SPRINT®
PNS SYSTEM

CLINICIAN INSTRUCTIONS FOR USE

Additional information is found in the following materials:

Patient Instructions for Use

This manual is intended for physicians prescribing the use of the SPRINT® PNS Systems.

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The SPRINT® PNS System is manufactured by:

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

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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.

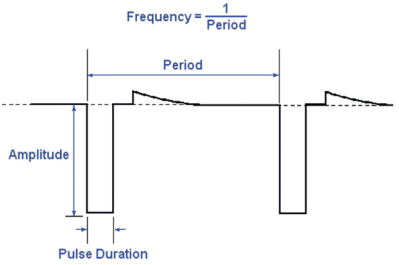


Figure G.1: Stimulus waveform; Two stimulus pulses are shown (not to scale)

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, plateau, ramp down, and gap periods of stimulation to each occur once (Figure G.2).

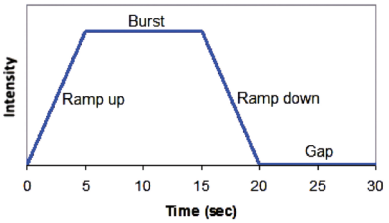


Figure G.2 One cycle of stimulation, composed of four periods: ramp up, plateau, ramp down, and gap.

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.

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

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 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 region innervated by the cranial and facial nerves.

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

Safety and effectiveness of the SPRINT® PNS System outside the scope of the indication for use statement is unknown.

1.2) Contraindications

Use of the SPRINT® PNS System is contraindicated for:

- Lead placement over the heart or across the thoracic volume.
- Lead placement in the front or side of the neck.
- Lead placement on the top of the head.
- 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 epilepsy, if the leads are intended to be placed in the head or neck.
- 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).

1.3.1) Patient Selection

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

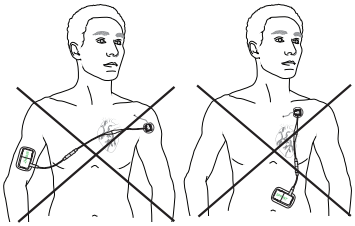
⚠ **Pediatric Use** – Safety and effectiveness have not been established for pediatric use (i.e., in a patient under 21 years of age).

⚠ **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.

1.3.2) Procedural

⚠ **SPRINT PNS System placement**

- **Do not place the SPRINT Mounting Pad on the head or on the front of the throat.** Placement of the Mounting Pad on head or front of the throat 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.
- **The line between the Mounting Pad and the tip of the MicroLead must not cross the heart; electrical current across the heart may cause rhythm disturbances, which could be lethal.**

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

⚠ **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.

⚠ **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.

⚠ **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.

⚠ **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.

1.3.3) Interference with Other Equipment

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

⚠ **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 disrupt 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 (2A02X-9610) is located on the label on the back the device.
- For more details on Electromagnetic Interference contact SPR Therapeutics. The company contact information is listed on the last page of this manual.

1.3.4) System Care

⚠ **The SPRINT System contains magnets that might interfere with active implantable medical devices in individuals that come in close contact with you.** To avoid any potential interactions, keep SPRINT components away (more than six inches/ 15 centimeters apart) from individuals who have these devices. Individuals should consult with their physician and medical device manufacturer for specific guidelines.

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

⚠ **Not waterproof** – 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.

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.

1.4.1) Procedural

Discard the Universal Test Cable (yellow) before beginning stimulation on dual channels. Failure to do so may result in uncomfortable or painful stimulation to the patient.

1.4.2) Other Medical Procedures/Treatments

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.

Electrocautery – Simultaneous connection of 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.

1.4.3) Patient Care

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.

MicroLead Dislodgement or Fracture – Avoid pulling on the MicroLead or anything connected to it, which may cause the MicroLead to be pulled out or to fracture. 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.

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

1.4.4) System Care

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.

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

Pulse Generator may get warm – The outside surfaces of the Pulse Generator may become warm to the touch during use (2.4°C [4.3°F] above ambient temperature). This warming is normal and does not represent a problem with the device or its settings. Should the Pulse Generator become uncomfortably warm, stop the stimulation and wait for it to cool, or move it to a nearby location where it is covered less by clothing or better able to remain cool.

Broken or Disconnected Cable – If a cable breaks or becomes disconnected, stop stimulation and replace the broken component or reconnect the components, as applicable. A broken or disconnected cable may deliver a safe but uncomfortable stimulation lasting a few seconds.

1.4.5) Interference with Other Equipment

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.

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. Pull out the Lead and remove all other System components from the patient before an MRI examination is performed.

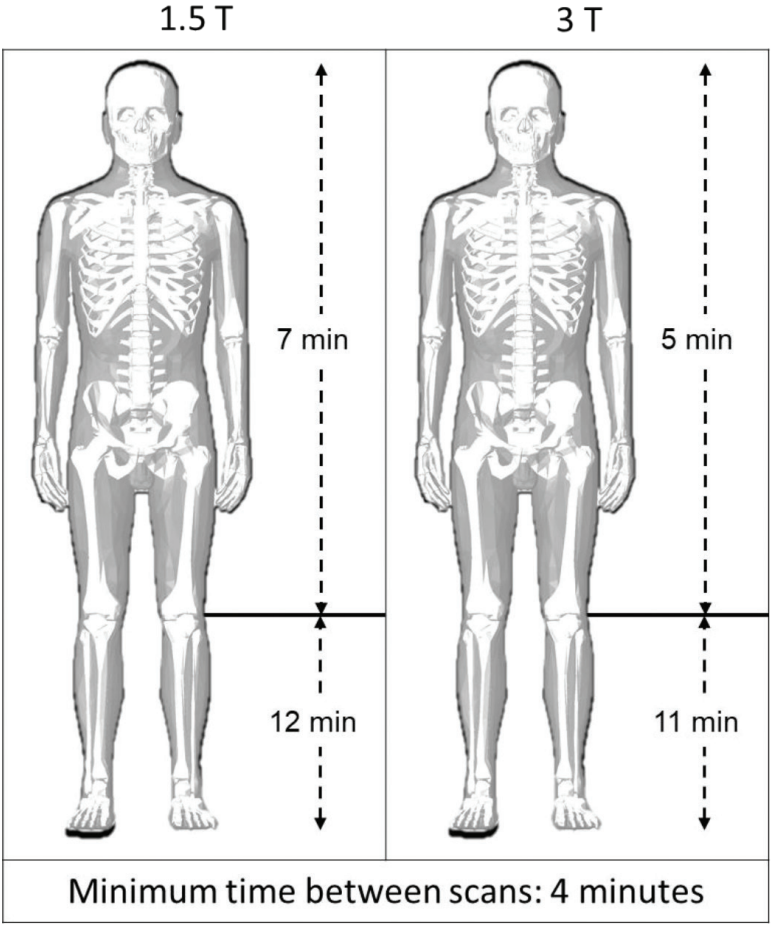
In the case of a Lead fracture beneath the skin resulting in a retained lead remnant, an MRI examination is safe to perform under the conditions described in the **MR Conditional** statement below.

