SPRINT®
PNS SYSTEM

SUPPLEMENTAL CLINICIAN INSTRUCTIONS FOR USE

Instructions for SPRINT® PNS Systems

2023-06-13

The SPRINT® PNS System is manufactured by:

SPR Therapeutics

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SprintPNS.com

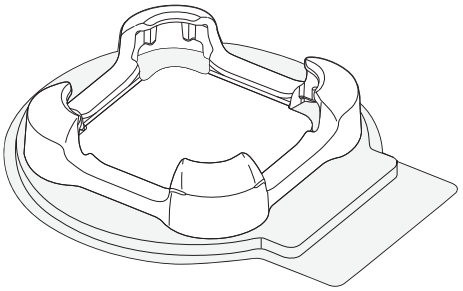
Information on patents can be found at:
sprtherapeutics.com/patents

The SPRINT® Lead Securement Component Kit is a set of product components that allow clinicians to use updated versions of the MicroLead Connector and MicroLead Connector Key along with the SPRINT PNS® System. The kit also contains a new Breakaway Connector Cable and Connector Mounting Cradles compatible with the updated version of the MicroLead Connector. The following instructions replace Section 4.3 instruction in the Clinician Instructions For Use (IFU): "**Confirming Location & Placing the MicroLead(s)**" when using these components.

COMPONENT KIT INCLUDES

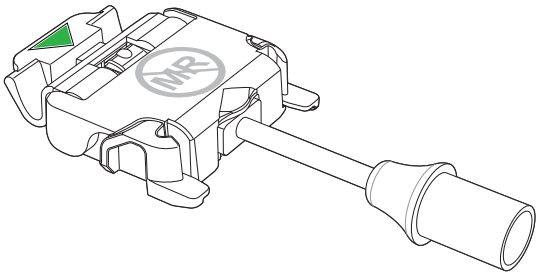
SPRINT System Components (non-sterile)

- **Mounting Cradles (REF 9663):** Adhesive pad that holds the MicroLead Connector in place near the MicroLead exit site to minimize the potential for Lead dislodgement.

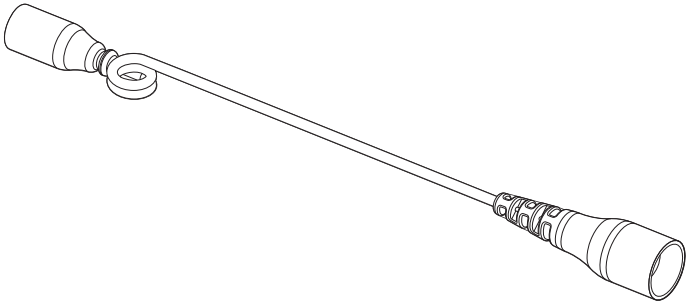


SPRINT System Components (sterile)

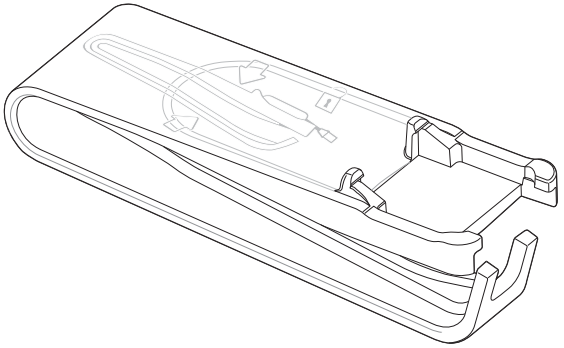
- **MicroLead Connectors (Light Gray and Dark Gray) (REF 9651 & 9656):** The connecting piece that creates an efficient electrical connection between the MicroLead and the Pulse Generator. (Dual-Lead Systems come with two MicroLead Connectors, one with a light gray cable connector (Light Gray) and the other with a dark gray cable connector (Dark Gray).)



- **Breakaway Connector Cables (Light Gray and Dark Gray) (REF 9691 & 9696):** The cable that connects to the MicroLead Connector and Magnetic Coupler.



- **MicroLead Connector Key (REF 9658):** The key that unlocks the MicroLead Connector.



