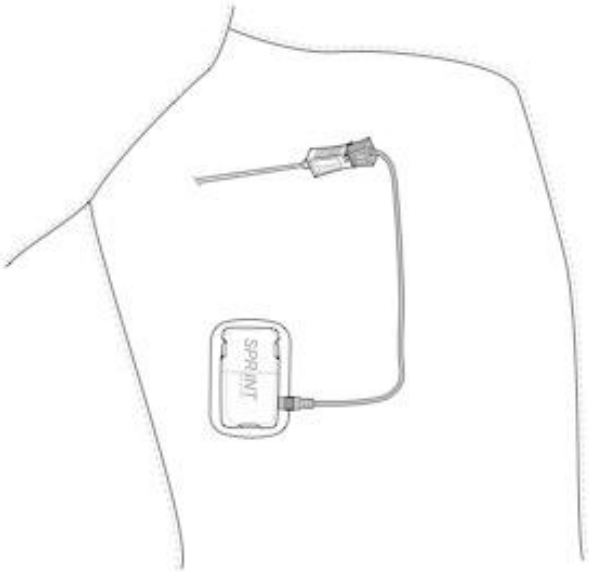
> ✎ NOTE: If using the Stimulating Needle instead of the OnePass Introducer™ System to test stimulation and place the MicroLead, see *Appendix F: Using the Stimulating Needle for MicroLead Placement Procedure*.





3. Insert the Percutaneous Sleeve with Stimulating Probe through the skin in a location that provides access to the target nerve, using ultrasound or fluoroscopic guidance as appropriate.

4. Connect the Stimulating Probe to the Pulse Generator. If the connection is too short, use an appropriate length Extension Cable.

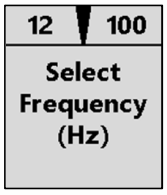
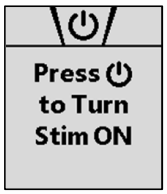


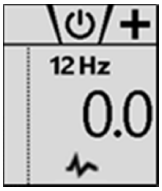
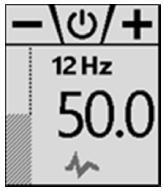
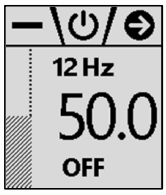
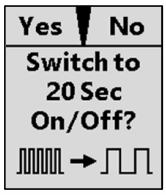
## 4.2) Testing Stimulation

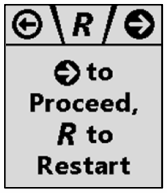
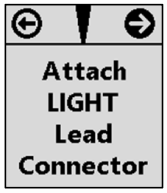
During the initial lead placement, use the Hand-Held Remote OR the Clinical Programmer to test stimulation with the Stimulating Probe. Refer to Section 4.2.1 below if you choose the Hand-Held Remote or 4.2.2 if you wish to use the Clinical Programmer. If testing stimulation for a lead replacement, the Clinical Programmer must be used to enter the testing stimulation screens.

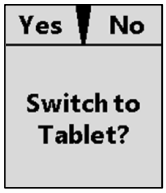
### 4.2.1) Testing Stimulation with the Hand-Held Remote

**DUAL LEAD SYSTEM:** Follow the instructions below, testing the first MicroLead (used with the light gray MicroLead connector and cables). After the screen instructing you to "Connect Light Lead Connector", you will be prompted to "Start Testing Second Lead" (which will be used with the dark gray MicroLead connector and cables).

| Remote Screens | Instructions |
|---|---|
|  | Unlock or Wake Up the Hand-Held Remote. (*see Section 2.2.1 Hand-Held Remote*) |
|  | To select the desired frequency (12 or 100 Hz), press the button associated with **12** or the button associated with **100.**<br><br>For 12 Hz, the goal is generally to induce a sense of tension in the muscle. At 100 Hz, the goal is generally to produce a comfortable tingling sensation. See Appendix G for additional recommendations regarding which frequency to use with different lead locations.<br><br>Use of 12 Hz will set the patient stimulation session time to 6 hours. Use of 100 Hz will set the patient stimulation session time to unlimited (continuous). |
|  | Ensure that the Stimulating Probe is in the desired location and that all connections to the Pulse Generator are in place before turning on stimulation.<br><br>To start stimulation press the button associated with the ⏻ icon. |

| Remote Screens | Instructions |
|---|---|
|  | *This is an instructional screen that appears for a set amount of time.*<br><br>To pause stimulation, press the ⏻ button.<br><br>Press ➔ to continue. The ➔ button will appear as an option only when stimulation is paused. |
|  | To begin increasing stimulation intensity press the + button.<br><br>**NOTE:** When stimulation is on, the ⁓ symbol will be shown on the screen. When stimulation is off, **OFF** will appear on the screen.<br><br>**NOTE:** Slowly increase intensity until the desired nerve response is obtained. A nerve response should be confirmed with comfortable sensations of tingling/pressure and in some cases tension in the muscle. Intensity is adjusted in increments of 2 during lead placement testing. |
|  | To decrease stimulation intensity, press the − button.<br><br>To increase stimulation intensity, press the + button.<br><br>**NOTE:** When targeting a mixed nerve in the periphery under ultrasound guidance, it may be beneficial to assess several different locations and stimulation intensities around the nerve until the optimal response is achieved. In some cases, it may be beneficial to advance the stimulating probe across the axis of the nerve to initiate stimulation at a low intensity and to withdraw the introducer slowly across the nerve to assess optimal location and response. |
|  | Once the desired level of stimulation has been reached, press the ⏻ button to turn stimulation OFF, then press the ➔ button to continue.<br><br>**NOTE:** If desired response cannot be obtained, stop stimulation, set intensity as low as possible and adjust position as needed before testing again. |
| 12 Hz<br>  | **IF TESTING AT 12 HZ:** Stimulation at 12 Hz has two options to control stimulation cycling:<br>1. **Fast Cycling (default):** stimulation is delivered in periods with one second of stimulation ON followed by one second of stimulation OFF. This is labeled "1 Sec On/Off", or<br>2. **Slow Cycling:** stimulation is delivered in periods with 20 seconds of stimulation ON (5 seconds ramp up, 10 second plateau, 5 seconds ramp down), followed by 10 seconds of stimulation OFF. This is labeled "20 Sec On/Off". |

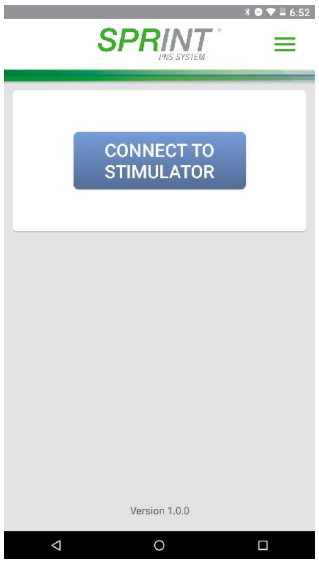
| Remote Screens | Instructions |
|---|---|
| | **NOTE:** The intent of the Fast Cycle approach is to allow for identification of changes in muscle tension as stimulation intensity is increased. This cycling approach is not available for procedures in which the 100 Hz frequency is used. It is also not available for patient home use (which utilizes Slow Cycling for 12 Hz stimulation).<br><br>If **"Yes"** is selected, the remote will return to the previous screen so stimulation can be tested at the new stimulation cycle. The option to switch to 1 Sec cycling will then be presented. Switching between Fast Cycling and Slow Cycling can be done as many times as desired.<br><br>Press **"No"** to continue to the next screen. |
|  | If all settings are correct, press the ➔ button to continue.<br><br>To erase settings and restart the process, press the **R** button.<br>To return to testing stimulation with the same needle or lead, press the ⬅ button. |
| **Single Lead**<br>  <br>**Dual Lead**<br>  | Continue confirming placement and placing the MicroLead by following steps in *Section 4.3) Confirming Location & Placing the MicroLead(s)*.<br><br>Once the MicroLead has been placed and the MicroLead Connector has been attached, press the ➔ button to continue.<br><br>To return and adjust placement before deploying the MicroLead, press the ⬅ button. |
|  | With the lead connector attached to the lead, confirm that the lead is in the desired location by testing stimulation again. |

| Remote Screens | Instructions |
|---|---|
|  | Once the desired level of stimulation has been reached, press the ⏻ button to turn stimulation OFF, then press the ➔ button to continue.<br><br>With stimulation OFF, unlock the lead connector and deploy the lead. Re-connect the lead connector to the lead and confirm that the lead is in the desired location by testing stimulation again.<br><br>**NOTE:** If desired response cannot be obtained, stop stimulation, set intensity as low as possible and adjust position as needed before testing again. To return to testing stimulation through the probe instead of the lead, press ➔ to proceed to the next screen. When on the next screen, press the ⬅ button 3 times to return to test stimulation through the probe. |
| **Dual Lead**<br>  | **Dual Lead Systems Only:** Ensure that the second Stimulating Probe is in the desired location and that all connections to the Pulse Generator are in place. Press the ➔ button to continue. This will repeat the stimulation testing screens (with the intensity bar on the right side of the screen for the second lead placement).<br><br>To return and adjust placement of the first MicroLead, press the ⬅ button. |
|  | To switch to the Clinical Programmer tablet, select **Yes** and see *Section 4.4.2 Establishing Therapy Settings using the Clinical Programmer Tablet*.<br><br>To continue establishing therapy settings with the Hand-Held Remote select **No** and see *Section 4.4.1 Establishing Therapy Settings using the Hand-Held Remote.* |

### 4.2.2) Testing Stimulation with the Clinical Programmer Tablet

**DUAL LEAD SYSTEM:** Follow the instructions below, testing the first MicroLead (used with the light gray connector cables). After connecting the light gray lead connector to the first MicroLead, press "Next" to begin testing of the second MicroLead (used with the dark gray connector cables)


Turn on the Clinical Programmer Tablet. The startup screen will briefly display.