A retained Lead Remnant ONLY is MR Conditional – A person with a retained Lead remnant may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	Retained MicroLead remnant
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	20 T/m (2,000 G/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2 W/kg Maximum Head SAR: 3.2 W/kg Maximum Partial Body SAR: 2-10 W/kg *
Scan Duration	For 1.5 T MR Scanner: Scan for up to seven minutes for landmarks above the knee and 12 minutes for landmarks below the knee. Wait a minimum of four minutes before the next imaging session. For three T MR Scanner: Scan for up to five minutes for landmarks above the knee and 11 minutes for landmarks below the knee. Wait a minimum of four minutes before the next imaging session.
Scan Regions	Any landmark is acceptable
Image Artifact	The presence of the MicroLead remnants may produce an image artifact of 0.8 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.

* The limit (pbSARlim) scales dynamically with the ratio of exposed patient mass to patient mass:
$pbSAR_{lim} = 10W/kg - (8W/kg \times \frac{\text{exposed patient mass}}{\text{patient mass}})$

Acceptable Scanning Regions and Duration

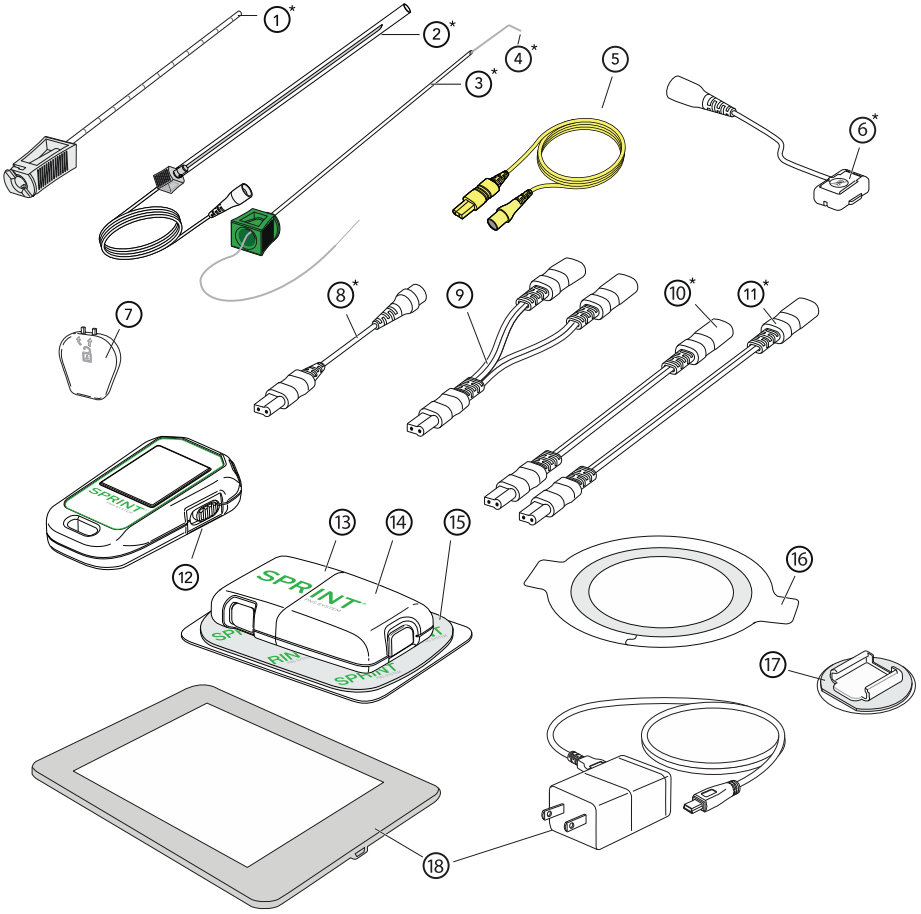


NOTE: There should be no section of Lead visible above the skin.

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

2 SYSTEM OVERVIEW

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



* Indicates that two (2) of each component are included for a Dual-Lead System.

NOTE: Components not shown to scale.

2.1) System Components

Sterile Components

1. **Percutaneous Sleeve (REF 80022):** Part of the MicroLead™ OnePass Introducer™ System, the Percutaneous Sleeve is used for testing stimulation and placing the MicroLead.
2. **Stimulating Probe (REF 80088):** Part of the OnePass Introducer™ System, used to test stimulation prior to MicroLead™ placement.
3. **MicroLead Introducer (REF 80024):** Part of the MicroLead™ OnePass Introducer™ System, the MicroLead Introducer is used to insert the MicroLead.
4. **MicroLead (REF 80067):** 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. **Universal Test Cable (REF 80090):** Used to connect the OnePass components to the Pulse Generator for testing stimulation levels during the implant procedure.
6. **MicroLead Connector (Light & Dark) (REF 9650 & 9655):** 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 cable connector (Light) and the other with a dark cable connector (Dark).)
7. **MicroLead Connector Key (REF 9659):** The key that unlocks the MicroLead Connector when reconnection by the clinician is desired.
8. **Magnetic Coupler (Light & Dark) (REF 9690 & 9695):** Breakaway system between the MicroLead Connector and the Pulse Generator intended to minimize the potential for MicroLead dislodgement. (Dual-Lead Systems come with two Magnetic Couplers, one with a light cable connector (Light) and the other with a dark cable connector (Dark).)
9. **Dual-Lead Adapter (REF 9670):** 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™ Systems)
10. **Short Extension (Light & Dark) (REF 9680 & 9681):** Allows for 15 cm of extra length between the Magnetic Coupler and the Pulse Generator. (Not necessary for use)
11. **Long Extension (Light & Dark) (REF 9685 & 9686):** Allows for 36 cm of extra length between the Magnetic Coupler and the Pulse Generator. (Not necessary for use)

Non-Sterile Components

12. **Hand-Held Remote (REF 9620):** 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.
13. **Rechargeable Battery (REF 9612):** The power source used to run the Pulse Generator.
14. **Pulse Generator (REF 9610):** The device that produces the electrical pulses used to deliver stimulation therapy.
15. **Mounting Pad (REF 9618):** 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.
16. **Waterproof Bandage (REF 9660):** Intended to keep the Lead exit site clean and dry and to minimize the risk for Lead dislodgement.
17. **Mounting Cradle (REF 9662):** Adhesive pad that holds the MicroLead Connector in place near the MicroLead exit site to minimize the potential for Lead dislodgement.
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. See [Clinical Programmer IFU] for details
    Clinical Programmer Charger: USB cord and AC adapter plug used to recharge the Clinical Programmer. See [Clinical Programmer IFU] for details
19. **Patient Take-Home Kit:** (Not shown) Includes Recharging Base and Power Supply (recharges the Rechargeable Batteries for the Pulse Generator), extra Rechargeable Battery, Mounting Cradles, Mounting Pads, and Waterproof Bandages.
20. **Starter Bag:** (Not Shown) Includes Instructions for Use, and helpful materials for using the system at home.

2.2) Programming Tools Overview

Initial programming of the Pulse Generator may be performed using either the Hand- Held Remote (provided non-sterile) or the Clinical Programmer (provided non-sterile – refer to the Clinical Programmer Instructions for Use, or IFU). 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 Clinical Programmer is able to access advanced programming features not available to be programmed by the Hand-Held Remote.

To unlock your Remote
Move the Lock/Unlock Switch to the up position.

To lock your Remote
Move the Lock/Unlock Switch to the down position.

To wake up your Remote
Your Remote will go to sleep after a period of inactivity. To wake up the Remote, press any button or move the Lock/Unlock Switch to the Up/Unlocked position.

