CURONIX

# FREEDOM PERIPHERAL NERVE STIMULATOR SYSTEM

# IMPLANTATION OF TRIAL LEAD

# INSTRUCTIONS FOR USE

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

**FREEDOM PNS TRIAL LEAD KIT**

| | |
|---|---|
| FR4A-TRL-A0 | FR8A-TRL-A0 |
| FR4A-TRL-B0 | FR8A-TRL-B0 |

# EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

| Symbol | English – EN |
|---|---|
|   | Device reference identification |
|   | Lot number |
|   | Quantity of product included in package |
|  | Consult instructions for use |
|  | Do not reuse |
|  | Do not resterilize |
|  | Do not use if package is damaged |
|  | Store in a cool, dark, dry place |
|  | Caution |
|  | Warning |
|   | MR Unsafe |
|   | MR Conditional |
|  | Use by |
|  | Manufacturing date |
|  | Manufacturer |
|   | Device length |
|   | Sterilization: ethylene-oxide gas |
|  | Temperature limits |
|  | Non-ionizing electromagnetic radiation |
|  | IEC 60601-1/EN60601-1, Type BF Equipment |

| | |
|---|---|
|  | Federal Communications Commission |
|  | Outer Diameter |
|  | Dispose of this product according to local regulations |
|  | Serial Number |
|  | Prescription Use Only |

# TABLE OF CONTENTS

# GLOSSARY OF TERMS

| Term and Synonyms | Definitions |
|---|---|
| **Electrode** | Contact |
| **Electrode Array (Lead)** | An implanted catheter with electrodes that are placed in the epidural space |
| **Guidewire** | A flexible wire used to create a pathway in the epidural space for the Electrode Array to follow |
| **Incision** | Stab wound, cut down, surgical incision |
| **Introducer** | An introducer is used as the tunneling tool to clear a pathway between the Electrode Array incision and the receiver pocket |
| **Neurostimulator (Stimulator)** | Electrode Arrays plus a Receiver |
| **Receiver** | An RF conductor that receives wireless signal during stimulation |
| **Stylet (Steering Stylet)** | Stiff wire that can be inserted into the Electrode Array body to aid in steering and positioning |
| **Transmitter** | The transmitter is an electronic device used to generate wireless power for the neurostimulator. The transmitter contains buttons, a rechargeable battery, an antenna cable port, and a micro-USB port (for charging only) |

# HOW TO USE THIS MANUAL

This manual describes the Freedom PNS Trial Lead implant procedure and the methods to optimally implant the device.

## DEVICE DESCRIPTION

The Freedom Peripheral Nerve Stimulator (PNS) System is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The therapy utilizes pulsed electrical current to create an electrical energy field that acts on peripheral nerves in the limbs and torso to inhibit the transmission of pain signals to the brain. The System is comprised of an implantable stimulator and an externally worn transmitter to power the implanted device. The System is implanted only following a successful trial period with the Freedom 8A/4A Trial Lead.

## INDICATIONS FOR USE

The Peripheral Nerve Stimulator (PNS) System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The PNS System is not intended to treat pain in the craniofacial region. The Trial Lead Kit is only to be used in conjunction with the Freedom Receiver Kit. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Refer to the Freedom PNS System Product Safety Sheet for applicable precautions, warnings, adverse event summary, as well as information about electromagnetic environment and wireless specifications.

# SAFETY INFORMATION

## CONTRAINDICATIONS

- **Poor surgical risks –** Peripheral nerve stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the Trial PNS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Peripheral nerve stimulators should not be used on patients who are unable to understand or operate the System.

- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated within the vicinity of a patient implanted with a Trial PNS System or when wearing the Transmitter Assembly. The energy from diathermy can be transferred through the Trial Lead and cause tissue damage, resulting in severe injury.
- **Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy –** Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the device and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation includes the following:
    - Radio or cell phone transmission stations
    - Facilities using radiofrequency heat sealers or induction heaters
    - Electric power infrastructure-controlled environments (i.e. step-down transformers or high voltage power lines)
- **Implanted cardiac systems –** Patients who have implanted cardiac systems should not use the Trial PNS System without proper peri-operative monitoring. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

## WARNINGS

**Electromagnetic interference (EMI) –** EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the Transmitter Assembly. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the Transmitter Assembly needs to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, that some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, because of the unexpected changes in stimulation, patients have fallen down and been injured.