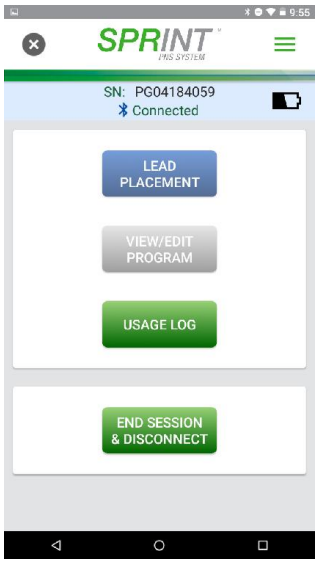



Select **Connect to Pulse Generator** to pair the Clinical Programmer with the Pulse Generator.


Press and hold the button on the side of the Pulse Generator until it beeps and begins flashing blue (about 8 seconds).

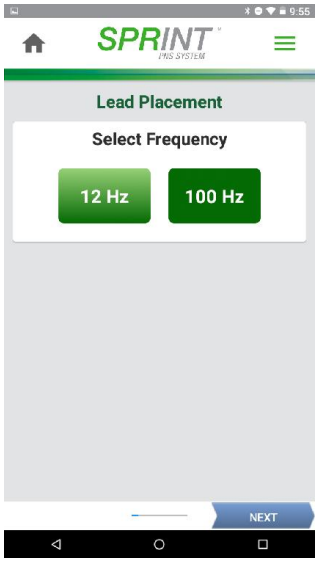

The Pulse Generator will appear in the *Available Devices* section at the bottom of the screen. If no devices are shown, select "**start scan**".

To confirm that the appropriate Pulse Generator is available for pairing, match the displayed serial number with the number displayed on the back of the Pulse Generator. Select **Connect** to pair the Pulse Generator with the Clinical Programmer.




Select **Lead Placement** to begin the process of testing stimulation and placing the MicroLead.

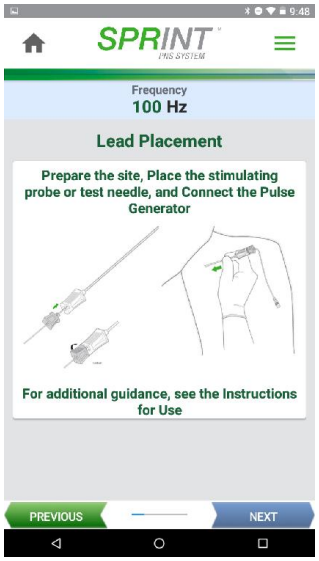
If performing a Lead Replacement with a previously programmed system, select **Lead Re-Placement** and then (if a two lead system) select which lead(s) to replace (Light Gray, Dark Gray, or Both).



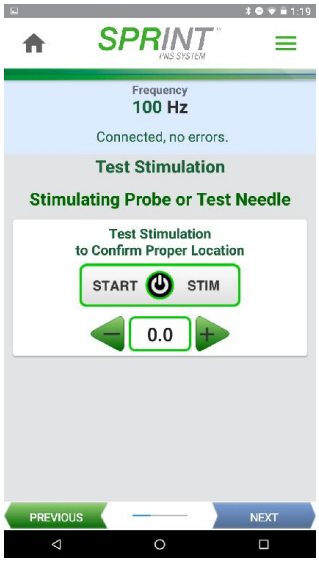

Select the desired frequency (*12Hz* or *100Hz*) appropriate for the therapeutic application.

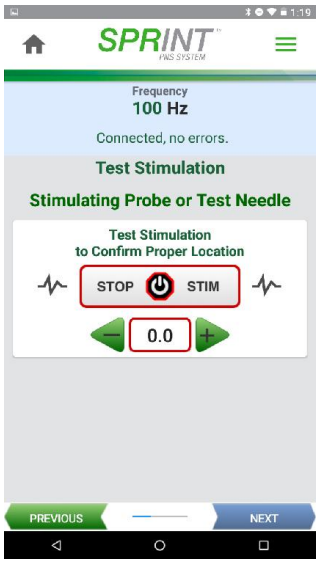
For 12 Hz, the goal is generally to induce a sense of tension in the muscle.

At 100 Hz, the goal is generally to produce a comfortable tingling sensation.




Ensure that the Stimulating Probe is in the desired location and that all connections to the Pulse Generator are in place before selecting **Next** to continue.




Select *Start* ⏻ *Stim* to begin testing stimulation.

Adjust the intensity as desired by using the (–) and (+) arrows. The number displayed between them is the intensity level. The intensity scale ranges from 1 (minimum possible intensity) to 100 (maximum possible intensity). If the intensity if set to 0, stimulation is OFF.

During Test Stimulation, intensity is adjusted in increments of 2.

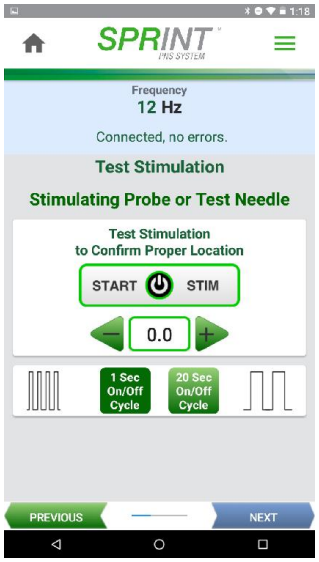
When stimulation is on, the ⏦ icon will appear on each side of the start/stop stim button.

**NOTE:** When targeting a mixed peripheral nerve under ultrasound-guidance, it may be beneficial to try several different locations and intensity levels around the nerve until an optimal response is achieved. In some cases, it may be beneficial to advance the stimulating probe across the axis of the nerve to initiate stimulation at a low intensity. It may also be useful to withdraw the introducer slowly across the nerve to assess optimal location and response.

**IF TESTING AT 12 HZ:** Stimulation at 12 Hz has two options to control stimulation cycling:

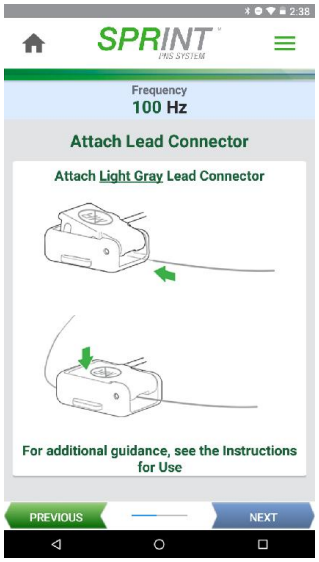
1. **Fast Cycling, or 1 Sec On/Off Cycle (default):** stimulation is delivered in periods with one second of stimulation ON followed by one second of stimulation OFF, or
2. **Slow Cycling, or 20 Sec On/Off Cycle:** stimulation is delivered in periods with a 5 second ramp up, 10 seconds of stimulation ON, and a 5 second ramp down followed by 10 seconds of stimulation OFF.

**NOTE:** The intent of the Fast Cycle approach is to allow for identification of changes in muscle tone as stimulation intensity is increased. This cycling approach is not available for procedures in which the 100 Hz frequency is used.



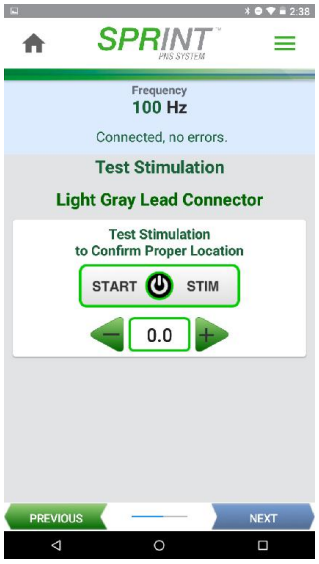

Once the desired level of stimulation has been reached, stop stimulation by pressing the *Stop* ⏻ *Stim* button and select **Next** to continue.

**NOTE:** If desired response cannot be obtained, stop stimulation, set the intensity as low as possible and adjust position as needed before testing again.




Continue optimizing MicroLead placement by following steps in *Section 4.3) Confirming Location & Placing the MicroLead(s)*.

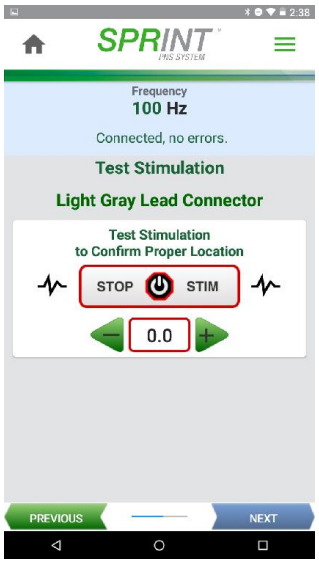
Once the MicroLead is in place select **Next** to continue




Select Start ⏻ Stim to begin testing stimulation.

Adjust the intensity as desired by using the (–) and (+) arrows. The number displayed between them is the intensity level. The intensity scale ranges from 1 (minimum possible intensity) to 100 (maximum possible intensity). If the intensity if set to 0, stimulation is OFF.

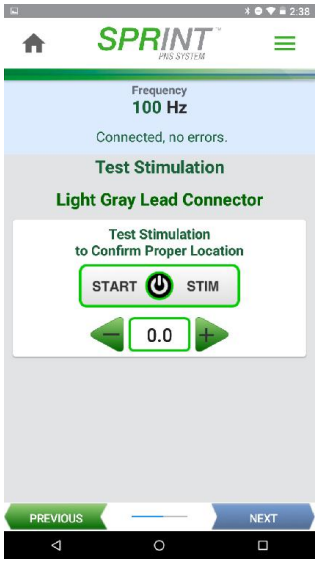
During Test Stimulation, intensity is adjusted in increments of 2.




When stimulation is on, the ⏦ icon will appear on each side of the start/stop stim button.

Once the desired level of stimulation has been reached confirming the Lead location, stop stimulation by pressing the Stop ⏻ Stim button.

With stimulation OFF, unlock the lead connector and deploy the lead. Re-connect the lead connector to the lead and confirm that the lead is in the desired location by testing stimulation again.




Select *Next* to continue with testing the second lead if performing a Dual Lead Placement or Select *Set Min/Max* for establishing therapy settings (see Section 4.4.2 Establishing Therapy Settings with the Clinical Programmer).