Hand-Held Remote

The startup screen will show for a few seconds while the Remote connects 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. Wait 30 seconds after removing plastic tab before turning "on" the Hand-Held Remote to allow to sync.

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. Instructions on the use of the Clinical Programmer are included in the Clinical Programmer IFU. Contact your SPR representative about receiving a Clinical Programmer or Clinical Programmer IFU.

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

NOTE: When not in use, power off the Clinical Programmer. This helps to clear the cache and reduces potential connectivity issues.

2.3) Device Types

There are three SPRINT systems: endura®, extensa®, and extensa XT™. The endura is used to deliver stimulation to a single MicroLead (Single-Lead) while extensa and extensa XT are designed to deliver stimulation to two MicroLeads (Dual-Lead).

When programing your device with the Hand-Held Remote the following configurations are possible. For additional configurations, including different timed sessions, use the Clinical Programmer.

- **endura:** Single-Lead 12 Hz with six hour timed session or Single-Lead 100 Hz untimed session
- **extensa:** Dual-Lead at 12 Hz with six hour timed session or Dual-Lead at 100 Hz untimed session. Intensity may be independently adjusted per Lead
- **extensa XT:** Dual-Lead Bimodal where one Lead delivers stimulation at 12 Hz and one Lead delivers stimulation at 96 Hz. The Clinician can select which Lead is 12 Hz and which lead is 96 Hz. The 12 Hz lead will default to a six hour timed session, while the 100 Hz lead will default to an untimed session. See table below:

		endura	extensa	extensa XT
Single Lead (Light)	**12 Hz** *Six Hour Session*	✓		
	100 Hz *Unlimited Session*	✓		
Dual Lead (Light & Dark)	**12 Hz** *Six Hour Session (Both Leads)*		✓	✓
	100 Hz *Unlimited Session (Both Leads)*		✓	✓
	Bimodal™			
	12 Hz *Six Hour Session (One Lead)* AND **96 Hz** *Unlimited Session (One Lead)*			✓

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:

- 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).

⚠ WARNING
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.

⚠ WARNING
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.

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

- The packaging has been pierced, damaged, or altered;
- A 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
- Mounting Pad
- Hand-Held Remote
- Clinical Programmer (non-sterile) (optional)
- MicroLead™ OnePass Introducer™ System
  - Percutaneous Sleeve
  - Stimulating Probe
  - MicroLead with MicroLead Introducer
- Universal Test Cable
- 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 ultrasound probe cover (if using ultrasound guidance)
- Dermabond®

3.4) Prepare the Patient Take-Home Kit

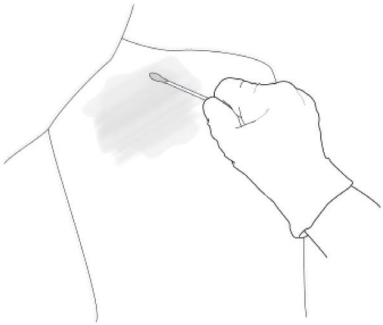
Ensure that the Patient Take-Home Kit is ready for patient use and includes the following:

- Recharging Base and Power Supply
- Second Rechargeable Battery (this is included in the Sterile tray and needs to be transferred to the patient Take-Home kit)
- Waterproof Bandages (Style may vary)

- Mounting Cradles
- Mounting Pads
- Patient Instructions for Use

3.5) Prepare the MicroLead Exit Site(s)

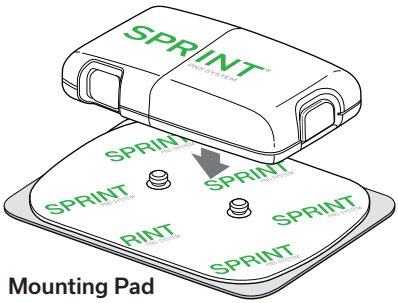
1. With the patient appropriately positioned, clean the skin following your institution's guidelines for aseptic technique. Clip (do not shave) hair as necessary.



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.

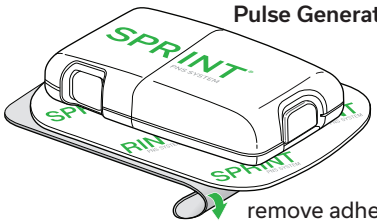
NOTE: Do not administer the local anesthetic into deep tissues. Administering anesthetics close to the terminal position of the electrode could affect the response to stimulation.

3. Snap the Pulse Generator onto the Mounting Pad.



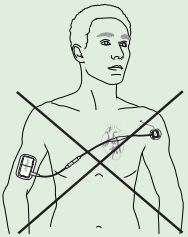
Mounting Pad

4. Slowly remove Mounting Pad from the clear adhesive liner.



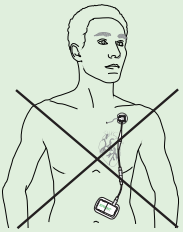
5. Attach the Mounting Pad with Pulse Generator onto clean skin outside of the sterile field, in an area away from motor points and away from the Lead insertion site. Sensations of motor activity may occur beneath the Mounting Pad and Pulse Generator.

⚠ WARNING
The line between the Mounting Pad and the tip of the MicroLead must not cross the heart; electrical current across the heart may cause rhythm disturbances, which could be lethal.



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

⚠ WARNING
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.

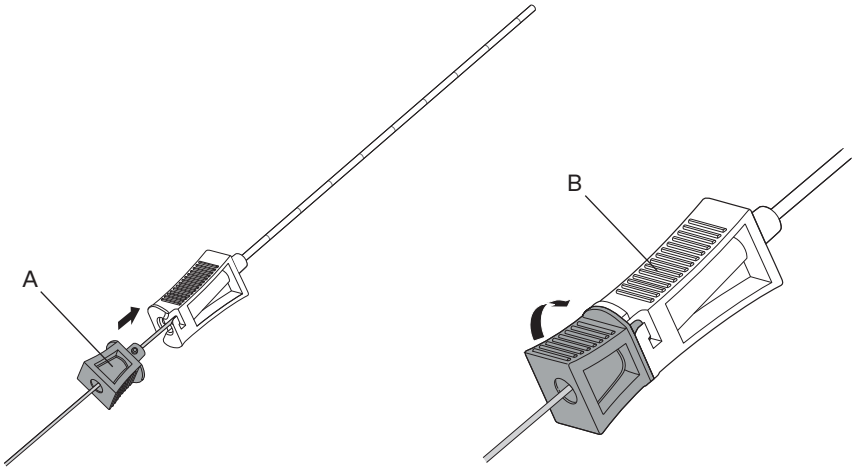


4 MICROLEAD PLACEMENT & SYSTEM SET-UP

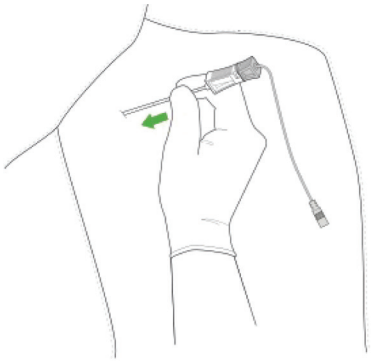
4.1) Identifying Lead Placement Target using the OnePass Introducer™ System