Patients who suspect the Trial PNS System is being affected by EMI should immediately move away from the equipment or object and the external Transmitter Assembly should be removed from the vicinity of the patient.

**Electromagnetic equipment/environments –** Avoidance of high electromagnetic equipment radiators or environments is highly encouraged. Examples of equipment and/or environments include the following:

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals

**Magnetic Resonance Imaging (MRI) – Trial devices are MR Unsafe** due to the lack of fixation of the device during the trial period.

**Magnetic Resonance Imaging (MRI) – The Trial Leads FR4A/FR8A are MR Unsafe.** Since the Trial Leads FR4A/FR8A are MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the device, and in the process cause serious harm to the patient or other people or damage to the MR system.

**Magnetic Resonance Imaging (MRI) – The Transmitter Assembly component is MR Unsafe; the Transmitter Assembly must not enter the MR system room.** Since the Transmitter Assembly is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the Transmitter Assembly, and in the process cause serious harm to the patient or other people or damage to the MR system.

**Electrostatic Discharge (ESD) –** Testing indicates the Transmitter Assembly can be susceptible to damage resulting from ESD greater than +/-6kV that can occur in certain environments, such as home use, when the relative humidity is below 30%. Trial PNS users and caregivers should avoid approaching or touching the Transmitter Assembly in these

situations and avoid contact with highly charged conductors, particularly synthetic materials (e.g., nylon, polyester) during periods of low relative humidity (less than 30%). ESD might result in temporary or permanent loss of function. If ESD with the Transmitter Assembly is observed, the device must be removed from patient's body and powered off; then the device can be powered back on. Before resuming therapy, confirm the device indicators/lights are operating correctly. If the device will not power on, the stimulation therapy will not be delivered and Curonix must be contacted for assistance or replacement.

**Computed Tomography (CT) Scanning –** Safety has not been established for CT scanning of patients with a Trial Lead. X-rays from the scan could cause unintended shocks or malfunctions of the Trial PNS System.

The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the Transmitter Assembly from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
    - Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
    - Make sure that X-ray beam does not dwell over the Trial PNS System for more than a few seconds.

After CT scanning directly over the implanted device:

- The Transmitter Assembly can be placed back on the patient and stimulation turn on.
- Proper stimulation must be confirmed, and that indicator lights are operating as expected.
- The Transmitter Assembly must be shut off if it is suspected that the device is not functioning properly.

**Radiation therapy –** Safety has not been established for high radiation sources such as cobalt 60 or gamma radiation when implanted with Trial PNS System. Use of radiation therapy could cause damage to the device or harm to the patient.

**Radiofrequency (RF) ablation –** Safety has not been established for radiofrequency (RF) ablation in patients with the Trial PNS System. RF ablation may cause induced electrical currents that result in heating and tissue damage. RF ablation should not be used anywhere near the Trial PNS System. If RF ablation is used, that ablation should not be performed over or near the Trial Lead.

**Radiofrequency Identification (RFID) Emitters – Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems –** Tests have been performed with an array of simulated RFID emitter systems and have demonstrated that the Trial PNS System (implanted device and Transmitter Assembly) can be affected by separation distances between the Trial PNS System and the RFID emitter of less than 3m (~10 ft). More powerful RFID emitters might cause effect at farther distances. RFID emitters can be hidden or portable and may not be obvious to the Curonix user. Any RFID emitter may temporarily interrupt stimulation or cause elevated levels of stimulation. It is recommended that if a patient feels a change in stimulation near a potential RFID emitter, the patient promptly moves away from the area and removes the Transmitter Assembly from the body. When possible, it is best to avoid RFID emitters or remove the Transmitter Assembly while passing near RFID emitters. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing any RFID emitter. If unavoidable, the patient should walk through the RFID emitter and promptly move away from the area. Patients should not lean on scanners or linger in the area of RFID emitters.