Note: graphic is shown with a Dual Lead Placement

## 4.3) Confirming Location & Placing the MicroLead(s)

⚠ Handle the SPRINT MicroLead, its Introducer, Percutaneous Sleeve and Stimulating Probe with extreme care. They may be damaged by excessive traction or sharp instruments.

- Do not bend, kink, or stretch the lead body or its Introducer, Percutaneous Sleeve, or Stimulating Probe.
- Do not handle the MicroLead with forceps due to risk of damaging the MicroLead.
- Be extremely careful when using sharp instruments around the MicroLead to avoid nicking or damaging the lead body insulation.
- Avoid the use of excessive force while passing the MicroLead and its Introducer through the Percutaneous Sleeve.

⚠ Retracting a MicroLead once its barb has been deployed in tissue will damage the barb. If a lead must be retracted, remove it from the body completely and insert a new MicroLead.

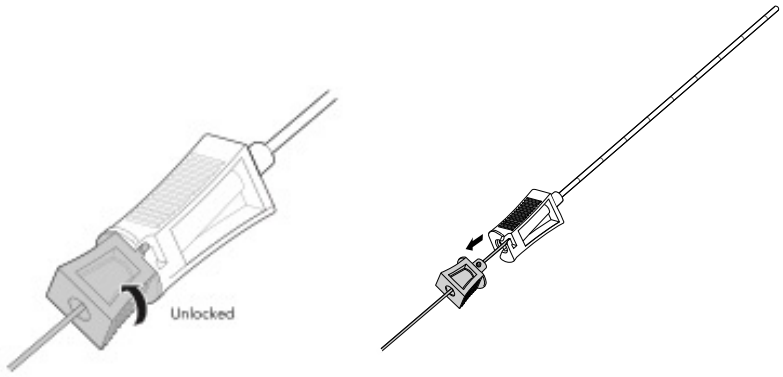
⚠ Do not reinsert a MicroLead that has been removed from the body. When a lead is removed, the anchoring barb is no longer suitable for reinsertion and anchoring into the tissue. There is also a risk that sterility of the removed MicroLead could be compromised and thus, it should not be reinserted.

⚠ Do not connect any SPRINT System component to any power source (such as A/C power mains, wall outlet) or other equipment not specified as safe for the System while it is in contact with or in use by a patient as this could result in serious injury or death.

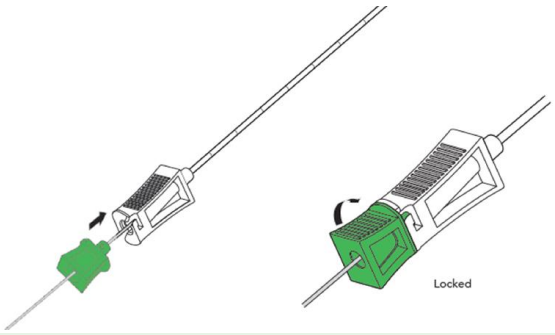
**DUAL LEAD SYSTEM:** Follow the instructions below, placing the first MicroLead (used with the light gray connector cables) and then the second MicroLead (used with the dark gray connector cables).

1. Once the optimal location for the electrode has been determined, disconnect the Stimulating Probe from the Pulse Generator.

2. Unlock the Stimulating Probe from the Percutaneous Sleeve by rotating the hub counter-clockwise and remove the Stimulating Probe, leaving the Percutaneous Sleeve in the tissue. Use one hand to hold the Percutaneous Sleeve in place to maintain its position for optimal MicroLead placement.

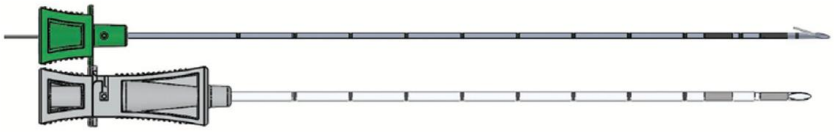



3. With the anchoring barb facing up and nested within the needle bevel, insert the MicroLead Introducer into the Percutaneous Sleeve. Align hub components and rotate the MicroLead Introducer clockwise to lock components together.

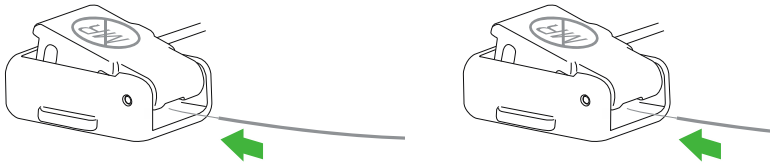



⚠ **Ensure that the distal barb of the MicroLead is hooked around the tip of the MicroLead Introducer.** If the MicroLead is protruding from the tip of the Introducer, gently pull back on the lead near the Introducer hub until the distal barb is hooked around the tip of the Introducer.

⚠ Take care when inserting the MicroLead Introducer into the Percutaneous Sleeve. The MicroLead Introducer is approximately 3mm longer than the Stimulating Probe (see image below). This ensures that the field generated by the MicroLead mimics the field that was created by the Stimulating Probe.

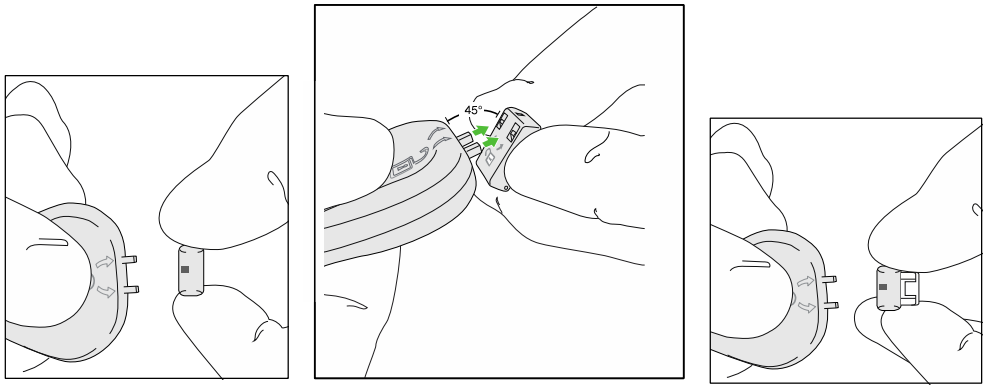


4. In order to confirm MicroLead location, insert the loose end of the MicroLead into the entry site on the hinged side of the MicroLead Connector. Shut the snap closure of the MicroLead Connector to de-insulate the MicroLead and create an electrical connection.

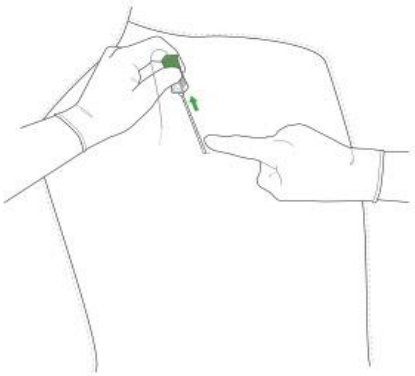


5. Use the Hand-Held Remote or the Clinical Programmer Tablet to confirm that the MicroLead location delivers desired results. Advance the MicroLead as desired or adjust stimulation settings as required to optimize results. Retracting the MicroLead Introducer will cause the barb to engage and prevent further adjustment. (*see Section: 4.2 Testing Stimulation*)

6. Once the desired location has been attained, unlock the MicroLead Connector by inserting the MicroLead Connector Key into the indented lock sites on the underside of the MicroLead Connector until the snap closure of the MicroLead Connector can be opened. Once opened, withdraw the MicroLead from the MicroLead Connector.

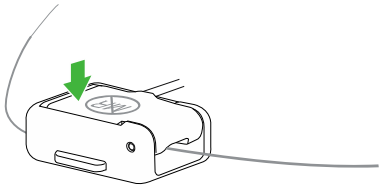



7. Deploy the MicroLead by applying pressure to the skin near the MicroLead exit site. With the other hand, gently retract the Percutaneous Sleeve with Introducer, leaving the MicroLead implanted.

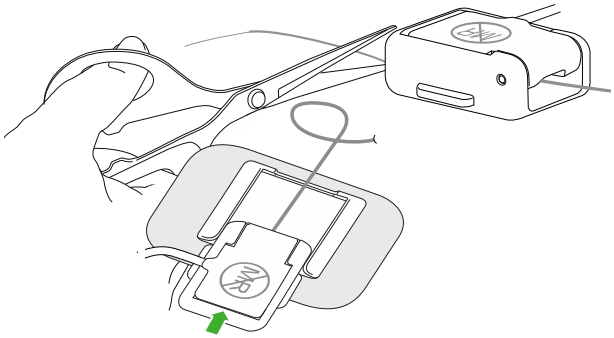


8. Re-insert the loose end of the MicroLead into the entry site on the hinged side of the MicroLead Connector assuring that adequate lead length exists between the skin exit site and the MicroLead Connector to create a strain relief loop (3-5 cm is typical). Make certain to secure the new connection closer to the skin (exit site) than the previous connection site to avoid creating a weak point in the lead.

9. Shut the snap closure of the MicroLead Connector to de-insulate the MicroLead and create an electrical connection.



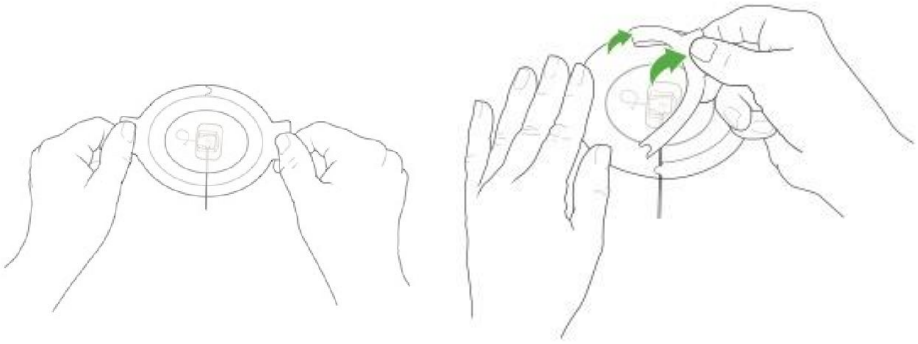
10. Trim the excess MicroLead wire.