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

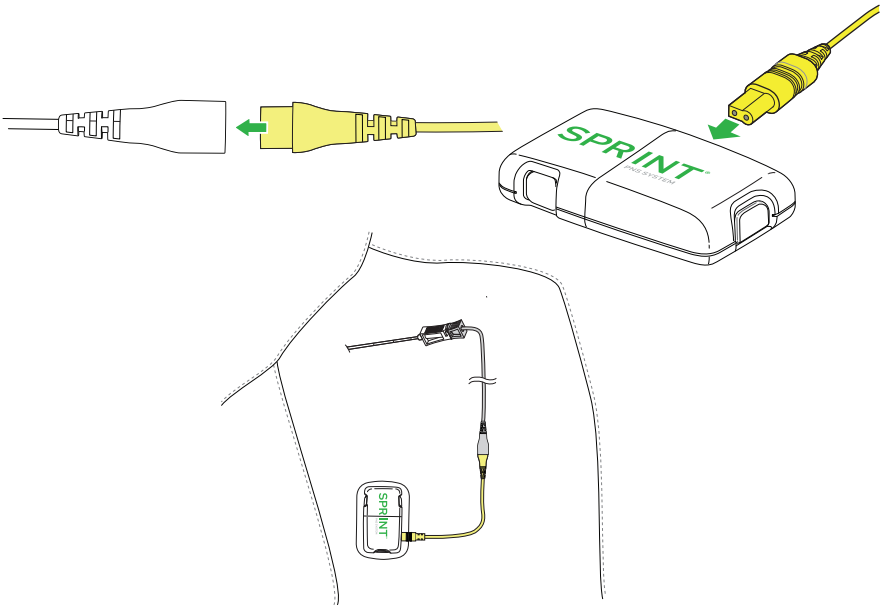
2. Insert the Stimulating Probe (A) into the Percutaneous Sleeve (B) (see figure below). Align hub components and rotate the Stimulating Probe clockwise to lock components together prior to insertion into the body.



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 Universal Test Cable and insert the connector end of the Universal Test Cable into the receptacle on the Pulse Generator.



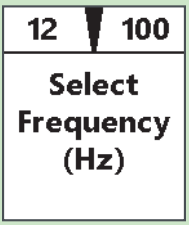
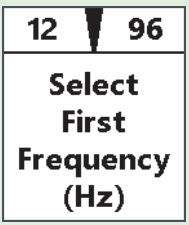
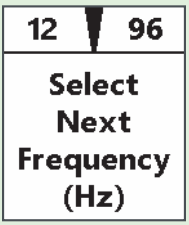
4.2) Testing Stimulation

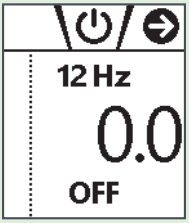
During the initial Lead placement, use the Hand-Held Remote OR the Clinical Programmer (Optional) to test stimulation with the Stimulating Probe. Refer to Section 4.2.1 below if you choose the Hand-Held Remote or Clinical Programmer IFU if you wish to use the Clinical Programmer. If testing stimulation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

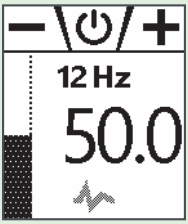
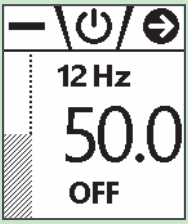
4.2.1) Testing Stimulation with the Hand-Held Remote

SINGLE-LEAD: Follow the instructions below using the light connector cables provided with the system.

DUAL-LEAD: Follow the instructions below, optimizing placement of the first MicroLead (used with the light connector cables) and then proceed to optimize placement of the second MicroLead (used with the dark connector cables).

Instructions	Remote Screens
Unlock or Wake Up the Hand-Held Remote. The type of system (endura, extensa, extensa XT) will briefly display on the wake up screen. Testing screens vary slightly when using extensa XT	
endura and extensa To select the desired frequency (12 or 100 Hz), press the button associated with 12 or the button associated with 100. 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 D for additional recommendations regarding which frequency to use with different lead locations. Use of 12 Hz will set the patient stimulation session time to six hours. Use of 100 Hz will set the patient stimulation session time to unlimited (continuous). Session time and frequency information is summarized in the table in section 2.3.	
extensa XT When configuring an extensa XT system you will be presented with the screen “Select First Frequency (Hz)”. Frequency options are 12 and 96 Hz. When testing is complete on the first lead a prompt to “Select Next Frequency (Hz)” will be displayed. Frequency options are 12 and 96 Hz. For 12 Hz, the goal is generally to induce a sense of tension in the muscle. At 96 Hz, the goal is generally to produce a comfortable tingling sensation. See Appendix D for additional recommendations regarding which frequency to use with different Lead locations. Use of 12 Hz will set the patient stimulation session time to six hours. Use of 96 Hz will set the patient stimulation session time to unlimited (continuous). If Bimodal is selected only the 12 Hz Lead will be a timed session. Session time and frequency information is summarized in the table in section 2.3.	 

Instructions	Remote Screens
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. To start stimulation press the ⏻ button.	
This is an instructional screen that appears for a set amount of time. To pause stimulation, press the ⏻ button. Press ➔ to continue. The ➔ button will appear as an option only when stimulation is paused.	
To begin increasing stimulation intensity press the + button. **NOTE:** When stimulation is on, the ⏦ symbol will be shown on the screen. When stimulation is off, **OFF** will appear on the screen. **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 two during Lead placement testing.	

Instructions	Remote Screens
To decrease stimulation intensity, press the **−** button. To increase stimulation intensity, press the **+** button. **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 Stimulating Probe and Sleeve 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. Continue confirming placement and placing the MicroLead by following steps in Section 4.3: Confirming Location & Placing the MicroLead(s). Then press the ➔ button to continue. **NOTE:** If desired response cannot be obtained, stop stimulation, set intensity as low as possible and adjust position as needed before testing again.	
If all settings are correct, press the ➔ button to continue. To erase settings and restart the process, press the **R button**. To return to testing stimulation press the ⬅ button.	

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.

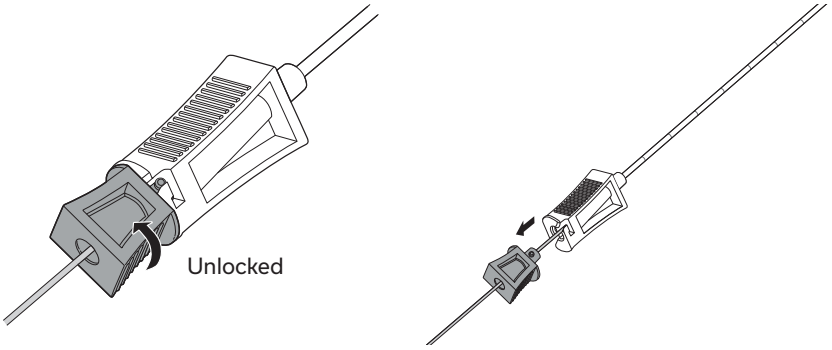
⚠ WARNING
Do not connect any SPRINT System component to any power source (such as A/C power mains, wall outlet) or other equipment not specified as safe for the System while it is in contact with or in use by a patient as this could result in serious injury or death.