**Transcutaneous Electrical Nerve Stimulation –** Safety has not been established for use of transcutaneous electrical nerve stimulation (TENS) when implanted with the Trial PNS System. Use of TENS could cause the device to turn off or cause intermittently increased stimulation.

**Electrocautery** – If electrocautery tools are used near the Trial PNS System then the insulation can be damaged. The Trial PNS System may fail or conduct induced currents. Induced electrical currents can cause heating that results in tissue damage.
When electrocautery is necessary, these precautions must be followed:

- The Transmitter Assembly should be removed from the vicinity of the patient.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
    - Only low-voltage modes should be used.
    - The lowest possible power setting should be used.
    - The current path (ground plate) should be kept as far away as possible from the Trial PNS System.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm the Trial PNS System is working as intended.

**High-Output Ultrasonics / Lithotripsy –** Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Trial PNS System. Use of lithotripsy may result in damage to the device or harm to the patient. When possible, it is best to avoid these security systems or to remove the Transmitter Assembly while passing through security systems. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing the security system. If unavoidable, the

patient should walk through the security system and promptly move away from the area. Patients should not lean on scanners or linger in the area of the security system.

**Active Implantable or Body Worn Medical Devices –** Safety has not been established for patients who use the Trial PNS System with other active implantable or body worn medical devices. These devices include other neurostimulation systems, insulin pumps, automated external defibrillators (AED), cochlear implants, and wearable medical sensors. Malfunction and/or damage could occur to either system that could result in harm to the patient or other people nearby.

**Bone Growth Stimulators –** Safety has not been established for bone growth stimulator systems within the vicinity of the Trial PNS System. Use of a bone growth stimulator may result in damage to the device or harm to the patient.

**Dental Drills and Ultrasonic Probes** – Safety has not been established for dental drills or ultrasonic probes within the vicinity of the Trial PNS System. Use of drills or probes may result in damage to the device or harm to the patient.

**Electrolysis** – Safety has not been established for electrolysis within the vicinity of the Trial PNS System. Use of electrolysis may result in damage to the device or harm to the patient.

**Laser procedures –** Safety has not been established for lasers within the vicinity of the Trial PNS System. Use of lasers may result in damage to the device or harm to the patient.

**Psychotherapeutic Procedures** – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have the Trial PNS System. Induced electrical currents can cause heating that may result in tissue damage.

**Other medical procedures –** EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet away from the implant site. Magnetic fields will generally not affect the Trial Lead.

**Machinery or Heavy Equipment –** Machinery and heavy equipment (including vehicles) should not be operated while using the Trial PNS System. Malfunction of the System could

result in loss of body control, body function, or a feeling that could render the patient incapable of controlling the system.

**Aircraft Usage** – Safety has not been established for use of the Trial PNS System on aircrafts. Use of the Trial PNS System on a commercial aircraft may result in damage to the device or harm to the patient.

**Electrode Arrays Fracture –** If the Trial Electrode Array insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

**Transmitter Assembly Skin Contact –** The Transmitter Assembly must not be placed directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The Transmitter Assembly must be placed overtop a thin layer of clothing or material at all times.

**Painful Stimulation –** If the patient experiences painful stimulation, the amplitude on the should be decreased immediately and/or removed from the vicinity of the patient.

**Stimulation Frequencies –** Stimulation between 1,500 Hz and 10,000 Hz has not been evaluated for safety, effectiveness or perception of paresthesia in any Trial PNS System.

## PRECAUTIONS

**Physician Training –** Prescribing clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the Trial PNS System. Implanting clinicians should be experienced in the peripheral nerve procedures and should review the Instructions for Use.

**Medical Tests and Procedures –** Patients should be instructed before undergoing medical tests or procedures, to contact the clinician to determine if the procedure could cause damage to the patient or to the System.

**Physician Instructions –** Patients should be instructed to always follow the programs and therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

**Use the Transmitter Assembly as directed –** Patients should be instructed to use the Transmitter Assembly only as explained by the clinician or as discussed in the Instructions for Use. Using the Transmitter Assembly in any other manner could result in harm.