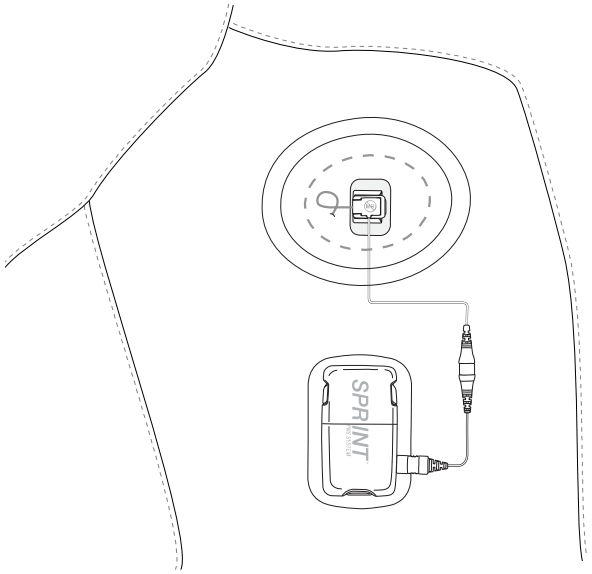
11. Slide the MicroLead Connector into the Mounting Cradle, then adhere the Mounting Cradle to the skin. The Mounting Cradle should be placed close enough to the lead exit site that the non-adhesive portion of the Waterproof Bandage can cover both the Mounting Cradle and the lead exit site.

⚠ To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.

12. Cover the MicroLead insertion site and Mounting Cradle with the non-adhesive center portion of the Waterproof Bandage, leaving the plug end of the MicroLead Connector exposed.



13. Connect the Magnetic Coupler to the Pulse Generator, using a long or short extension cable if needed.

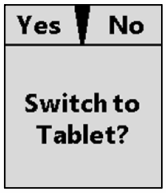
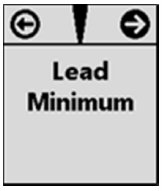
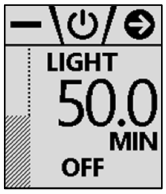


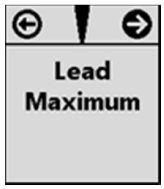
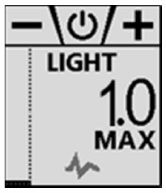
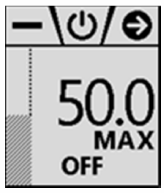
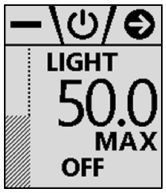
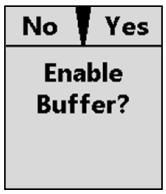

**DUAL LEAD SYSTEM:** Repeat instructions above for the second MicroLead (used with the dark gray connector cables). Connect system using the Dual Lead Adapter and long or short extensions as needed.

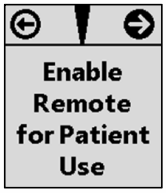
## 4.4) Establishing Therapy Settings

Use the Hand-Held Remote OR the Clinical Programmer to establish therapy settings for use by the Patient. Refer to Section 4.4.1 below if you choose the Hand-Held Remote or 4.4.2 if you wish to use the Clinical Programmer.

### 4.4.1) Establishing Therapy Settings using the Hand-Held Remote

| Single-Lead | Dual-Lead | Instructions |
|---|---|---|
|  | | Unlock or Wake Up the Hand-Held Remote. (*see Section 2.3 Operating the Hand-Held Remote*) |
|  | | To switch to the Clinical Programmer tablet select **Yes** and see *Section 4.4.2 Establishing Therapy Settings with the Clinical Programmer*.<br><br>To continue establishing therapy settings with the Hand-Held Remote select **No**. |
|  |  | To proceed to setting the minimum stimulation intensity press the ➔ button to continue.<br><br>**Dual Lead:** The MicroLead used with the light gray connector cables will be programmed first. |
|  |  | To decrease stimulation, press the − button.<br>To increase stimulation press the + button.<br><br>Once desired minimum stimulation has been reached, turn stimulation OFF by pressing the ⏻ button. |
|  |  | To set the minimum intensity and advance to setting the maximum stimulation intensity level, press the ➔ button. |

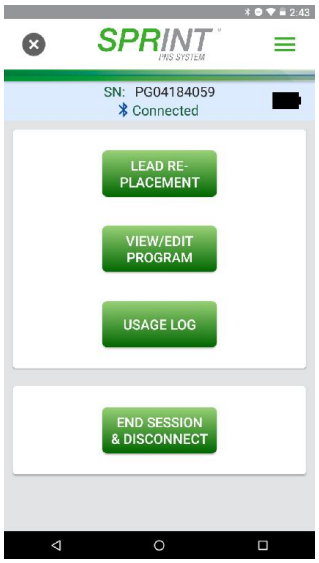
| Single-Lead | Dual-Lead | Instructions |
|---|---|---|
|  |  | The screen will briefly display **Minimum is Set,** then advance automatically to enable setting of the maximum stimulation intensity level. |
|  |  | To proceed to setting the maximum stimulation, press the ➔ button to continue.<br><br>To return to setting the minimum stimulation intensity level press the ← button. |
|  |  | To decrease stimulation, press the − button.<br>To increase stimulation press the + button.<br><br>Once the desired maximum stimulation level is reached, turn stimulation OFF by pressing the ⏻ button. |
|  |  | To set the maximum to the displayed intensity and advance, press the ➔ button. |
|  | | Enabling a buffer (or automatic maximum / auto max) allows the patient to exceed the maximum stimulation settings (by up to 12 greater intensity) for instances where higher settings may become desirable over the course of treatment.<br><br>To enable buffer press **Yes**. To move forward without enabling buffer press **No.** |

| Single-Lead | Dual-Lead | Instructions |
|---|---|---|
|  |  | The screen will briefly display **Maximum is Set**. |
| |  | **Dual Lead System:** Continue setting stimulation parameters for the second MicroLead (used with the dark gray connector cables).<br><br>Setting parameters for the second (dark) MicroLead repeats the steps used to set the parameters for the first MicroLead. |
|  | | When all settings are as desired, press the ➔ button to enable the Hand-Held Remote for patient use. This will complete lead placement, and any further setting changes will require the use of the Clinical Programmer Tablet.<br><br>To make further adjustments to stimulation settings press the ⟵ button. |
|  | | The screen will briefly display **Settings Saved & Enabled for Patient Use**. The Hand-Held Remote screen will then change to the patient user interface. |

### 4.4.2) Establishing Therapy Settings using the Clinical Programmer Tablet

If the Clinical Programmer Tablet is not connected to the Pulse Generator, turn on the tablet and connect to the Pulse Generator now (see Section 4..2.2 for instructions on connecting to the Pulse Generator).

If the Clinical Programmer Tablet was just used to test and confirm lead placement(s) and the Set Min/Max button has been pressed, the first step below (selected View/Edit Program) can be skipped.

| | |
|---|---|
|  | Select **View/Edit Program** to begin setting stimulation minimum and maximum levels. |
| **Single Lead** | Select **Start** ⏻ **Stim** to begin setting minimum and maximum stimulation levels.<br><br>To set the minimum stimulation the patient is allowed to reach, use the ◀ and ▶ buttons to decrease or increase stimulation until the desired minimum level is reached. Then tap the number below the word **MIN** to set the minimum at the currently displayed stimulation intensity level.<br><br>Immediately after placing the leads, the maximum stimulation level is set automatically by the system so that patients will have access to higher stimulation levels that may be useful during therapy. See Note below on setting the maximum intensity manually. |


Dual Lead


To adjust favorites that allow the patient to easily reach a desired stimulation level, tap one of the boxes below the word FAVORITES. This will set the currently displayed stimulation intensity value as a favorite. You can set up to 3 favorites. To remove a favorite, tap on the box of the favorite you wish to delete.

When the desired settings have been entered, tap the **Save & Finish** button in the bottom-right.

Note: To adjust the maximum stimulation intensity setting manually, tap the gear icon in the top-right of the screen and select **Manual Maximum.** This menu also allows for direct manipulation of individual parameters and changes of stimulation intensities at a finer resolution. See *Appendix B: Optional Features When Using the Clinical Programmer* for additional information.

# 5 Patient Counseling

Review the *Patient Instructions for Use*, including the warnings and precautions listed in the *Patient Instructions for Use*, with the patient. Also discuss the following topics with the patient to ensure optimal use of the SPRINT® PNS System.

## 5.1) System Use at Home

In addition to reviewing the Patient Instructions for Use, advise the patient on the following topics prior to at-home use:

- System components and use
- System set-up and appropriate placement of the Pulse Generator specific to the patient
    - Pulse Generator placement should not induce tension on the MicroLead Connector cable or MicroLead.
    - Pulse Generator placement should not be positioned in such a manner that it unduly induces motor activation.
- Care and caution should be taken to assure that the lead does not become dislodged during bandage changes.
- Physical activities that place undue stress on the MicroLead Connector or MicroLead should be avoided.
- The purpose and use of the MRI Safety Card provided on the back of the *Patient Instructions for Use*.

## 5.2) MicroLead Exit Site Care and Bandaging Instructions

Instruct the patient on proper care of the MicroLead exit site(s) and protection of the MicroLead to minimize potential for inadvertent or unintentional dislodgement.

- The Waterproof Bandage should be changed when it becomes soiled or no longer adheres well to the skin. This may also be a good time to replace the Mounting Cradle, especially if moving it to a different position would be helpful in minimizing skin irritation.
- Take care when removing the Waterproof Bandage and Mounting Cradle to prevent dislodging the MicroLead.
- Take care when placing the new Waterproof Bandage to ensure that the non-adhesive center is located over the MicroLead and Connector. The adhesive portion of the Waterproof Bandage should not come in contact with the MicroLead itself.
- Assure that all adhesive components are placed on clean, dry skin, free of lotions or cosmetic products.
- The Waterproof Bandage, Mounting Cradle, or Mounting Pad may be difficult to apply to oily skin or skin to which lotion has been applied. The skin should be cleaned with mild soap and water and allowed to dry. If adhesion is still a problem, wipe the skin with alcohol and allow it to dry.

