



FREEDOM PERIPHERAL NERVE STIMULATOR SYSTEM



















IMPLANTATION OF NEUROSTIMULATOR INSTRUCTIONS FOR USE

FREEDOM PNS RECEIVER KIT

STQ4-RCV-A0	FR4A-RCV-A0
STQ4-RCV-B0	FR4A-RCV-B0
STQ4-SPR-A0	FR8A-RCV-A0

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
 Length	Device length
	Sterilization: ethylene-oxide gas
	Temperature limits









	Non-ionizing electromagnetic radiation
	IEC 60601-1/EN60601-1, Type BF Equipment
	Federal Communications Commission
	Dispose of this product according to local regulations
	Serial Number
	European Authorized Representative
	Swiss Authorized Representative
	Medical Device

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GLOSSARY OF TERMS

Terms and Synonyms

Definitions

Antenna The antenna connects to the transmitter and transfers power and data from the transmitter, through the skin and to the implanted neurostimulator.

Caution A statement describing actions that could result in damage to or improper functioning of a device.

Contraindication	A condition or circumstance that suggests or indicates that a particular technique or drug should not be used in the case in question.
Electrode	Contact
Electrode Array (Lead)	An implanted catheter with electrodes that are placed near a targeted nerve
Electromagnetic interference (EMI)	A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly
Guidewire	A stainless steel, rigid, solid core guidewire used to create a hollow pathway for the lead to pass through easily.
Incision	Stab wound, cut down, surgical incision
Introducer	A 15-gauge stainless steel dilator and yellow Hytrel introducer assembly that is used to create a pathway for the stimulator to be placed next to peripheral nerves for the Stimulator to pass through easily.
Neurostimulator (Stimulator)	Electrode Array(s) and connected Receiver
PNS	Peripheral Nerve Stimulator implanted for pain relief
Receiver	The receiver is a PEEK coated copper implant that is connected to the electrode array. The receiver couples energy from transmitter to the neurostimulator.

Stimulation The delivery of electrical pulses to the area where pain signals are blocked as they move to the brain. Stimulation blocks some pain signals from reaching the brain.

Stylet (Steering Stylet) A stainless steel wire with a polypropylene handle that is inserted into the open central lumen of the stimulator to provide rigidity during implantation.

Transmitter The transmitter is an external electronic device that generates wireless power and programs for the implanted neurostimulator. The transmitter contains buttons, a rechargeable battery, an antenna cable port, and a micro-USB port (for charging only).

WAA Wearable Antenna Assembly – describes the total assembly of a Transmitter and Antenna. The WAA is used in conjunction with the appropriate wearable to apply therapy to the target nerve.

Warning A statement describing an action or situation that could harm the patient.

HOW TO USE THIS MANUAL

This manual describes the Freedom Neurostimulator implant procedure and the methods to implant the device optimally.

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 neurostimulator and an externally worn transmitter to power the implanted device.

INDICATIONS FOR USE

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

Refer to the Wearable Antenna Assembly Instructions for Use for applicable precautions, warnings, adverse event summary, information about the 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, active general infections, or other potential surgical risks as identified by the clinician. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.

- **Pregnancy** – The safety and effectiveness of the Freedom 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 Freedom PNS System or when wearing the Wearable Antenna Assembly (WAA). The energy from diathermy can be transferred through the Neurostimulator 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. stepdown transformers or high voltage power lines)
- **Implanted cardiac systems** – Patients who have implanted cardiac systems should not use the Freedom PNS System without proper perioperative 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. A very strong EMI can interfere with the System. The device includes features that provides protection from EMI. Most electrical devices and magnets encountered on 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 WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA needs to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described it 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, patients could fall or be injured due to unexpected changes in stimulation.
- Patients who suspect the Freedom PNS System is being affected by EMI should: Immediately move away from the equipment or object.
- The WAA should be removed from the patient's vicinity.

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) – The PNS FR4A and STQ4 Electrode Array with Connected Receiver are MR Conditional. An MRI examination with the FR4A/STQ4 Electrode Array with a connected Receiver may be safely performed under certain conditions.

The PNS FR8A Electrode Array with Connected Receiver is MR Unsafe. Since the FR8A Electrode Array with Connected Receiver is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the System and, in the process, cause serious harm to the patient or other people or damage to the MR system.

Magnetic Resonance Imaging (MRI) – The WAA component is MR Unsafe; the WAA must not enter the MR system room. Since the WAA is MR Unsafe, the strong magnetic field of the MR system could attract or otherwise damage the WAA, 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 WAA 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%. Freedom PNS users and caregivers should avoid approaching or touching the WAA 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 WAA 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 Stimwave must be contacted for assistance or replacement.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with a Neurostimulator. X-rays from the scan could cause unintended shocks or malfunctions of the Freedom 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 WAA 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 Freedom PNS System for more than a few seconds.