**Keep the Transmitter Assembly dry –** The Transmitter Assembly is not waterproof. Patients should be instructed to keep it dry to avoid damage.

**Clean the Transmitter Assembly –** Patients should be instructed to clean the outside of the Transmitter Assembly with a damp cloth when needed to prevent dust and grime. Mild household cleaners will not damage the device or labels.

**Handle the Transmitter Assembly with care –** The Transmitter Assembly is a sensitive electronic device. Patients should be instructed to avoid dropping the device onto hard surfaces and to keep the Transmitter Assembly out of the reach of children and pets.

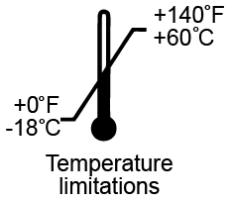
**Do not dismantle the Transmitter Assembly –** Patients should be instructed to not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, a Curonix representative should be contacted for assistance.

**Flammable or Explosive Environments –** Patients should be instructed to not use the Transmitter Assembly in flammable or explosive environments. Using the Transmitter Assembly in one of these environments could result in harm.

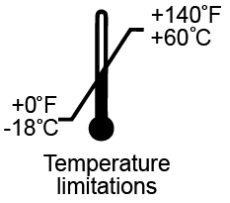
**Use of another patient's Transmitter Assembly –** Patients should be instructed to never use another patient's Transmitter Assembly. The therapy programmed is a unique prescription for each patient. Use of another patient's Transmitter Assembly could result in overstimulation.

**Storage Temperatures –** The Trial Freedom PNS System should be kept within the storage temperatures listed on product packaging. Exceeding the storage temperature could cause harm to the patient or the component. Manufacturer should be contacted if a storage temperature is surpassed.

Freedom PNS Trial Lead Kit
Storage Temperature




Transmitter Assembly
Storage Temperature




**Unexpected changes in stimulation –** Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation. Some patients have described this as a jolting or shocking sensation. Before engaging in activities that could become unsafe, the amplitude should be reduced to the lowest setting and the System should be turned OFF. Discuss these activities with the clinician.

**Interference during programming –** If interference is suspected during programming of the Transmitter Assembly, the clinician should confirm that the Bluetooth® data transmission is operating by ensuring the blue light indicator is blinking. If during the programming session the light indicator is not blinking, then the clinician should do the following:

- Terminate current programming session and shut down the WaveCrest™ application.
- Check for sources of Bluetooth interference in the surrounding area.
- Remove or turn off the source of interference.
- Re-establish the Bluetooth® link with the Transmitter Assembly through pairing.
- Resume programming by opening the WaveCrest application.
- Confirm the light indicator is now blinking.

**Activities requiring excessive twisting or stretching –** Patients should be instructed to avoid activities that potentially can put undue stress on the device. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause the Trial Lead to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

**Scuba diving or hyperbaric chambers –** Patients should be instructed to not dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Patient should discuss the effects of high pressure with the clinician before diving or using a hyperbaric chamber.

**Skydiving, skiing, or hiking in the mountains –** High altitude should not affect the System; however, undue stress on the Trial Lead must be avoided. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the Trial Lead. This can result in a loss of stimulation, intermittent stimulation, and additional medical procedures.

**Airline policies** - Follow airline policies for use of medical Peripheral nerve stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

## ADVERSE EVENT SUMMARY

Implantation of a Trial Neurostimulation system is similar to any surgical procedure. Risks include the following:

- Allergic or immune system response to implanted material
- Infection
- Hemorrhage or hematoma

Therapeutic use of the Trial PNS System incurs the following risks:

- Undesired change in stimulation
- Trial Lead migration, erosion through the skin, or fracture leading to loss of therapeutic effect
- Electromagnetic interference leading to change in System performance
- Loss of therapeutic effect despite a functioning system

Adverse events that could occur with the Trial PNS System:

- Trial Lead migration, resulting in altered stimulation therapy that may be uncomfortable
- Trial Lead fracture, resulting in loss of stimulation
- Infection, resulting in tissue sensitivity, redness and swelling

Adverse effects of stimulation are usually mild and go away when stimulation is turned off. Patients should be instructed to contact their clinician immediately if they experience any problem or if they experience a change in stimulation. Over time there could be changes in the level of pain control.