- Check the skin beneath the Waterproof Bandage for signs of irritation, redness, or infection. If signs of infection are present, a healthcare provider should be notified.

## 5.3) Air Travel

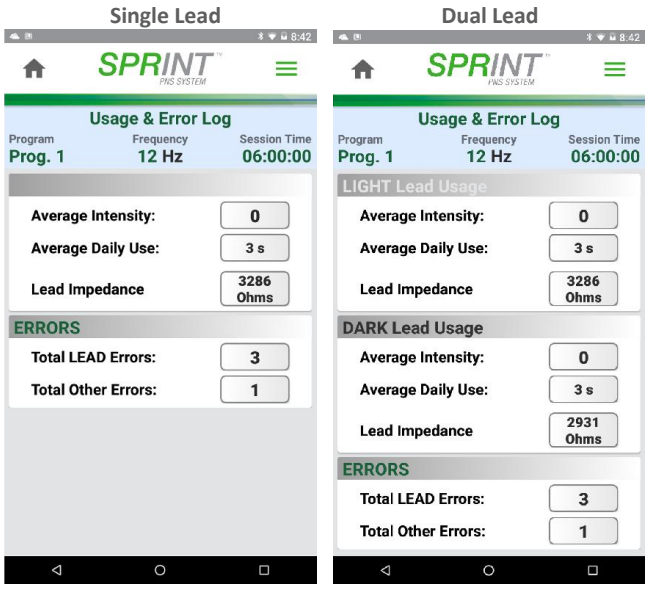
The Pulse Generator's Rechargeable Batteries contain lithium. Storage and packing the batteries during air travel must comply with all federal and international aviation regulations for spare, uninstalled, lithium batteries in carry-on bags.

Instruct the patient that it is safe to travel while using their SPRINT® PNS system, but their system may set off airport security systems. To avoid major delays or problems, patients should bring their Patient Instructions for Use which explains the purpose and nature of their system.

## 5.4) Usage Log

The Pulse Generator will keep a log of the amount (time) of stimulation used, the average intensity of stimulation used, and any Lead Connect or Other errors. This information can be useful to access when patients return to the office to help assess patient compliance with the prescribed therapy regimen.

To access the Usage Log, connect to the Pulse Generator with the Clinician Programmer (see *Section 4.4.2 Establishing Therapy Settings using the Clinical Programmer Tablet* for instructions on wirelessly connecting to a Pulse Generator). From the home screen, select *Usage Log*.




This Usage and Error Log will report the Average Intensity and Average Daily Use (in hrs) (for Dual Lead Systems, these will be reported separately for each MicroLead).

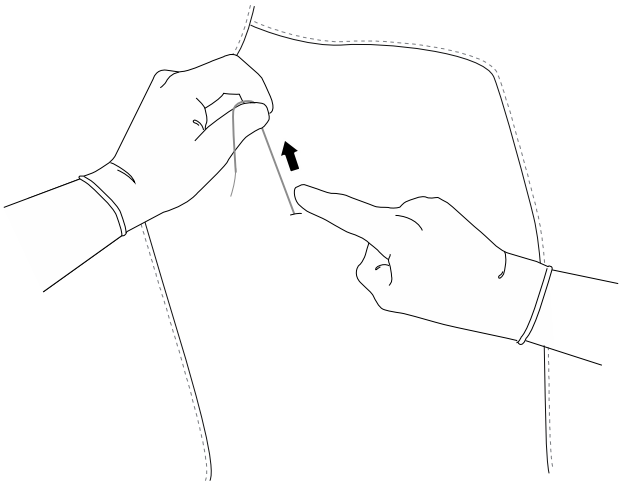
Press the ⌂ button to return to the stimulator home screen.

# 6 End of Treatment

## 6.1) MicroLead(s) Withdrawal

**To withdraw the MicroLead(s):**

1. Turn stimulation OFF.
2. Disconnect and remove all external system components.
3. If desired, cut the MicroLead close to the MicroLead Connector between the skin and the MicroLead Connector, ensuring that the potion of MicroLead that remains exposed may be easily grasped.
4. Apply pressure adjacent to the exit site and gently pull the MicroLead out of the body. The MicroLead uncoils and the barb straightens as the lead is being pulled. Repeat steps above for Dual-Lead systems.



5. Clean and bandage the MicroLead exit site.

⚠ It is possible that a fragment (or fragments) of the MicroLead could break off and remain in the body after removal. Upon removal, inspect the MicroLead for signs of damage.

If a MicroLead fragment remains after lead removal, clinical judgment should be used to determine if the fragment should be removed. The risk of fragment removal should be discussed with the patient. Refer to the MRI Safety Information in Section 1.6 for information regarding the MR compatibility of the lead fragment.

## 6.2) System Disposal

Disposal of all SPRINT® PNS System components must comply with national, state, and local laws.

The SPRINT components (other than the Clinical Programmer and it's accessories that are reusable) are for single-use and should be disposed of in compliance with all national, state, and local laws.

Rechargeable Batteries and the Hand-Held Remote must never be disposed of in a fire because they contain batteries.

APPENDIX A

# Troubleshooting

| Problem | Possible Causes | Actions to be Taken |
|---|---|---|
| Mounting Pad is not adhering to skin | Skin is not clean | Clean skin with mild soap and water and allow skin to dry OR wipe skin with an alcohol pad and allow to dry OR apply a drop of tap water to adhesive side of mounting pad OR use a new mounting pad |
| Battery icon is blinking on Remote | Rechargeable Battery is low | Replace the Rechargeable Battery |
| Screen(Remote or Clinical Programmer) shows “Recharge Battery” | Rechargeable Battery is low | Replace the Rechargeable Battery |
| Hand-Held Remote buttons are not working | Lock Switch is on | Move switch to unlocked (up) position |
| Screen (Remote or Clinical Programmer) shows “Internal Error” | Pulse Generator issue | Try removing and replacing the Rechargeable Battery; Turn stimulation back on and resume use<br><br>If problems persist, replace Pulse Generator |
| Pulse Generator not working correctly | Pulse Generator issue | If the Hand-Held Remote displays “Internal Error”, “Wireless Error”, “Lead Connect Error”, “Recharge Battery”, or “Replace Remote Battery” see the corresponding troubleshooting section<br><br>Try removing and replacing the Rechargeable Battery; turn stimulation back on and resume use<br><br>If problems persist, replace |

| Problem | Possible Causes | Actions to be Taken |
|---|---|---|
| | | Pulse Generator |
| Screen (Remote or Clinical Programmer) shows “Wireless Error” | Hand-Held Remote or Clinician Programmer out of range | Ensure the component is within arm’s length of the Pulse Generator;<br>Hand-Held Remote: Toggle lock switch down to retry connection<br>Clinician Programmer: Attempt to re-connect |
| | Bluetooth wireless connection issue | Hand-Held Remote: - Make sure the Clinical Programmer has disconnected and is OFF - Wait for the Hand-Held Remote to go to sleep and then try again<br>Clinician Programmer: Attempt to re-pair to retry connection (turn OFF and restart the Tablet Computer if necessary) |
| Stimulation sensation changes | Mounting Pad in different place than usual | Reposition Mounting Pad |
| | Mounting Pad not sticking to skin well | See troubleshooting section “Mounting Pad is not adhering to skin” |
| | MicroLead has moved | If desired response cannot be obtained by adjusting stimulus parameters, remove MicroLead and replace with new MicroLead |
| Stimulation is painful | Stimulus intensity is too high | Decrease stimulus intensity |
| | MicroLead has moved | Replace MicroLead |
| Session time remaining not decreasing | Stimulation paused or was not turned on yet | Turn stimulation on; Note that only therapies with 6hr session times will display the session time remaining |

| Problem | Possible Causes | Actions to be Taken |
|---|---|---|
| Stimulation will not turn on | Rechargeable battery is too low | Replace and recharge the Rechargeable Battery |
| | Lead Connect Error | See troubleshooting section “Screen shows Lead Connect Error” |
| Hand-held remote Screen shows “Lead Connect Error”<br><br>OR<br><br>Clinical Programmer screen shows “Connected-Lead Error” or "Open Lead" | Magnetic Coupler or Short or Long Extension not fully connected to Pulse Generator | Check connection between cable and Pulse Generator |
| | Magnetic Coupler not fully connected to Short or Long Extension | Check connection between cables |
| | Magnetic Coupler not fully connected to MicroLead Connector | Check connection between Magnetic Breakaway and MicroLead Connector |
| | Mounting Pad not well adhered to skin | Ensure Mounting Pad is secured to skin OR see troubleshooting section “Mounting Pad is not sticking to skin” |
| | Issue with the MicroLead Connector or MicroLead | Replace MicroLead Connector. If problem does not resolve, replace MicroLead. |
| Stimulation turns off on its own | Rechargeable Battery is too low | Replace and recharge the Rechargeable Battery |
| | An error has occurred | Turn stimulation back on and continue use; If the screen displays an error message, follow directions in the corresponding troubleshooting section |

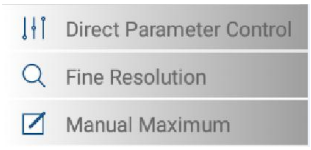
| Problem | Possible Causes | Actions to be Taken |
|---|---|---|
| MicroLead breaks away from the MicroLead Connector | MicroLead is damaged or broken at connection to MicroLead Connector | Use the Connector Key to remove the MicroLead from the MicroLead Connector; Move the MicroLead Connector approximately 1 cm closer to the MicroLead exit site, then close the MicroLead Connector (connecting the MicroLead again) |
| MicroLead will not insert into MicroLead Connector | MicroLead being inserted into wrong side of the MicroLead Connector | Thread the MicroLead through side where the hinge and funnel are located |
| | MicroLead Connector is closed | Use Connector Key to open MicroLead Connector prior to inserting MicroLead |

APPENDIX B

# Optional Features when Using the Clinical Programmer

## B.1) Optional Features

Several optional features are available while in the View/Edit Program screen. These features are described below, and can be accessed by pressing the icon (menu shown below). For a dual lead system, the menu will only make the selected feature available for the MicroLead it is associated with.




*Menu of optional features*

**Direct Parameter Control / Standard Parameter Control**

Selecting *Direct Parameter Control* will allow you to directly change the Amplitude and Pulse Duration, and to use those parameters to set the minimum and maximum allowed values.