Additional Components

- Supplemental Clinician Instructions For Use for the Lead Securement Component Kit.

NOTE: 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 Simulating 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: 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).

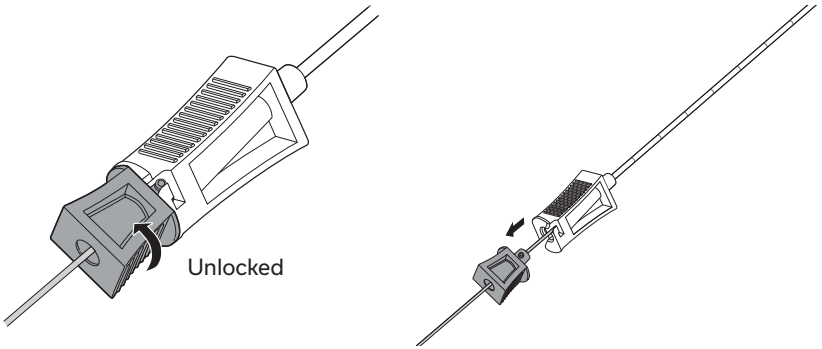
INSTRUCTIONS FOR USE

Confirming Location & Placing the MicroLead(s)

When the SPRINT Lead Securement Component Kit is being used during initial Lead placement(s), you will need to use the following components from the SPRINT PNS System to complete the Lead Procedure: The tray containing the SPRINT MicroLead with OnePass Introducer (REF 80103) and the Patient Kit Box containing the Mounting Pads and Waterproof Bandages.

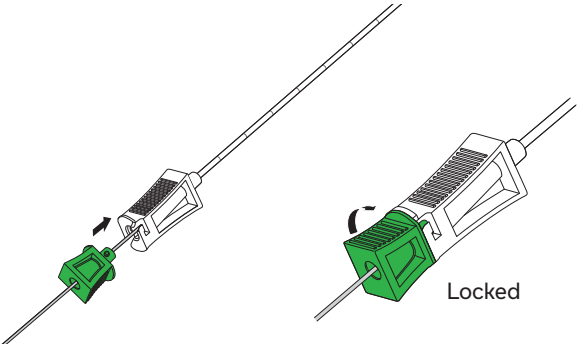
1. Once the optimal location for the electrode has been determined, disconnect the Stimulating Probe from the Pulse Generator.

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.

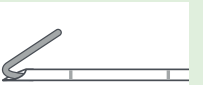


NOTE: Hold the proximal end of the MicroLead when removing the protective sheath from the MicroLead Introducer to prevent Lead displacement.

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.

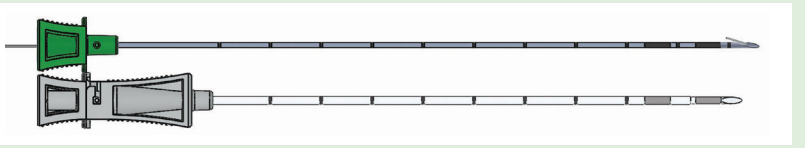


Ensure that the distal barb of the MicroLead is hooked around the tip of the MicroLead Introducer. If the MicroLead is protruding from the tip of the Introducer, gently pull back on the Lead near the Introducer hub until the distal barb is hooked around the tip of the Introducer.