# DEVICE SPECIFICATIONS

**Table 1. Freedom PNS Trial Electrode Array (s) Specifications**

| | |
|---|---|
| Trial FR4A-A1 |  |
| Trial FR4A-B1 |  |
| Trial FR8A-A1 |  |
| Trial FR8A-B1 |  |

| Trial Electrode Array (s): | **FR4A** | **FR8A** |
|---|---|---|
| Length | 45 cm | 45 cm |
| Diameter | 1.35 mm | 1.35 mm |
| Electrode(s): | | |
| Number | 4 | 8 |
| Shape | Cylindrical | Cylindrical |
| Length | 3 mm | 3 mm |
| Spacing | 4 mm | 4 mm |
| Array Length | 24 mm | 52 mm |
| Marker Band distance from tip | 13 cm | 17 cm |
| Number of Independent Channels: | 2 | 2 |
| Maximum recommended implant depth | 6 cm | 6 cm |
| Implant period | Up to 30 Days | Up to 30 Days |

**Table 2. Trial Receiver Specifications**

| | |
|---|---|
| Receiver | |
| Length | 47 cm |
| Diameter | 0.35 mm |

| | |
|---|---|
| Maximum recommended implant depth | 6 cm |
| Implant period | Up to 30 Days |

**Table 3. Material in contact with human tissue**

| Component | Material | Tissue contact |
|---|---|---|
| **Electrode Array** | | |
| Flexible circuit board | Polyimide | No |
| Flexible circuit trace | Copper | No |
| Circuit encapsulation | Parylene C | No |
| Electrodes | Platinum-Iridium | Yes |
| Insulation | Polyurethane | Yes |
| Tip | Polyurethane | Yes |
| Adhesive | Silicone | No |
| **Receiver** | | |
| Insulation | Polyether Ether Ketone (PEEK) | No |
| Wire | Copper | No |
| Handle | Polypropylene, Polycarbonate, Brass | No |
| **Guidewire** | Stainless Steel | Yes |
| **Introducer Assembly** | | |
| Dilator | Stainless Steel | Yes |
| Introducer | Yellow Hytrel | Yes |
| **Stylets** | | |
| Handle | Polypropylene, Polycarbonate, Brass | Yes |
| Wire | Stainless Steel | No |
| Wire | Stainless Steel with Polytetrafluoroethylene (PTFE) | Yes |

# PACKAGE CONTENTS

**Freedom PNS Trial Kits (FR4A-TRL-A0, FR4A-TRL-B0)**

- (1) Trial 4-Contact Electrode Array
- (2) Trial Receiver
- (2) Steering Stylet
- (1) Yellow Introducer
- (1) Guidewire

**Freedom PNS Trial Kit (FR8A-TRL-A0, FR8A-TRL-B0)**

- (1) Trial 8-Contact Electrode Array
- (2) Trial Receiver
- (2) Steering Stylet
- (1) Yellow Introducer
- (1) Guidewire

# INSTRUCTIONS FOR IMPLANTATION

Implanting clinicians should be experienced in procedures that gain access to the peripheral nerves, peripheral nerve stimulators, ultrasound and/or fluoroscopy, and Trial Freedom PNS product labeling.

This document details the implantation of the Trial Freedom PNS Electrode Array and Trial Receiver.

## COMMON PERIPHERAL NERVE TARGETS

Common peripheral nerves treated with PNS include the suprascapular, brachial plexus, femoral, sacral, pudendal, sciatic, intercostal, ulnar, median, radial, superior cluneal, middle cluneal, ilioinguinal, genicular (including the infrapatellar saphenous), peroneal, sural, and posterior tibial nerves.