*Direct parameter controls for setting maximum and minimum intensities*

The selected minimum and maximum values will become the stimulation minimum and maximum intensities when programmed for patient use.

To test stimulation with the newly set minimum and maximum values from a patient's perspective, press the Intensity button (indicated by green arrow in figure above) and tap the *Start Stim* button. This will change the available parameter to an intensity control now based off the minimum and maximum values that you set using amplitudes and pulse durations. This screen will allow you to set favorites for patient use (see *Section 4.4.2: Establishing Therapy Settings using the Clinician Programmer*).


*Intensity testing option using the directly set minimum and maximum intensities*

Press the Min/Max button to return to directly controlling amplitude and pulse duration to change the minimum and maximum. Tap the *Save and Finish* button to save your changes in the direct parameter control. If you return to standard parameter control without saving, your changes will be discarded.

To return to using standard parameter control (intensity adjustment only), press the icon and select *Standard Parameter Control*.

**Fine Resolution / Standard Resolution**

Selecting *Fine Resolution* will increase the resolution of the intensity adjustment step sizes (e.g., from step sizes of 1 to 0.5).

To return to standard resolution, press the icon and select *Standard Resolution*.

**Manual Maximum / Auto Maximum**

Selecting *Manual Maximum* will enable you to directly set the maximum value in a similar manner to setting the minimum value instead of utilizing the auto maximum (which automatically adds in a buffer above the highest level of stimulation tested to provide patients with additional options during the therapy period).

To return to auto maximum, press the icon and select *Auto Maximum*.

APPENDIX C

# Contacting SPR Therapeutics

Via Mail:
SPR Therapeutics, Inc.
22901 Millcreek Blvd, Suite 110
Cleveland, OH, 44122 USA

Via Telephone:
Toll Free: 844-378-9108

Via Fax:
216-803-0777

Via Email:
support@sprtherapeutics.com

APPENDIX D

# Technical Description and Specifications

## Technical Description

The SPRINT PNS System is a neurostimulation system using one or two percutaneous leads and a skin worn Pulse Generator to deliver low levels of pulsing electrical currents to selected nervous system tissue. The Pulse Generator has a rechargeable battery incorporating a Lithium Ion polymer cell. The Pulse Generator is microcontroller based 1 or 2-channel device that delivers biphasic stimulus current waveforms to percutaneous electrodes controlled by a pushbutton and a Hand-Held Remote controller and clinical programming tablet computer via Bluetooth (Low Energy) wireless communications.

## Specifications

All the components of the SPRINT System are suitable for storage and transportation between at least -20°C (-4°F) and 55°C (131°F). This includes the products in their shipping carton as well as the product as stored by the clinician or patient between uses.

All* the components of the SPRINT System are suitable for use under the following operating conditions:
- a temperature range of 5°C (41°F) to 40°C (104°F)*;
- a relative humidity range of 15 % to 90 %, non-condensing, with not more than 50 hPa of water vapor pressure; and
- an atmospheric pressure range of 700 hPa to 1,060 hPa.

None of the components of the SPRINT System are serviceable. There are no user serviceable fuses, adjustments or components other than the Coin Cell in the Hand-Held Remote. Any suspected malfunctions should be addressed by the notification of SPR Therapeutics, the return of the suspect component to SPR Therapeutics, and the replacement by SPR Therapeutics.

**Note: the Clinical Programmer (REF 9630) has an maximum operating temperature of +35°C (95°F)*

### SPRINT Waterproof Bandage (REF A0009)

| Parameter | Specification |
|---|---|
| Bandage | 3M Tegaderm™ + Pad REF 3587 |

### SPRINT MicroLead (with Introducer) (REF 80037)

| Parameter | Specification |
|---|---|
| Stimulating electrode | Length: 1.5 cm<br>Surface area: 10mm$^2$ (minimum) |
| Maximum resistance | 150 ohms |
| Introducer Length | 12.5 cm |
| Sterility | Provided sterile by Ethylene Oxide and non-pyrogenic |

### SPRINT Test Needle (REF 9645-2575 & 9645-24125)

| Parameter | Specification |
|---|---|
| Needle Length | 7.5 cm (REF 9645-2575)<br>12.5 cm (REF 9645-24125) |
| Sterility | Provided sterile by Ethylene Oxide and non-pyrogenic |

### SPRINT Stimulating Probe (REF 80048)

| Parameter | Specification |
|---|---|
| Probe Length | 12.3 cm |
| Sterility | Provided sterile by Ethylene Oxide and non-pyrogenic |

### SPRINT Percutaneous Sleeve (REF 80022)

| Parameter | Specification |
|---|---|
| Sleeve Length | 9.4 cm |
| Sterility | Provided sterile by Ethylene Oxide and non-pyrogenic |

### SPRINT Pulse Generator (REF 9610, with Rechargeable Battery: REF 9612)

| Parameter | Specification |
|---|---|
| Dimensions | Approximately 6.2cm X 3.7cm X 1.4cm |
| Mass | Approximately 30g |
| Controls & Indicators | Control and multicolor Visual Indicator is a Momentary Pushbutton on the side of the Pulse Generator's housing;<br>The Pulse Generator also generates audio attention tones |
| Wireless Communications | Bluetooth (Low Energy) |
| Output Control | Amplitude range: 0.2mA to 30mA (+/-5% for all Amplitudes above 5.0mA; below 5.0mA, accuracy of total per pulse charge is specified)<br>Frequency range: 12 – 100 Hz (+/- 0.5% averaged over 10 pulses; +/- 10% pulse-to-pulse)<br>Pulse duration range: 10µs - 200µs (+/- 4µs; below 2mA, the minimum Pulse Duration is 20µs)<br>Duty cycle range: 50% - 100% |
| Stimulus Waveform | Asymmetric biphasic, no net DC |
| Maximum Charge Per Pulse | 4 µC (For stimulus pulses with 50nC or less charge, the total per pulse |

| Parameter | Specification |
|---|---|
| | charge delivered accurate to +/- 15%) |
| Maximum Charge Density at Stimulating Electrode | 0.4 µC/$mm^2$ (when in use with the SPRINT MicroLead) |
| Maximum Current Density at Return Electrode (Pad) | 0.06$mA_{RMS}$ / $cm^2$ (1.4$mA_{RMS}$ / 25$cm^2$) |
| Range of Load Impedance | 200Ω to 1,300Ω |
| Maximum DC Current Component of Output | <1µA |
| Rechargeable Battery | 240mA-hr Lithium Ion Polymer cell with protective circuitry in protective housings |
| Time to recharge a fully exhausted Battery | Approximately 4 hours |
| Typical Battery Operating Time | Dependent on the stimulus parameters in use; most patients will be able to use the Pulse Generator for 12 to 24 hours on a fully charged Battery;<br>Baseline Operating Life: 24 hours of continuous stimulation with 1-channel stimulating at 100Hz, 20mA, 80µs, 100% duty cycle into a 1,500Ω patient circuit resistance. |
| IEC 60601-1 classification and designations | • Type BF equipment<br>• Internally powered<br>• NOT suitable for use with flammable anesthetic agents<br>• Suitable for use in the Home Healthcare Environment and the Professional Healthcare Environment |
| Service Life | 60 calendar days after the Pulse Generator is first programmed |

### SPRINT Recharging Base (REF 9615)

| Parameter | Specification |
|---|---|
| Size | Approximately 7.2cm X 4.2cm X 2.6cm |
| Mass | Approximately 60g |
| Controls & Indicators | No controls; two visual indicators; Blue light (next to the receptacle for the USB Power Adapter plug) indicates DC power is being supplied to the unit; The indicator on the top of the housing indicates if the Rechargeable Battery is charging (flashing Green), is fully charged (continuous Green), or is not charging (Yellow). |
| Charging Protections | Circuitry prevents recharging unless Rechargeable Battery cell is within specifications and the cell voltage is suitable for charging |

| Parameter | Specification |
|---|---|
| Charging Current | 115mA. |

### SPRINT Recharging Base Power Supply (REF 9616)

| Parameter | Specification |
|---|---|
| Size | Approximately 3.9cm X 3.3cm X 2.4cm |
| Description | Commercially available USB Power Adapter (with integral plug cap for US market) |
| Safety Certifications | UL (60950-1); FCC Part 15 class B; |
| Output | 5.00V (+/- 0.24V) at up to 1.0A DC (0.15A is required) |
| Mains Power | 90VAC – 264VAC; 50Hz or 60Hz |

### SPRINT Mounting Pad (REF 9618)

| Parameter | Specification |
|---|---|
| Size | Approximately 7.9cm X 5.4cm X 3.9cm |
| Skin Contacting Material | Hydrogel |

### SPRINT Hand-Held Remote (REF 9620)

| Parameter | Specification |
|---|---|
| Size | Approximately 6.5cm X 4cm X 1.7cm |
| Mass | Approximately 25g |
| Wireless Communications | Bluetooth (Low Energy) |
| Internal Battery | Lithium Coin Cell (CR2032)<br>{user replaceable with the use of a screwdriver} |
| Service Life | 60 days of typical daily use |

### SPRINT Clinical Programmer (REF 9630)

| Parameter | Specification |
|---|---|
| Size | Approximately 10.2cm X 19.3cm X 0.9cm |
| Screen | Approximately 18cm<br>1280 x 720 resolution |
| Mass | Approximately 250g |

| Parameter | Specification |
|---|---|
| Wireless Communications | Bluetooth 4.0 |
| Internal Battery | Rechargeable Lithium-Ion Battery |
| Operating Temperature | 0°C to +35°C (32°F to 95°F) |
| Safety Certifications | CE Marked; IEC 60950-1 compliant; FCC Part 15 class B; |
| Input | 5.0V DC |

### SPRINT Clinical Programmer Charger (REF 9631)

| Parameter | Specification |
|---|---|
| Size | Approximately 5.8cm X 4.2cm X 2.7cm |
| Safety Certifications | UL Listed; FCC Part 15 class B; |
| Output | 5.2V at up to 2.0A DC [max power output 10W] |
| Mains Power Input | 100-240VAC @ 50/60Hz |