After CT scanning directly over the implanted device:

- The WAA 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 WAA 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 Freedom 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 Freedom 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 Freedom PNS System. If RF ablation is used, that ablation should not be performed over or near the Neurostimulator.

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 Freedom PNS System (implanted device and WAA) can be affected by separation distances between the Freedom 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 Stimwave 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 WAA from the

body. When possible, it is best to avoid RFID emitters or remove the WAA 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 Freedom 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 Freedom PNS System, then the insulation can be damaged. The Freedom 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 WAA 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 Freedom PNS System
 - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm the Freedom PNS System is working as intended.

High-Output Ultrasonics / Lithotripsy – Safety has not been established for highoutput ultrasonics or lithotripsy when implanted with the Freedom 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 WAA 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 Freedom 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 Freedom 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 Freedom 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 Freedom 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 Freedom 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 Freedom 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 Neurostimulator.

Machinery or Heavy Equipment – Machinery and heavy equipment (including vehicles) should not be operated while using the Freedom 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 Freedom PNS System on aircrafts. Use of the Freedom PNS System on a commercial aircraft may result in damage to the device or harm to the patient.

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

WAA Skin Contact – The WAA must not be placed directly on the skin. Direct skin contact may cause irritation and/or sensitivity to the materials. The WAA must always be placed over a thin layer of clothing or material.

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

Stimulation Frequencies – Stimulation between 1,500 Hz and 10,000 Hz has not been evaluated for safety, effectiveness, and perception of paresthesia in any Freedom PNS System. Specifically, for stimulation frequencies above 1,500 Hz, amplitudes that produce paresthesia have not been evaluated, and therefore, it is unknown whether injury may occur.

PRECAUTIONS

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

Medical Tests and Procedures – Before undergoing medical tests or procedures, patients should be instructed to contact the clinician to determine if the procedure could cause damage to the patient or 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 WAA as directed – Patients should be instructed to use the WAA only as explained by the clinician or as discussed in the Instructions for Use. Using the WAA in any other manner could result in harm. Use only the device and accessories directly from the Manufacturer; use of third-party accessories may damage the device and is prohibited.

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

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

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

Do not dismantle the WAA – 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 Stimwave representative should be contacted for assistance.

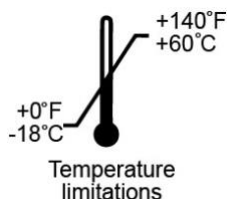
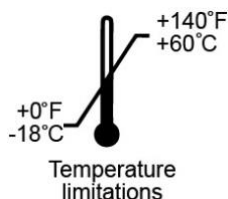
Flammable or Explosive Environments – Patients should be instructed to not use the WAA in flammable or explosive environments. Using the WAA in one of these environments could result in harm.

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

Storage Temperatures – The 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 Receiver Kit	Wearable	Antenna	Assembly	Storage
Temperature	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 System should be turned OFF. Discuss these activities with the clinician.

Interference during programming – If interference is suspected during programming of the WAA, 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.
- 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 WAA 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 neurostimulator 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 Neurostimulator must be avoided. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the Neurostimulator. 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.

POST-OPERATIVE CARE

During the two weeks following surgery, care must be taken to ensure that appropriate healing secures the implanted neurostimulator and closes the surgical incisions:

- Do not engage in rigorous physical activity such as twisting, bending, lifting heavy objects, or climbing.
- Do not remove or alter wound dressings without consulting clinical personnel.
- Continue to take any medications prescribed, such as antibiotics, unless otherwise directed by your clinician.
- Do not touch the wound or push, pull, or twist the implanted neurostimulator.
- Follow any other care instructions provided by your clinician.

Temporarily, you may experience some pain around the implant site as the incisions heal. If you experience significant pain, swelling, discharge, or excessive redness around the wound, contact your clinician. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

ADVERSE EVENT SUMMARY

Implantation of a 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 Freedom PNS System incurs the following risks:

- Undesired change in stimulation, sometimes resulting in pain or muscle spasms
- Neurostimulator 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 Freedom PNS System:

- Neurostimulator migration, resulting in altered stimulation therapy that may be uncomfortable
- Neurostimulator 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. The clinician must be contacted immediately if the patient experiences any problems. 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. The clinician must be contacted if the patient experiences a change in stimulation that could be a result of the Neurostimulator migrating from the implant site.