## PREPARING FOR PROCEDURE

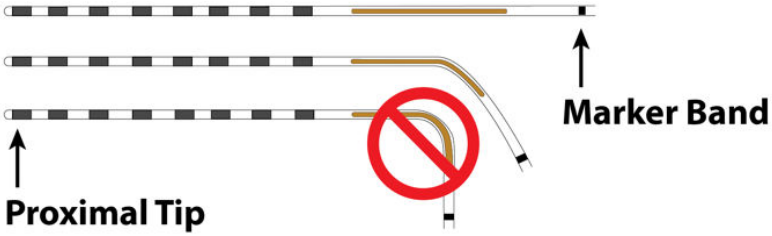

CAUTION:

To reduce the risk of damage that might result in intermittent or lost stimulation:

- Use only the Introducer Assembly supplied in the kit.
- Do not bend, kink, or stretch the Trial Electrode Array or Receiver.
- Do not use any instrument to handle the Lead.
- Use care when replacing a Trial Receiver.
- Avoid excessive pressure on the Trial Electrode Array.

This product is provided sterile. Before opening the package, verify the package integrity, model number, and use-by date. Do not use the product if the package is damaged. Do not use the product if the date has expired. Contact Curonix for any questions regarding packaging and expiration dates.

The Trial Electrode Array consists of electrodes, a circuit, and marker bands. Handle the Trial Electrode Array with care. Do not bend the Trial Electrode Array. Bending will damage the device. The Trial Electrode Array should be implanted straight for optimal performance and must be internalized from proximal tip to distal end of Trial Electrode Array. Handle the Trial Receiver with care.




# IMPLANTATION OF THE TRIAL ELECTRODE ARRAY

**Steps:**

1. Place the tip of the Trial Electrode Array on the prepared sterile skin at the approximate location where the first electrode will be placed.
2. Mark the incision site using a skin marker at the first marker band on the skin. (Figure 1)
3. Prep the incision site by administering local anesthetic. Apply as needed throughout procedure.
4. As necessary, perform "Time Out" or any other pre-op procedures.

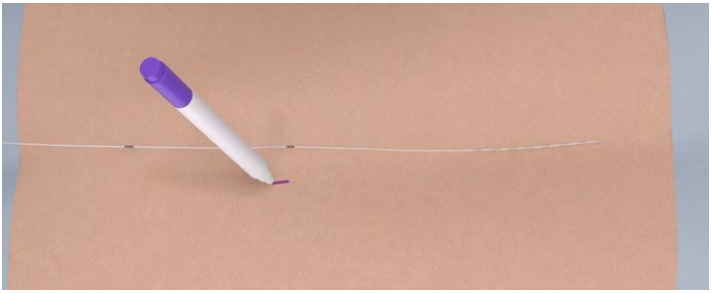


**Figure 1**

## PLACING THE TRIAL ELECTRODE ARRAY

***Notes:***

- *Use ONLY the introducer provided in the device kit. Do not remove the dilator from the introducer assembly when driving into the tissue.*
- *If resistance is encountered during advancement of the Trial Electrode Array with a bent stylet, exchange the bent stylet for a straight stylet and use short, firm movements to advance the device or use the guidewire.*
- *Physician may use ultrasound or a nerve conduction technique to identify the location of the peripheral nerve.*

- *Plan the introducer entry point so that it is far enough away from the target nerve so that the device may be fully implanted. Measurements and skin marking may be performed before the procedure.*

**Steps:**

1. If necessary, make a puncture incision before inserting the introducer assembly. (Figure 2 and 3).
2. Advance the introducer assembly through the incision in the direction of the peripheral nerve.
3. Remove the dilator from the introducer assembly leaving the introducer in place.
4. Advance the Trial Electrode Array through the introducer to be parallel or perpendicular to the target nerve as clinically indicated.
5. Gently retract the introducer to expose the electrodes.