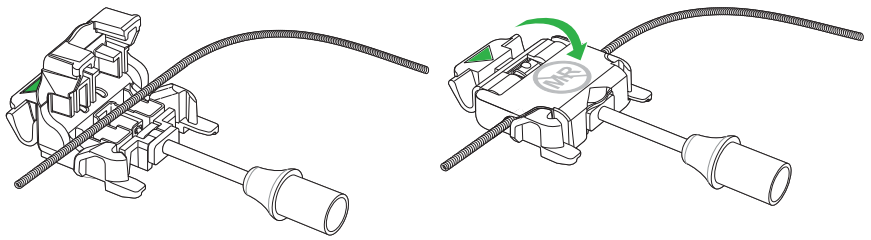


⚠ WARNING

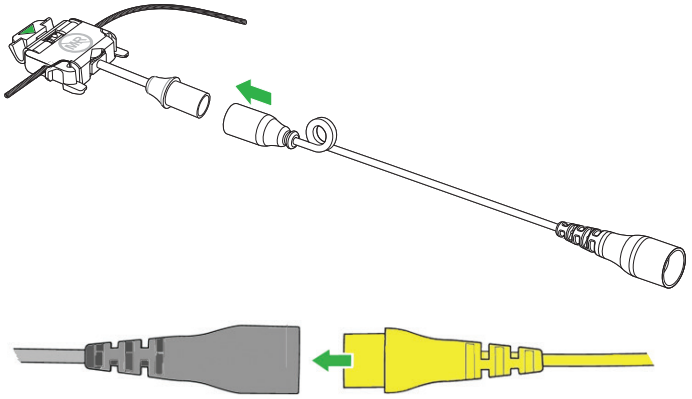
Take care when inserting the MicroLead Introducer into the Percutaneous Sleeve. The MicroLead Introducer is approximately 3mm longer than the Stimulating Probe (see image below). This ensures that the field generated by the MicroLead mimics the field that was created by the Stimulating Probe.



4. To confirm the MicroLead location, lay the loose end of the MicroLead across the metal contacts in the trough of the MicroLead Connector. Shut the snap closure of the MicroLead Connector to deinsulate the MicroLead and create an electrical connection.

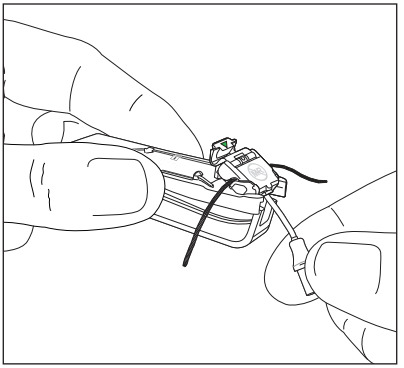


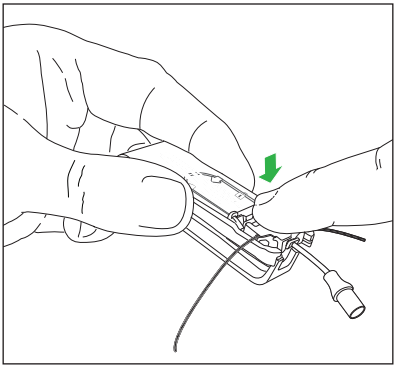
5. Connect the small magnetic plug to the Breakaway Connector Cable provided in the kit and connect it to the yellow Universal Test Cable. Connect the Universal Test Cable to the Pulse Generator to complete the electrical connection to allow testing of stimulation at current MicroLead location.



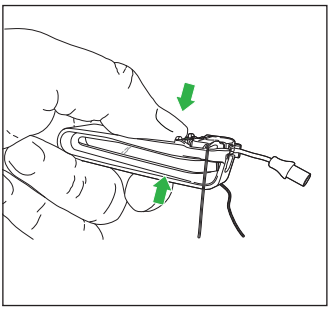
6. Use the Hand-Held Remote or the Clinical Programmer Tablet to confirm that the MicroLead location delivers desired results. Advance the MicroLead as desired or adjust stimulation settings as required to optimize results. Retracting the MicroLead Introducer will cause the barb to engage and prevent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

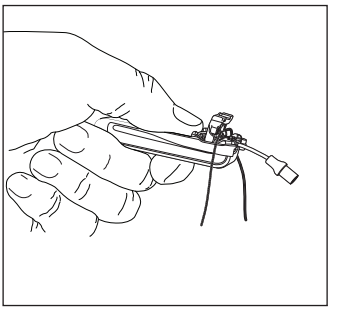
7. Once the desired location has been attained, unlock the MicroLead Connector by tilting the tabs on the MicroLead Connector into the MicroLead Connector Key (with the MR symbol facing up), then press down gently until the MicroLead Connector snaps into place. DO NOT squeeze the MicroLead Connector Key before the MicroLead Connector is snapped into place.