### SPRINT MicroLead Connectors (REF 9650 & 9655)

| Parameter | Specification |
|---|---|
| Colors | Light Gray (REF 9650)<br>Dark Gray (REF 9655) |
| Connector | Proximal end: touchproof magnetic connector<br>Distal end: insulation displacement connector |

### SPRINT Mounting Cradle (REF 9661)

| Parameter | Specification |
|---|---|
| Skin Contacting Material | Elastic fabric and non-woven pad with perforated PE liner |

### SPRINT Dual Lead Adapter (REF 9670)

| Parameter | Specification |
|---|---|
| Connector | Proximal end: two touchproof keyhole connectors<br>Distal end: touchproof keyhole connector |

### SPRINT Short Extensions (REF 9680 & 9681)

| Parameter | Specification |
|---|---|
| Colors | Light Gray (REF 9680)<br>Dark Gray (REF 9681) |
| Connector | Proximal end: touchproof keyhole connector<br>Distal end: touchproof keyhole connector |

### SPRINT Long Extensions (REF 9685 & 9686)

| Parameter | Specification |
|---|---|
| Colors | Light Gray (REF 9680)<br>Dark Gray (REF 9681) |
| Connector | Proximal end: touchproof keyhole connector<br>Distal end: touchproof keyhole connector |

### SPRINT Magnetic Couplers (REF 9690 & 9695)

| Parameter | Specification |
|---|---|
| Colors | Light Gray (REF 9690)<br>Dark Gray (REF 9695) |
| Connector | Proximal end: touchproof magnetic connector<br>Distal end: touchproof keyhole connector |

APPENDIX E

# Symbols & Messages

### Table A: Hand-Held Remote Symbols and Messages

Table A explains the symbols and messages that appear on the Hand-Held Remote and its screen.

| Symbol or Message | Description |
|---|---|
|  | Stimulation on/off button |
|  | Stimulation is on |
| OFF | Stimulation is off |
| + | Increase |
| − | Decrease |
|  | Continue/Proceed to next screen |
|  | Go back to previous screen or action |
| R | Restart testing from the beginning |
|  | Home (return to home screen) |
|  | Lock switch is off (buttons are enabled) |
|  | Lock switch is on (buttons are disabled) |
| MIN | Intensity being set will be the minimum available |
| MAX | Intensity being set will be the maximum available |
| LIGHT | Intensity is being adjusted/set for the first MicroLead (uses light gray Connector and cables) |
| DARK | Intensity is being adjusted/set for the second MicroLead (uses dark gray Connector and cables) |
| Wireless Error | BLUETOOTH® connection issue has occurred; See Appendix A |
| Lead Connect Error | A lead connection issue has occurred; See Appendix A |
| Internal Error | An issue has occurred; See Appendix A |
| Recharge Battery | Replace and recharge the Rechargeable Battery |
| Replace Remote Battery | Replace the Hand-Held Remote battery |

### Table B: Pulse Generator Lights and Tones

Table B explains the lights and tones that are output by the Pulse Generator.

| Light or Tone | Description |
|---|---|
| Short beep<br>5 second Green light | Newly inserted Rechargeable Battery high to medium charge |
| Short beep<br>5 second Yellow light | Newly inserted Rechargeable Battery low charge |
| Short beep<br>Flashing Yellow light | Newly inserted Rechargeable Battery critically low charge; Replace and recharge |
| Short beep<br>Short Green light flash | Session started by press of Pulse Generator button |
| Single Blue light flash | Wireless command received |
| 3 short beeps<br>Flashing Yellow light | Stimulation stopped due to a low battery **OR** stimulation stopped due to an error **OR** internal error |
| Flashing Blue light | Pulse Generator is in BLUETOOTH® pairing mode |
| Short beep | Sequenced session start request (*Systems with Advanced Settings only*) |

### Table C: Clinician Programmer Symbols and Messages

Table C explains the symbols and messages that appear on the Clinical Programmer and its screen.

| Symbol or Message | Description |
|---|---|
|  | Menu |
|  | Wifi, Battery Level, and Time on the Clinician Programmer Tablet |
|  | Return to the previous screen |
|  | BLUETOOTH® signal strength between the Pulse Generator and the Clinician Programmer |
| Connected<br>OR<br>Connected, no errors. | BLUETOOTH® connection is active with the Pulse Generator with no errors |
| Connected – Lead Error<br>OR<br>Open Lead | Pulse Generator is reporting a physical connection error (e.g., unplugged cable, Mounting Pad that has peeled off, etc.) |

| Symbol or Message | Description |
|---|---|
| Low Battery<br>OR<br>Recharge Battery | Pulse Generator Battery is low |
| Hardware Error<br>OR<br>Internal Error | Hardware/Internal error in the Pulse Generator |
|  | Full Rechargeable Battery in the Pulse Generator |
|  | Mostly full Rechargeable Battery in the Pulse Generator |
|  | Partially full Rechargeable Battery in the Pulse Generator |
|  | Low Rechargeable Battery in the Pulse Generator; Replace and recharge |
|  | Disconnect from the Pulse Generator and exit to the main tablet screen |
|  | Start (or when stimulation is running, Stop) stimulation |
|  | Decrease (-) or increase (+) the displayed value (typically the stimulation intensity) |
|  | Return to the Pulse Generator home screen |
|  | Menu for optional programming features |
|  | Minimum intensity value set for the MicroLead. Pressing the box will set the minimum intensity to the current intensity value displayed for the given MicroLead |
|  | Maximum intensity value set for the MicroLead. Typically set automatically, with a buffer above the highest stimulation intensity tested.<br>If using manual maximum, pressing the box will set the maximum intensity to the current intensity value displayed for the given MicroLead |
|  | Favorites programmed for the MicroLead. Pressing the box will set the favorite to the current intensity value displayed for the given MicroLead, or if the favorite is already set will erase the favorite. |
|  | Open help overlays for the current screen |

| Symbol or Message | Description |
|---|---|
|  | Open Admin Mode (Only accessible by SPR representative) |
|  | Decrease setting to the minimum possible value |
|  | Increase setting to the maximum possible value |
|  | Information displayed relates to the Light Gray MicroLead (MicroLead connected to the light gray MicroLead Connector and cables) |
|  | Information displayed relates to the Dark Gray MicroLead (MicroLead connected to the Dark Gray MicroLead Connector and cables) |

Table D explains the symbols on products and packaging related to the SPRINT® PNS System. Not all symbols apply to the parts provided to you.

Table D: Label Symbols

| Symbol or Message | Description |
|---|---|
|  | **Model Number** |
| **Rx** only | Restricted for sale by or on the order of a physician. |
|  | **Consult accompanying documents** |
|  | **Caution:** Consult accompanying documents |
|  | **Do not reuse** |
|  | **Do not use if the product sterilization barrier or its packaging is compromised** |
|  | **Sterilized** using ethylene oxide |
|  | **Non-pyrogenic** |

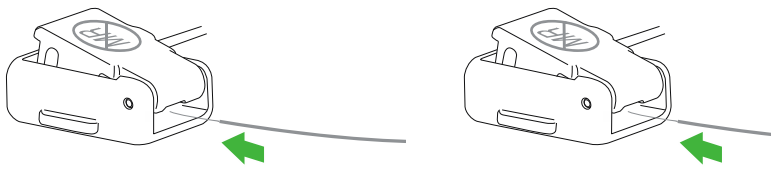
| Symbol or Message | Description |
|---|---|
|   | **Lot number** |
| SN | **Serial Number** |
|   | **Use by date (YYYY-MM-DD):** This product should be used before the specified day. |
|  | **Keep dry** |
| IP 22 | The degree of protection from water and dust offered by the Pulse Generator and Hand-Held Remote. {unintentional and limited duration exposure to light rain} |
|   | **Upper and Lower Limits of Temperature for shipping and storage** |
|  | **Type BF applied part** |
|  | **Manufacturing date** |
|  | **Manufacturer** |
|   | **MR Unsafe** |
|   | **MR Conditional** |
|   | **Not made with natural rubber latex** |

**APPENDIX F**

# Using the Stimulating Needle for MicroLead Placement Procedure

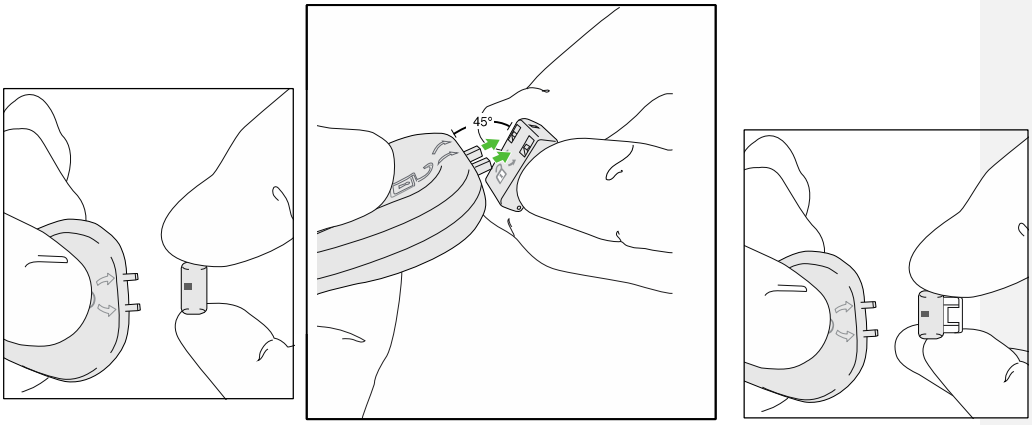
Based on physician preference, the MicroLead can be tested and placed using the Stimulating Needle in conjunction with the MicroLead Introducer.