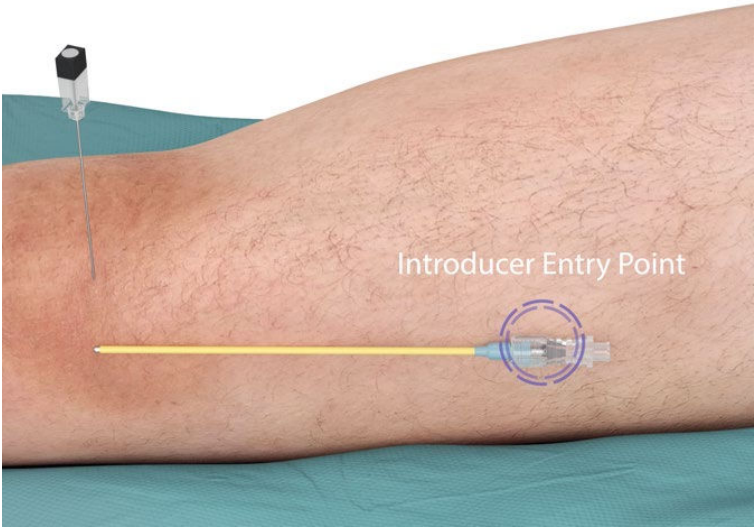



**Figure 2**

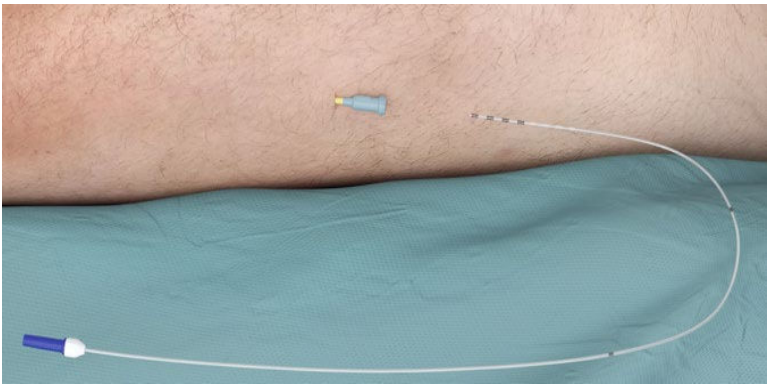


**Figure 3**

# IMPLANTATION OF TRIAL RECEIVER

***Notes:***

- *An additional Receiver is included in the kit as a spare. If not needed, it may be discarded.*

#### CONNECTING THE TRIAL RECEIVER WITH THE TRIAL ELECTRODE ARRAY

**Steps:**

1. Remove the steering stylet from the Trial Electrode Array.
2. Insert the Trial Receiver into the central lumen of the Trial Electrode Array.
3. Continue advancing the Trial Receiver until it reaches the distal tip of the Trial Electrode Array and there is only 2 cm extruding from the proximal tip of the Trial Electrode Array. The Trial Receiver is now connected to the Trial Electrode Array.
4. Remove the handle from the proximal tip of the Trial Receiver and confirm that it has advanced as far as possible.

# TESTING STIMULATION INTRAOPERATIVELY

CAUTION:

To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensations):

- Change parameter settings in small increments when approaching the patient's perception threshold.
- Decrease the amplitude before changing electrode polarities or placing the Transmitter Assembly over the implant.

***Notes:***

- *This procedure requires a Transmitter Assembly (packaged separately). Refer to the Instructions for Use of the Transmitter Assembly. Place the Transmitter Assembly directly over the stimulator just inferior of the electrodes.*
- *Metal stylets can block the energy from the Transmitter Assembly. The stylet must be removed before intraoperative testing. The plastic introducer can be used throughout intraoperative testing.*
- *If good paresthesia coverage of the painful area is not obtained, change the electrode settings before repositioning the stimulator.*

**Steps:**

1. Place the Transmitter Assembly in a sterile drape or sterile fluoroscope bag over the region directly above the most proximal implanted electrode on the stimulator (see Figure 4).

2. Identify the most appropriate stimulation parameters, beginning at a medium pulse width and frequency range. Increase the amplitude while asking the patient close-ended questions to identify the perception threshold, the discomfort threshold, and the area of paresthesia coverage.
3. In the patient's chart, document the device position that provided appropriate stimulation coverage. Record the stimulation settings and patient responses. Include a fluoroscopic image of the final position.