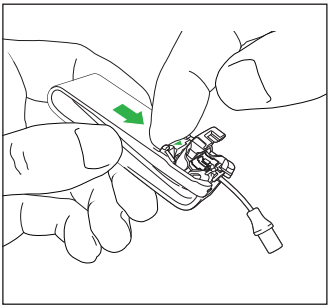


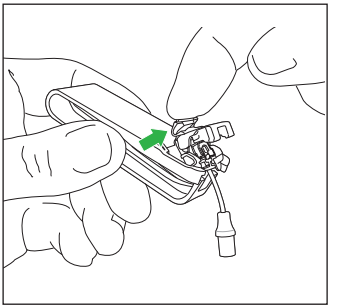


Squeeze the top and bottom of the MicroLead Connector Key together until the MicroLead Connector opens. Remove the MicroLead from the MicroLead Connector. Press in the release on the MicroLead Connector and tilt it up and out of the MicroLead Connector Key.

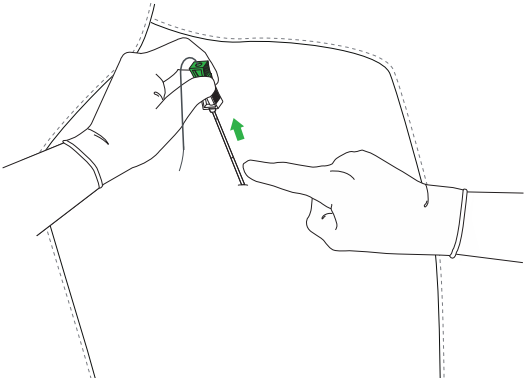




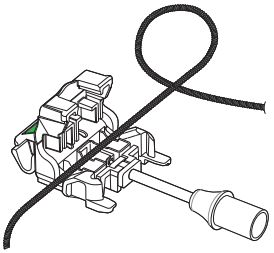




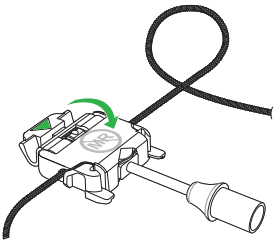
8. Deploy the MicroLead by applying pressure to the skin near the MicroLead exit site. With the other hand, gently retract the Percutaneous Sleeve with Introducer, leaving the MicroLead implanted.



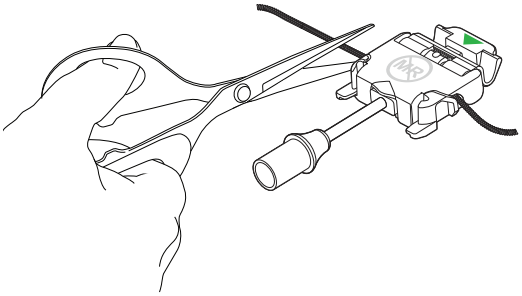
9. Once deployed, lay the loose end of the MicroLead across the metal contacts in the trough of the MicroLead Connector, assuring that adequate MicroLead length exists between the skin exit site and the MicroLead Connector to create a strain relief loop (3-5 cm is typical). Make certain to secure the new connection closer to the skin (exit site) than the previous connection point to avoid creating a weak point in the MicroLead.



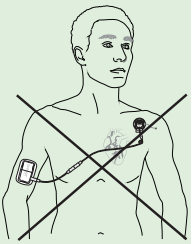
10. Shut the snap closure of the MicroLead Connector to de-insulate the MicroLead and create an electrical connection.



11. Trim excess MicroLead wire.

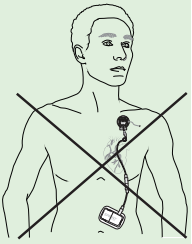


⚠ WARNING
The line between the Mounting Pad and the tip of the MicroLead must not cross the heart; electrical current across the heart may cause rhythm disturbances, which could be lethal.

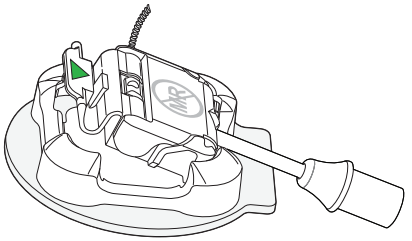


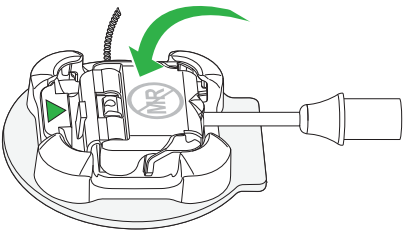
⚠ WARNING
Do not place the SPRINT Mounting Pad on the head or on the front of the throat. Placement of the Mounting Pad on head or front of the throat may cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.