1. Follow preparation steps in *Section 3: Procedure Preparation*.
2. Locate the target peripheral nerve. (*see Appendix G: Lead Placement in Proximity to Peripheral Nerves*)
3. Insert the Stimulating Needle through the skin in a location that provides access to the target nerve, using ultrasound or fluoroscopic guidance as appropriate.
4. Connect the Stimulating Needle to the Pulse Generator. If the connection is too short, use an appropriate length Extension Cable.
5. Follow instructions in *Section 4.2 Testing Stimulation*.
6. Once an optimal position has been identified, disconnect the Stimulating Needle from the Pulse Generator. Remove the Stimulating Needle, taking care to note the location and depth, and replace it with the MicroLead Introducer.
7. Before deploying the MicroLead, confirm location by inserting the loose end of the MicroLead into the funnel-shaped entry site on the hinged side of the MicroLead Connector. Shut the snap closure of the MicroLead Connector to de-insulate the MicroLead and create an electrical connection.



8. Use the Hand-Held Remote or the Clinical Programmer Tablet to confirm that the MicroLead location delivers desired results. Advance the MicroLead as desired or adjust stimulation settings as required to optimize results. Retracting the MicroLead Introducer will cause the barb to engage and prevent further adjustment. (*see Section: 4.2 Testing Stimulation*)

9. Once the desired location has been attained, unlock the MicroLead Connector by inserting the MicroLead Connector Key into the indented lock sites on the underside of the MicroLead Connector until the snap closure of the MicroLead Connector can be opened. Once opened, withdraw the MicroLead from the MicroLead Connector.




10. Deploy the MicroLead by applying pressure to the skin near the MicroLead exit site. With the other hand, gently retract the MicroLead Introducer, leaving the MicroLead implanted.

11. Continue following *Section 4.3 Confirming Location and Placing the MicroLead(s) step 8.*

APPENDIX G

# MicroLead Placement in Proximity to Peripheral Nerves

**The following sections provide more detailed instructions for placing the MicroLead in proximity to several common nerves targeted for pain relief:**

- the femoral nerve (lower extremity example),
- the axillary nerve (upper extremity example), and
- the medial branch of the dorsal primary ramus (back example).

These instructions are presented as possible approaches for the clinician's consideration, but are not intended as definitive or rigorous descriptions of correct lead placement technique. Lead placement decisions and technique should be determined by the clinician, based on the type and location of the pain being treated, and on standard clinical practice. The general guidance provided below can be adapted to other peripheral nerves in the upper and lower extremity or back, as needed.

### General objectives and overview of lead placement:

- The objective of peripheral nerve stimulation is to achieve pain relief.
- Stimulation delivered prior to lead implantation can assist in identifying the optimal lead location.
- The patient's report of comfortable stimulus-evoked sensations can provide guidance for lead placement.
- Lead placement may be guided by imaging (e.g. ultrasound).

### Considerations for Percutaneous Insertion Site:

When identifying the percutaneous insertion site for the MicroLead, it is important to consider where the Mounting Pad will be worn in relation to the lead exit site.

- The pad should be placed in a location such that there is minimal to no tension on the lead.
- It is recommended that the Mounting Pad and Pulse Generator be placed in a location that will be comfortable and easily accessible for the patient.
- As necessary, the lead insertion site should be adjusted to meet these criteria.

### Other considerations when placing the lead and determining the location for the lead exit location are:

- Susceptibility to motion from postural changes.
- Susceptibility to pressure from body weight, clothing, or position, and cleanliness and ease of access to clean.
- If the patient is an amputee, consideration should be given to the location of the prosthetic.

Patients generally report that the treatment induces a tingling/pressure sensation and in some cases, may report increased tension within the muscle.

It may be easier to increase muscle tension by setting the frequency to 12 Hz, and easier to induce tingling sensations with the frequency set to 100 Hz. The stimulation intensity should be adjusted until

the desired response is achieved. If the desired response cannot be obtained with the highest intensity setting, the electrode may need to be repositioned.

### Lower Extremity Example: Femoral Nerve Stimulation

As an example, the target nerve may be the femoral nerve. The MicroLead may be advanced, generally under ultrasound guidance, to the target location using an approach similar to those used for delivering regional anesthesia to the femoral nerve.

To determine a suitable location for placement of the MicroLead, electrical stimulation may be applied via the Stimulating Probe placed in various positions near the femoral nerve while evaluating the resulting desired tingling/pressure sensation. The lead may be directed toward the femoral nerve using an anterior and lateral approach. The landmarks may include the inguinal ligament, inguinal crease, tensor fasciae latae, fascia iliaca and femoral artery.

The subject may be in the supine position with ipsilateral extremity slightly (approximately 10-20$^{o}$) abducted; however, the approach may vary as needed to account for differences in individual patient body habitus. The introducer is then inserted below the inguinal crease and approximately 1 cm lateral to the femoral artery, and the MicroLead is advanced toward the nerve. Though the lead placement procedure is similar to the procedure used for a nerve block using regional anesthesia, the lead should generally not need to be as close to the nerve as the needle is for application of anesthesia during a nerve block; positioning the electrode 5–15 mm from the nerve is typical.

The lead should be placed in the optimal location, following the instructions in *Section 4: MicroLead Placement & System Set-Up.* In this location, the pad may be placed on the anterior thigh, lateral and distal to the lead exit site or in an alternative location following the guidelines in the patient Instructions for Use.

When placing the lead near the femoral nerve, the frequency should generally be set to 100 Hz. The intensity should be adjusted until a comfortable sensation covers a majority of the subject's region of pain in the distribution of the femoral nerve. If a comfortable sensation cannot be obtained, consider re-positioning the electrode.

### Upper Extremity Example: Axillary Nerve Stimulation

As an example, the target nerve may be the peripheral branches of the axillary nerve located in the deltoid muscle. The Stimulating Probe or Stimulating Needle may be used to locate the motor points of the deltoid muscle using standard locations for clinical electromyography. With the shoulder fully adducted and in neutral rotation, the target location may be approximately 3–4 cm distal and posterior to the acromion at the mid-point between the humeral tubercle and the deltoid tuberosity.

In order to induce comfortable sensations in this location, the frequency should generally be set to 12 Hz. Identification of optimal lead location will be evidenced by strong but comfortable stimulus-evoked tingling or pressure sensations during stimulation. Stimulation may also cause the muscle to be held in tension. If necessary, the electrode can be repositioned until the desired comfortable response is attained.

The lead should be placed in the optimal location, following the instructions in *Section 4: Lead Placement and System Set-up.*

**Back Example: Medial Branch of Dorsal Ramus Stimulation**

As an example, the target nerves may be the medial branches of the dorsal rami of the lumbar spinal nerve located in the multifidus (paraspinal muscle). It is necessary to use either the Stimulating Probe or the Stimulating Needle to identify the optimal position for MicroLead placement. When the electrode is in the proper location, the patient should describe comfortable sensations as tingling or pressure. These sensations may be accompanied by visible, imageable (e.g. ultrasound), or palpable changes in the degree to which the muscle is held in tension.

Desired sensations may be achieved in this region using a single MicroLead. To target this location, position the patient in a comfortable, prone position. Insert the Stimulating Probe approximately 2 cm lateral to the midline, adjacent to the spinal level of the region of greatest pain, approximately 3–5 cm deep (this may vary considerably based on patient habitus), near the anticipated location of the targeted. This technique is similar to the procedure often used for needle-based lesioning of this peripheral nerve structure.

In order to induce comfortable sensations in this location, the frequency should generally be set to 12 Hz. Identification of optimal lead location will be evidenced by strong but comfortable stimulus-evoked tingling or pressure sensations during stimulation. Stimulation may also cause the muscle to be held in tension. If necessary, the electrode can be repositioned until the desired comfortable response is attained.

The lead should be placed in the optimal location, following the instructions in *Section 4: MicroLead Placement & System Set-Up.*

APPENDIX H

# Limited Warranty

SPR warrants to Buyer that Products manufactured by SPR that are sold to Buyer will be free from defects in material and workmanship under normal use consistent with regulatory clearance for the earlier of: (a) the expiration date of the Products; or (b) one (1) year from the date of delivery of the Products ("Limited Warranty"). The exclusive remedies for failure of the Product to meet the foregoing warranty are, at SPR's option, either: (a) replacement of the defective Product; or (b) credit for the affected Product. Product complaints may be reported to SPR at any time, but to qualify for the foregoing warranty the defective Product must be returned to SPR in accordance with the Return Product Procedure, specified below . The foregoing Limited Warranty shall be void with respect to any Product that following delivery: (a) has been subject to accident, abuse, misapplication, improper repair or installation; (b) has been repaired, altered, or modified in any way; or (c) has been improperly stored or used, (d) has expired; or (e) has been used for something other than the Product's intended purpose. Buyer assumes all liability resulting from the misuse or abuse of the Product. Buyer understands Product is single use only per the Product Instructions For Use and agrees not to attempt to repurpose, relabel, recondition, reuse or reverse engineer Product.

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SPR makes no representation or warranty that the Product, in the environment of the human body, will not fail or the human body will not react adversely to the use or implantation of the Product. Suitability of the Product for a particular patient is solely a matter of the professional medical judgment of the treating medical provider(s).

This Limited Warranty is made only to, and the remedies set forth in this Limited Warranty are only available to, the original purchaser of the Product. No person has any authority to change any of the foregoing or assume or bind SPR to any additional liability or responsibility in connection with this warranty. Buyer's use of this Product shall be deemed acceptance of the terms and conditions of this Limited Warranty.

If any part or term of this Limited Warranty is held to be illegal or unenforceable by a court of competent jurisdiction, the validity of the remaining portions of this Limited Warranty shall not be affected, and the rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the part or term determined to be illegal or unenforceable.

**Return Product Procedure**

Authorization to return Products is required for all returns and may be withheld at the sole discretion of SPR. Defective Product must be returned to SPR within thirty (30) days from the invoice date, under a Return Goods Authorization (RGA) obtained from SPR. SPR will examine the returned Product and determine whether it is defective under the terms of the Limited Warranty below. Product that is opened (including the opening of and/or tampering with any packaging), damaged, expired or tampered with may not be returned for credit at any time except when a warranty claim is made. Shipping damage claims must be made by Buyer directly with the shipping company in accordance with such company's policies, and Buyer will advise SPR of such claims. Products which have been opened (including Products for which the packaging has been opened or tampered with in any way) – regardless of whether they were exposed to human tissue in any way, should be returned using an SPR-provided biohazard shipping bag and box (or similar) to ensure potentially biohazardous materials are properly quarantined to prevent exposure and/or contamination of processing personnel.


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