**Figure 4**

# PLACING ADDITIONAL TRIAL ELECTRODE ARRAYS WITH TRIAL RECEIVER

***Notes:***

- *Follow these instructions If additional device(s) are indicated.*
- *Ensure that the additional Trial Electrode Array is labeled Channel B. If the additional Trial Electrode Array is labeled Channel A, it will receive the same programming parameters as the initial Trial Electrode Array with Receiver.*
- *Additional Channel A and B devices may be used, but cannot be programmed independent of the two main channels.*
- *Only one Transmitter Assembly needs to be worn by the patient to provide stimulation to the initial Trial Electrode Array and the additional device.*

**Steps:**

1. Repeat steps for implantation of the Trial Electrode Array.
2. Implant the second Trial device at the appropriate location for the target nerve as clinically indicated.
3. Repeat the steps for the implantation, coil and securement of the Trial Receiver.

***Notes:***

- *If resistance is encountered during advancement of the additional Trial Electrode Array with the bent stylet, exchange the bent stylet for the straight stylet and use short, firm movements to advance the device or use the guidewire.*

## SECURING THE TRIAL LEADS (ELECTRODE ARRAY WITH TRIAL RECEIVER)

**Steps:**

1. Tie 2-0 non-absorbable suture material (such as silk or some other types of braided polyester mesh) around the body of the Trial Lead.
2. Tie the Trial Lead to the skin using the suture material.
3. Tie a knot into the tubing proximal to the MOST proximal receiver maker in each Trial Lead implanted, ensure the knot is larger than the introducer entry.
4. Cover the entry points with sterile dressing and place additional bandage over the remaining device tubing/knots to secure to body externally (see Figure 5).

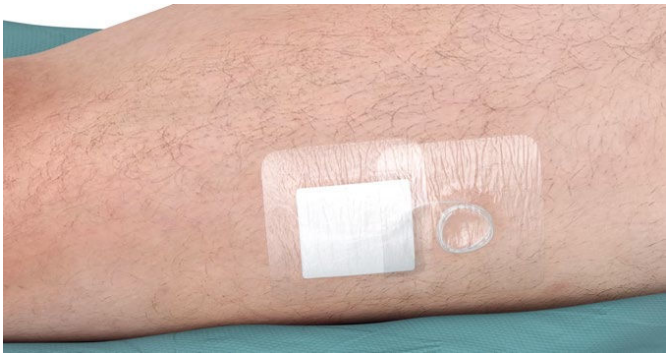


**Figure 5**

## DEVICE EXPLANT PROCEDURE

**Steps:**

1. Use fluoroscopy to visualize the marker band on the implanted device.
2. Make an incision to the depth of the proximal end of the device.
3. If applicable, cut sutures free of any tissue structures or scarring.
4. Remove the device by slowly pulling on the proximal end.
5. After the device has been removed, verify that all components are intact and that all implanted materials are accounted for.
6. Close the incision using standard surgical techniques and dressings.

## DEVICE DISPOSAL

Explanted devices are not to be re-sterilized or re-implanted. Dispose of the used Trial Leads according to local laws and regulations. Alternatively, contact Curonix for information on returning the devices for safe disposal.

# MRI SAFETY INFORMATION

The Freedom PNS Trial System is MR Unsafe, and must not be allowed in the MR system room. The Trial PNS System components are labeled as follows:


MR Unsafe Components

- Freedom-8A Trial Lead (Trial Electrode Array with Trial Receiver)
- Freedom-4A Trial Lead (Trial Electrode Array with Trial Receiver)
- Transmitter Assembly
- Programmer
- USB Battery Charger
- Introducer
- Guidewire
- Steering Stylet
- Accessory components

Patients shall not have an MRI examination while the Freedom PNS Trial Leads are implanted or with any accessory components.

Failure to adhere to the specific requirements described in this manual can result in tissue damage, severe injury, or death. Use the contact information found on the last page of this manual for additional information.

# CONTACT INFORMATION

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