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

4.3.1) Deploying a Lead

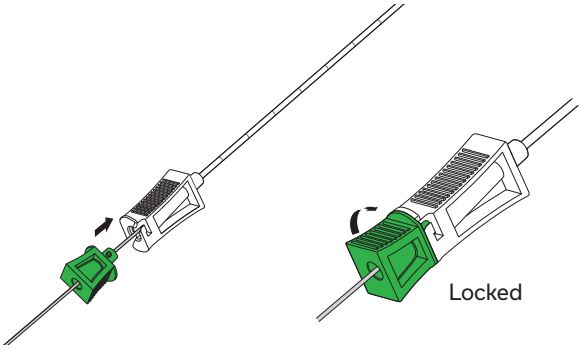
1. Once the optimal location for the electrode has been determined, disconnect the Stimulating Probe from the Pulse Generator.

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.

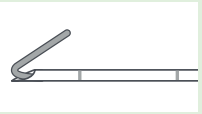


NOTE: Hold the proximal end of the MicroLead when removing the protective sheath from the MicroLead Introducer to prevent Lead displacement.

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.

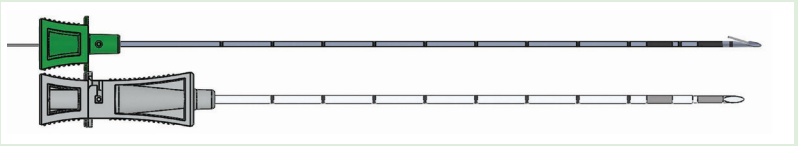


Ensure that the distal barb of the MicroLead is hooked around the tip of the MicroLead Introducer. If the MicroLead is protruding from the tip of the Introducer, gently pull back on the Lead near the Introducer hub until the distal barb is hooked around the tip of the Introducer.

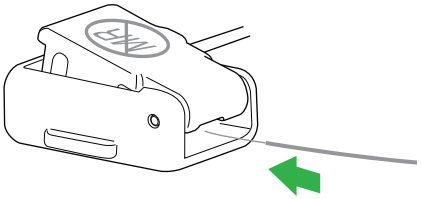


⚠ WARNING

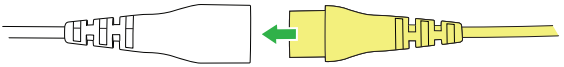
Take care when inserting the MicroLead Introducer into the Percutaneous Sleeve. The MicroLead Introducer is approximately 3mm longer than the Stimulating Probe (see image below). This ensures that the field generated by the MicroLead mimics the field that was created by the Stimulating Probe.



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.

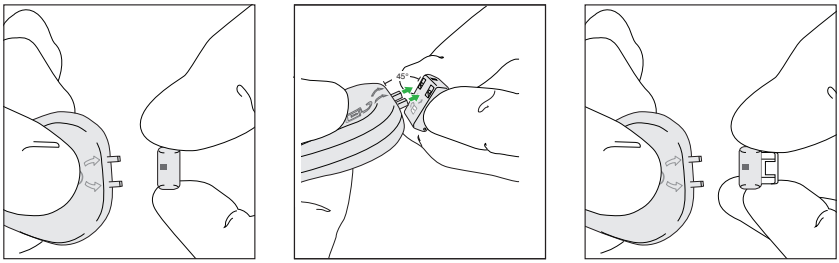


5. Connect the MicroLead Connector to the straight, de-insulated end of the Lead. Connect the magnetic end of the Universal Test Cable to the MicroLead Connector.

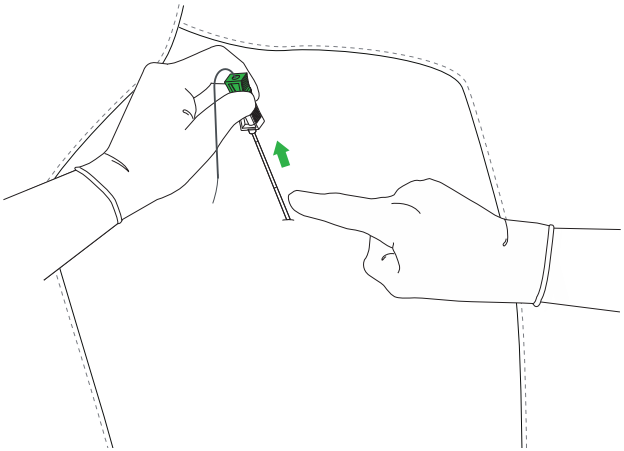


6. Use the Hand-Held Remote or the Clinical Programmer Tablet to confirm that the MicroLead location delivers desired results. Advance the MicroLead as desired or adjust stimulation settings as required to optimize results. Retracting the MicroLead Introducer will cause the barb to engage and prevent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

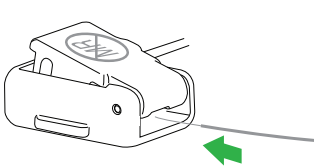
7. Once the desired location has been attained, unlock the MicroLead Connector by inserting the MicroLead Connector Key into the indented lock sites on the underside of the MicroLead Connector until the snap closure of the MicroLead Connector can be opened. Once opened, withdraw the MicroLead from the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



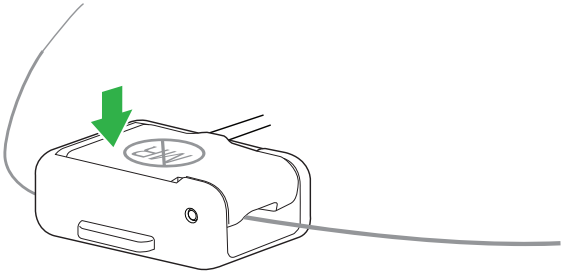
8. Deploy the MicroLead by applying pressure to the skin near the MicroLead exit site. With the other hand, gently with Introducer, leaving the MicroLead implanted.



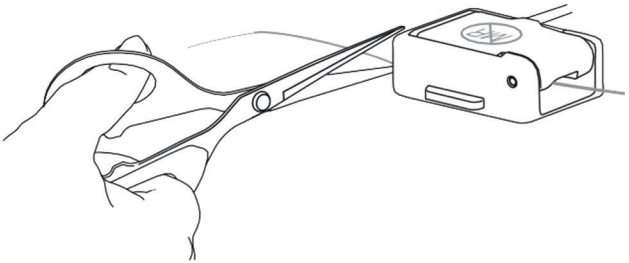
9. Re-insert the loose end of the MicroLead into the entry site on the hinged side of the MicroLead Connector assuring that adequate Lead length exists between the skin exit site and the MicroLead Connector to create a strain relief loop (3-5 cm is typical). Make certain to secure the new connection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



10. Shut the snap closure of the MicroLead Connector to create an electrical connection.

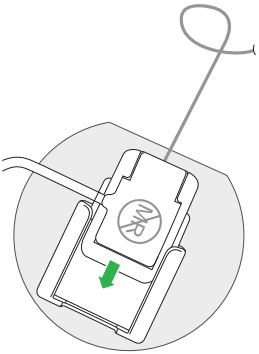


11. Trim the excess MicroLead wire.

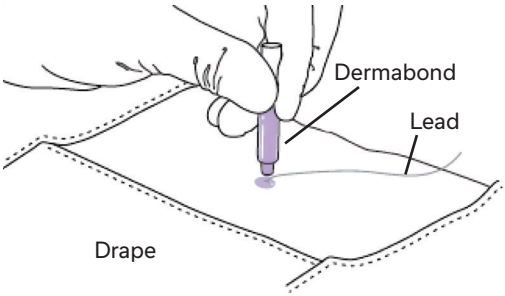


12. Slide the MicroLead Connector into the Mounting Cradle, then adhere the Mounting Cradle to the skin. The Mounting Cradle should be placed close enough to the Lead exit site that the non-adhesive portion of the Waterproof Bandage can cover both the Mounting Cradle and the Lead exit site.