⚠ 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.



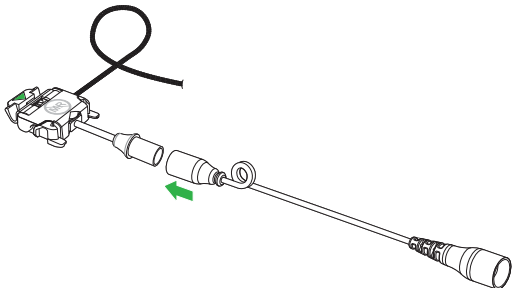
12. Snap the MicroLead Connector into the Mounting Cradle, then adhere the Connector Mounting Cradle to the skin. Tilt the tabs of the MicroLead Connector into the new Mounting Cradle (with the MR symbol facing up), then press down gently until locked in place.



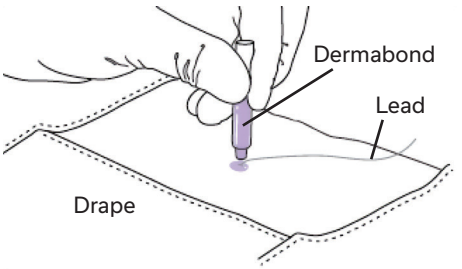


⚠ To reduce the risk of infection, do not place the MicroLead Connector or the Mounting Cradle directly on top of the MicroLead exit site.

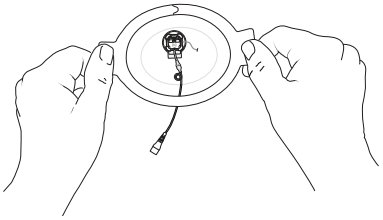
13. Connect the small magnetic plug on the MicroLead Connector to the Breakaway Connector Cable provided in the kit.

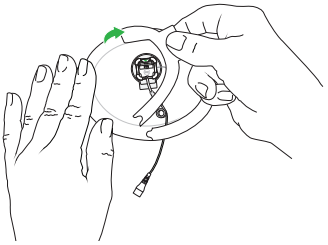


14. Place a small drop of Dermabond® at the MicroLead exit site to help secure the MicroLead. Allow the Dermabond® to dry completely before bandaging. Applying the bandage before the Dermabond® has completely dried may result in inadvertent removal of the MicroLead.



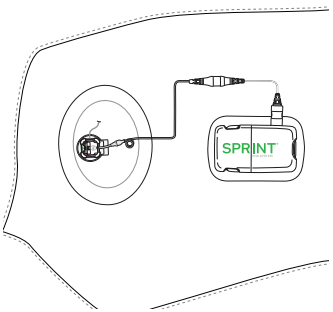
15. Cover the MicroLead insertion site and Mounting Cradle with the non-adhesive center portion of the Waterproof Bandage, leaving the plug end of the Breakaway Connector Cable exposed.





NOTE: The style/appearance of the Waterproof Bandage may vary.

16. Connect the Magnetic Coupler to the Pulse Generator and the exposed end of the Breakaway Connector Cable, using a long or short extension cable if needed.



DUAL-LEAD: 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.

Proceed by following the instructions for establishing therapy settings in the Clinician IFU, beginning in Section 4.4: **"Establishing Therapy Settings"**.

NOTE: The patient will need to use the Mounting Pads and Waterproof Bandages provided in the SPRINT PNS System. The MicroLead Connector(s), Connector Mounting Cradles, and MicroLead Connector Key provided in the kit replaces the ones in the SPRINT PNS System box. The duplicate components included with the SPRINT PNS System are to be discarded.

For full instructions, including indications, contraindications, warnings, and precautions, see Clinician Instructions For Use.

NOTES

Clinician Instructional Videos

Scan this QR code with a smart phone camera or visit:
sprtherapeutics.com/video/lead-secu

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