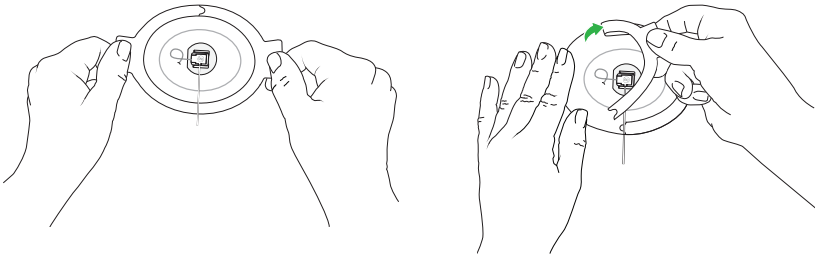
⚠ To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.



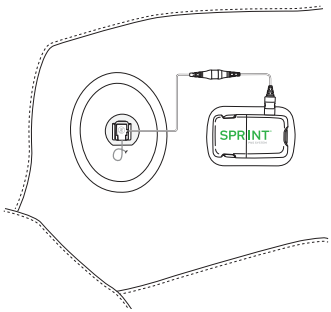
13. Place a small drop of Dermabond® at the MicroLead exit site to help secure the MicroLead. Allow the Dermabond® to dry completely before bandaging. Applying the bandage before the Dermabond® has completely dried may result in inadvertent removal of the Lead.



14. 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.



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



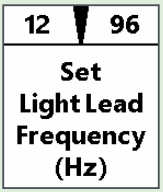
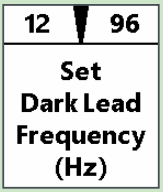
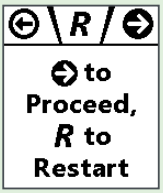
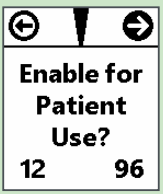
DUAL-LEAD SYSTEM: Repeat instructions above for the second MicroLead (used with the dark connector cables). Connect System using the Dual-Lead Adapter and long or short extensions as needed.

4.4) Establishing Therapy Settings

Hand-Held Remote – endura and extensa

Instructions	Remote Screens
To make further adjustments to stimulation settings press the ⊖ button. 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.	
The screen will briefly display **Settings Saved & Enabled for Patient Use**. The Hand-Held Remote screen will then change to the patient user interface.	

Hand-Held Remote – extensa XT

Instructions	Remote Screens
Upon completing the 2nd round of test stimulation (pressing the ➔ button), the Hand-Held Remote will prompt selection of 12 Hz or 96 Hz for the LIGHT Lead.	
After making a selection for the LIGHT Lead, a prompt to select 12 Hz or 96 Hz for the DARK Lead will display.	
You may press the ← button to amend your selection, [R] to restart the test process, or ➔ to proceed to a confirmation screen.	
The confirmation screen displays the frequencies selected. LIGHT Lead frequency selection is on the Left. DARK Lead frequency is on the right. By default, Leads programmed to deliver 12 Hz stimulation will be configured with a six hour timer. Session time and frequency information is summarized in the table in section 2.3.	
The screen will briefly display **Settings Saved & Enabled for Patient Use**. The Hand-Held Remote screen will then change to the patient user interface.	

Using the screens above, extensa XT may be programmed using the Remote to deliver the same stimulation frequency on both Leads (Dual-Lead) or different stimulation on each Lead (Bimodal). NOTE: If 96 Hz is selected for both Leads, the confirmation screen will default to 100 Hz stimulation on both Leads.

Once settings are saved and the Remote is enabled for patient use, discard the Universal Test Cable. If further testing is required for either Lead or additional parameter control is desired, use a Clinical Programmer.

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 ensure that the Lead does not become dislodged during bandage changes. For additional instruction, see section 5.2 – MicroLead Exit Site Care and Bandaging Instructions.
- Limit strenuous physical activity and motion (such as twisting, bending, climbing, lifting) near the implant for at least one week to minimize the likelihood of Lead dislodgement or fracture.
- Avoid undue stress on the MicroLead Connector or MicroLead (such as tugging, pressure, heat) that may damage the System or cause the Lead to dislodge or fracture.
- The purpose and use of the MRI Safety Card provided in the Patient Take-Home Kit.

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 dislodgement.

- The Waterproof Bandage should be changed weekly or when it becomes soiled or no longer adheres well to the skin. This may also be a good time to replace the Mounting cradle (which should also be changed weekly), especially if moving it to a different position would be helpful in minimizing skin irritation.
- Do not submerge the MicroLead exit site(s) in water.
- 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 contact the MicroLead.
- Assure 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 of the batteries during air travel must comply with all federal and international aviation regulations for spare, uninstalled, lithium batteries in carry-on bags.

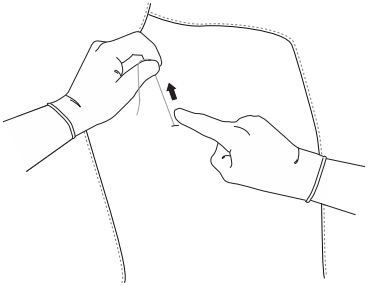
Instruct the patient that it is safe to travel while using their SPRINT® PNS System, but their System may set off airport security systems. To avoid major delays or problems, patients should bring their Patient Instructions for Use which explains the purpose and nature of their System. Similar information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

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 portion 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 MicroLead is being pulled. If resistance is encountered while removing the MicroLead, pause briefly and release any pressure that was applied adjacent to the exit site. Once released, resume gently pulling on the MicroLead. Repeat steps above for a Dual-Lead Systems.



5. Clean and bandage the MicroLead exit site.

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

⚠ WARNING
If a MicroLead remnant remains after Lead removal, clinical judgment should be used to determine if the remnant should be removed. The risk of remnant removal should be discussed with the patient. Refer to the MRI Safety Information for information regarding the MR compatibility of the Lead remnant.

6.2) System Disposal

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

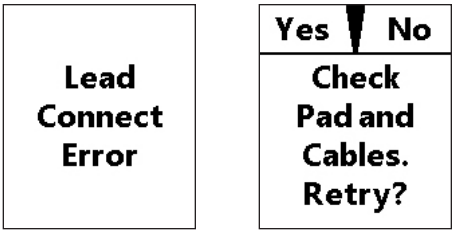
The SPRINT components (other than the Clinical Programmer and its accessories) are for single-use and should be disposed of in compliance with all national, state, and local laws.

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

TROUBLESHOOTING

A.1) "Lead Connect Errors"

During Lead Placement – while using Stimulating Probe



Actions to be taken in order: Test stimulation between each step as appropriate.

1. Confirm screen says, "Lead Connect Error; Check Pad and Cables. Retry?"
2. Ensure that the correct screen is displayed (note that the Stimulating Probe should NOT be used when the testing screen says "CONFIRM")
3. Confirm Pulse Generator is firmly connected to the Mounting Pad. Confirm the Mounting Pad is firmly connected to the Patient's skin.
4. Confirm the Stimulating Probe's cable is firmly connected to the Pulse Generator. (If using Extension Cables, including the Universal Test Cable,between the Stimulating Probe and Pulse Generator, confirm all connections are secure.)
5. Replace the Mounting Pad with a new one.
6. Replace the Stimulating Probe with a new one.
7. Replace the Pulse Generator with a new one.

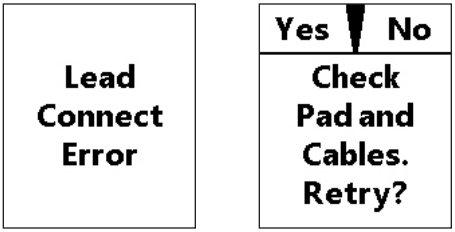
During Lead Placement – while using MicroLead Connector

Actions to be taken in order: Test stimulation between each step as appropriate.

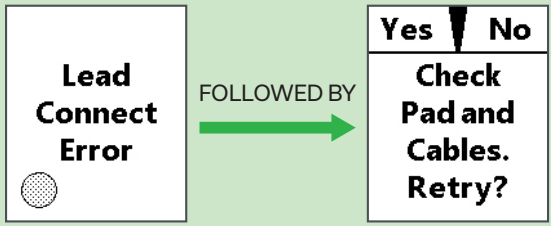
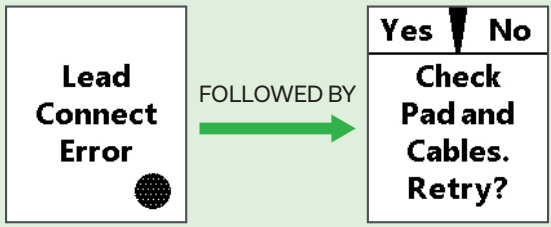
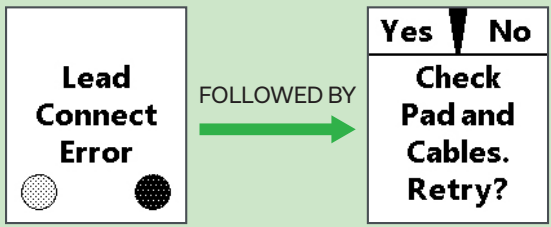
1. Confirm screen says, "Lead Connect Error. Check Pad and Cables. Retry?"
2. Using the Connector Key, unlock the MicroLead Connector and move it back slightly to a different location on the Lead. Snap the MicroLead Connector to the MicroLead.
3. Confirm Pulse Generator is firmly connected to the Mounting Pad. Confirm the Mounting Pad is firmly connected to Patient's skin.

4. Confirm all plugs (cable connections) are securely connected: MicroLead Connector to the Magnetic Coupler, Coupler to Extension Cables, and Extension Cables.
5. Gently squeeze down on the closure of the MicroLead Connector.
6. Check magnetic connection points of the Magnetic Coupler and MicroLead Connector. If connection points aren't clean and shiny, replace with new components.
7. Replace the MicroLead Connector and the Magnetic Coupler with new ones.

During Patient Home Use



Single-Lead System	
Single-Lead System – Treatment is not able to be properly delivered	Lead Connect Error → FOLLOWED BY → Yes / No: Check Pad and Cables. Retry?

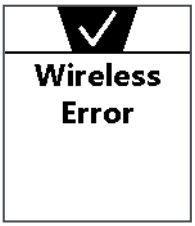
Dual-Lead System	
Dual-Lead System – Treatment on the Light Lead is not able to be properly delivered	
Dual-Lead System – Treatment on the Dark Lead is not able to be properly delivered	
Dual-Lead System – Both Leads are not properly connected	

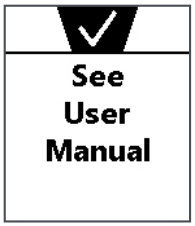
Actions to be taken in order: Test stimulation between each step as appropriate.

1. Confirm that the Hand-Held Remote screen says, "Lead Connect Error; Check Pad and Cables. Retry?"
2. Confirm that all plugs (cable connections) are securely connected.
3. Replace the Mounting Pad and place on clean and dry skin.
4. Check magnetic connection points of the Magnetic Coupler and MicroLead Connector. If connection points aren't clean and shiny, replace with new components.
5. Remove any unnecessary cables.
6. If patient has a Dual-Lead System (extensa or extensa XT), test each Lead connection by setting the intensity level to zero on the opposite Lead.
7. Gently squeeze down on the closure of the MicroLead Connector.

8. Use the Connector Key to unlock the MicroLead Connector. Move the MicroLead Connector approximately 1 cm closer to the MicroLead exit site. Then close the MicroLead Connector. (This step requires the patient to be on-site.)
9. Gently squeeze down on the closure of the MicroLead Connector.
10. Replace the Magnetic Coupler and MicroLead Connector.
11. Replace the Pulse Generator.
12. Replace the MicroLead.

A.2) "Wireless Errors"





Key Recommendations:

- Wait 30 seconds after removing the plastic pull- tab on the Hand-Held Remote before turning "on".
- Confirm that the Pulse Generator power is "on".
- Ensure the Hand-Held Remote is within arm's length of the Pulse Generator
- Ensure the Hand-Held Remote has an unobstructed path ("line-of-sight") to the Pulse Generator;
- Ensure the Pulse Generator and Battery are connected, and the Pulse Generator's green indicator light has turned off.

"Wireless Errors" – while using the Hand-Held Remote

Actions to be taken in order:

Hand-Held Remote:

1. Confirm that Hand-Held Remote screen says, "Wireless Error".
2. Press the middle button on the Hand-Held Remote.

3. If the patient screen is still not displayed, move the "lock/unlock" switch to the "locked" position and wait for the screen to go blank before unlocking again.

4. If the patient screen is still not displayed, lock the Hand-Held Remote. Remove the Rechargeable Battery from the Pulse Generator and reinsert. Wait for 5 seconds after the Pulse Generator's green light and audible beep. Wait for the Remote screen to go blank. Then unlock the Hand-Held Remote.

5. Ensure the Hand-Held Remote has an unobstructed path ("line-of-site") to the Pulse Generator. Then move the "lock/unlock" switch to the "unlocked" position.

6. Position the Pulse Generator and Mounting Pad to a location that allows for clear line-of-site with the Hand-Held Remote.

Pulse Generator:

1. Ensure the power on the Pulse Generator is turned "on". Lock the Hand-Held Remote. Remove the Rechargeable Battery from the Pulse Generator and reinsert. Wait for 5 seconds after the Pulse Generator's green light and audible beep. Then unlock the Hand-Held Remote.

A.3) "Internal Errors"

Actions to be taken in order: Test stimulation between each step as appropriate.

1. Confirm the Hand-Held Remote Screen says, "Internal Error".

2. Remove the Rechargeable Battery from the Pulse Generator and reinsert.

3. Replace the Pulse Generator with a new one.

A.4) "System Power Up" Pulse Generator Does Not Power On – Rechargeable Battery

Actions to be taken in order:

1. Remove the Rechargeable Battery from the Pulse Generator and reinsert.

2. Replace the Rechargeable Battery with a new one.

3. Replace the Pulse Generator with a new one.

Hand-Held Remote Does Not Power On

Actions to be taken in order:

1. Lock and Unlock the Hand-Held Remote.
2. Replace the Coin Cell Battery located within the Hand-Held Remote. A small Phillips head screwdriver and CR2032 Lithium Coin Cell Battery are required.

   To access the Coin Cell Battery;
   - Peel up the label located on the back of the Hand-Held Remote to expose cover screw.
   - Gently press the small black retaining tab to remove the battery. (Slight pressure many need to be applied to pop out the battery once the tab is pressed.)
   - Insert new coin cell battery with the "+" side facing up.
   - Replace the cover and tighten screw until snug.
3. Replace the Hand-Held Remote and Pulse Generator with new ones.

A.5) "Adhesive and Skin Irritation"

Mounting Pad Is Not Adhering To Patient's Skin

The following steps may be recommended:

1. Clean skin with mild soap and water and allow skin to dry.
2. Wipe skin with an alcohol pad and allow skin to dry.
3. Apply a drop of tap water to adhesive side of the Mounting Pad.
4. Skin Prep products (e.g., TENS Pre-wipes, Benzoin Prep) may be used prior to application of the Mounting Pad.
5. Change Mounting Pad regularly.
6. Hold Pulse Generator and Mounting Pad in place (e.g., ACE Bandage Wrap).

Skin Irritation – Mounting Pad

Physician may consider the following steps:

1. Regularly change the location of the Mounting Pad on skin.
2. Skin Prep Wipes may be used prior to application of the Mounting Pad.
3. Contact your SPR Representative to request an alternative (hydrogel) Mounting Pad.
4. Topical Hydrocortisone, Topical Antihistamine, or Benzoin Tincture/Swabs may also be prescribed to treat effected area.

Skin Irritation – Tegaderm Bandage

Physician may consider alternative hypoallergenic bandages (e.g., Smith & Nephew IV3000 Transparent Dressings).

Skin Irritation – Mounting Cradle

Adjust the location of the Mounting Cradle. If irritation persists, discontinue use of the Mounting Cradle.

A.6) Additional Troubleshooting Steps:

Problem	Possible Causes	Actions to be Taken
Battery symbol is blinking on remote	Rechargeable Battery is low	Replace and recharge the Battery
Screen (Remote or Clinical Programmer) shows "Recharge Battery"	Rechargeable Battery is low	Replace and recharge the Battery
Hand-Held Remote buttons are not working	Lock Switch is on	Move switch to unlocked (up) position
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 6 hour 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"
Stimulation turns off on its own	Rechargeable Battery is too low	Replace and recharge the Rechargeable Battery
	Treatment is complete 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
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

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) in their shipping carton. All the components of the SPRINT System are suitable for storage and transportation between at least -5°C (23°F) and 45°C (113°F) outside of 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 10°C (50°F) to 40°C (104°F)*;
- a relative humidity range of 15 % to 85 %, non-condensing, with not more than 50 hPa of water vapor pressure; and
- an atmospheric pressure range of 700 hPa to 1,060 hPa.

Allow components to acclimate (warm or cool) for a minimum of 2 hours prior to operation at typical operating temperature of 20°C (68°F) when stored at maximum or minimum storage conditions.

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 MicroLead (with Introducer) (REF 80104)

Parameter	Specification
Stimulating electrode of the MicroLead	Length: 1.5 cm Surface area: 10mm^2 (minimum)
Maximum resistance	150 ohms
Introducer Length	12.5 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; The Pulse Generator also generates audio attention tones
Wireless Communications	Bluetooth (Low Energy)
Output Control	Amplitude range: 0.2mA to 30mA (+/-10% for all Amplitudes above 5.0mA; below 5.0mA, accuracy of total per pulse charge is +/-25%) Frequency range: 5-150 Hz (+/- 0.5% averaged over 10 pulses; +/- 10% pulse-to-pulse) Pulse duration range: 10µs - 200µs (+/- 4µs; below 2mA, the minimum Pulse Duration is 20µs) Duty cycle range: <1% - 100%
Stimulus Waveform	Asymmetric biphasic, no net DC
Maximum Charge Per Pulse	4 µC
Maximum Charge Density at Stimulating Electrode	0.4 µC/mm2 (when in use with the SPRINT MicroLead)
Maximum Current Density at Return Electrode (Pad)	Single Channel System: 0.14mA/cm2 (0.9mA/inch2) Dual Channel System: 0.19mA/cm2 (1.2mA/inch2)
Range of Load Impedance	200Ω to 1,300Ω

Parameter	Specification
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 While charging one of the rechargeable batteries, the stimulator can be powered with the second rechargeable battery
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; 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 • Internally powered • NOT suitable for use with flammable anesthetic agents • Suitable for use in the Home Healthcare Environment and the Professional Healthcare Environment)

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
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 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) {user replaceable with the use of a screwdriver}

SPRINT Clinical Programmer (REF 9630)

Parameter	Specification
Size	21.0cm x 12.4cm x 0.8cm
Screen	Approximately 20cm (1280 x 800 resolution)
Mass	Approximately 345g
Wireless Communications	Bluetooth 4.2
Internal Battery	Rechargeable Lithium-Ion Battery
Operating Temperature	0°C to +35°C (32°F to 95°F)
Safety Certifications	EN 60950-1
Input	5.0V DC

SPRINT Clinical Programmer Charger (REF 9631)

Parameter	Specification
Size	Approximately 6.5cm x 4cm x 1.7cm
Safety Certifications	UL Listed
Output	5.0V at up to 1.55A DC [max power output 7.75W]
Mains Power Input	100-240VAC @50/60Hz

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 (Single-Lead or Dual-Leads at the same frequency)
OFF	Stimulation is OFF
+	Increase
–	Decrease
	Home (return to home screen)
	Full Rechargeable Battery
	Mostly full Rechargeable Battery
	Partially full Rechargeable Battery
	Low Rechargeable Battery; Replace and recharge
	Lock switch is off (buttons are enabled)
	Lock switch is on (buttons are disabled)
	Select Light Lead (Systems with Dual-Leads only)
	Select Dark Lead (Systems with Dual-Leads only)
	Light Lead Stimulation is ON (Systems configured to Bimodal only)
	Dark Lead Stimulation is ON (Systems configured to Bimodal only)

Symbol or Message	Description
	Light Lead Simulation is set to “0” intensity (Dual-Lead Systems only)
	Dark Lead Stimulation is set to “0” intensity (Dual-Lead Systems only)
	Light Lead Stimulation is OFF – timer expired (Systems configured to Bimodal stimulation only)
	Dark Lead Stimulation is OFF – timer expired (Systems configured to Bimodal stimulation only)
	Select Light Lead and Dark Lead to start stimulation simultaneously (Systems configured to Bimodal only)
Session Complete	The treatment session is done
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
Con	Continue paused session (Systems with Session Treatment only)
New	Start new session (Systems with Session Treatment only)

Table B: Pulse Generator Lights and Tones

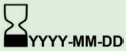
Table B explains the lights and tones that are output by the Pulse Generator.

Symbol or Message	Description
Short beep 5 second Green light	Newly inserted Rechargeable Battery high to medium charge
Short beep 5 second Yellow light	Newly inserted Rechargeable Battery low charge
Short beep Flashing Yellow light	Newly inserted Rechargeable Battery critically low charge; Replace and recharge
Short Green light flash	Session started by press of Pulse Generator button or Hand-Held Remote button
Single Blue light flash	Wireless command received
3 short beeps 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

Table C: Label Symbols

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

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
Symbol or Message	**Description**

	Sterilized using ethylene oxide
	Non-pyrogenic
	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. {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
	Caution/Warning
	MR Unsafe
	MR Conditional
	Not made with natural rubber latex

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.

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 10-20o) 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 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 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.

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