DEVICE SPECIFICATIONS

Table 1. Freedom PNS Electrode Array(s) Specifications

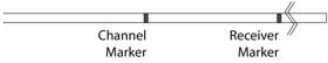

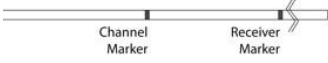



STQ4-A1		
STQ4-B1		
FR4A-A1		
FR4A-B1		
FR8A-A1		
FR8A-B1		
Electrode Array (s):	STQ4/FR4A	FR8A
Length	45 cm	45 cm
Diameter	1.35 mm	1.35 mm
Electrode(s):		
Number	4	8
Shape	Cylindrical	Cylindrical
Length	3 mm	3 mm
Spacing	4 mm	4 mm
Array Length	24 mm	52 mm
Marker Band distance from tip	13 cm	17 cm
Number of Independent Channels:	2	2
Maximum recommended implant depth	6 cm	6 cm
Implant period	Permanent	Permanent

Table 2. Receiver Specifications


Receiver Length	
Diameter	47 cm
	0.35 mm
	
Maximum recommended implant depth	6 cm
Implant period	<u>Permanent</u>

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
Yellow 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 Permanent Kits

(STQ4-RCV-A0, STQ4-RCV-B0, STQ4-SPR-A0, STQ4-SPR-B0)

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

Freedom PNS Permanent Kits

(FR4A-RCV-A0, FR4A-RCV-B0)

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

Freedom PNS Permanent Kit

(FR8A-RCV-A0, FR8A-RCV-B0)

- (1) 8-Contact Electrode Array
- (2) 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 Freedom product labeling.

This document details the implantation of electrode array, pocket creation and connection of electrode array to receiver.

COMMON PERIPHERAL NERVE TARGETS

Common peripheral nerves treated with PNS include the suprascapular, brachial plexus, femoral, 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



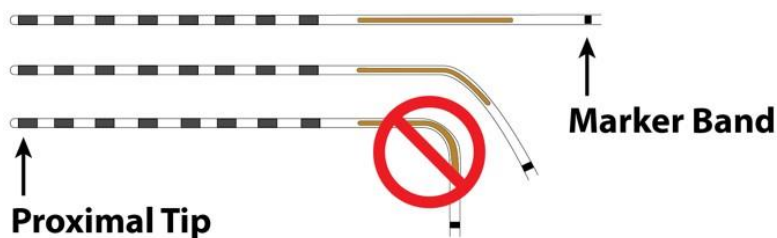
CAUTION:

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

- Use only the introducer or needle supplied.
- Do not bend, kink, or stretch the Electrode Array.
- Do not use any instrument to handle the Electrode Array.
- Use care when positioning or removing a stylet.
- Avoid excessive pressure on the 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 Stimwave for any questions regarding packaging and expiration dates.

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



PROCEDURE 1: IMPLANTATION OF ELECTRODE ARRAY

Steps:

1. Using fluoroscopic or ultrasound guidance, identify the targeted nerve with anatomical landmarks and place a marker needle at the desired location for electrode placement. (Figure 1)

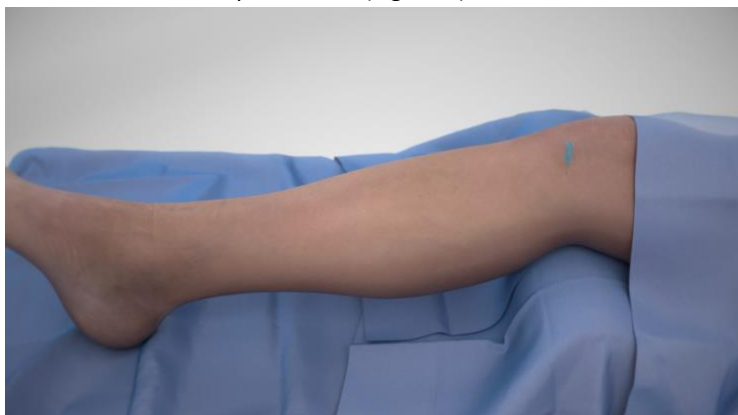


Figure 1

2. Place the electrode array on the sterile skin using the marker needle as a guide in fluoroscopic view. (Figure 2)
3. Place a mark at the first channel marker band (proximal to the electrodes) using a sterile marker, signifying the first incision site. Place

another mark 1 cm past the receiver marker band to estimate the location of the pocket. (Figure 2)

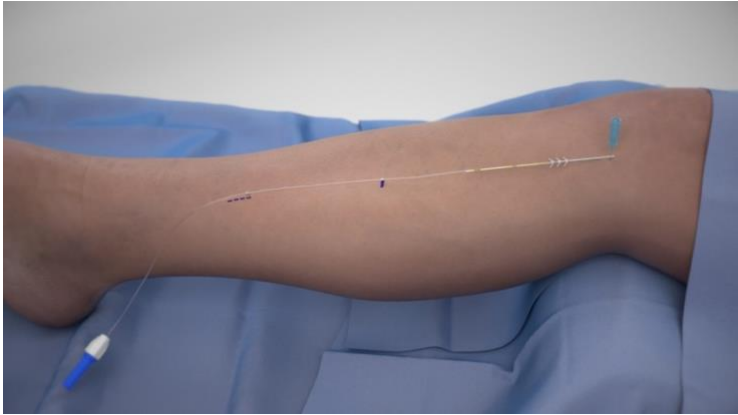


Figure 2

4. Prepare the entry site by administering a local anesthetic superficially and deeply along the proximal needle tract and as needed throughout the procedure.
5. Make a small stab incision at the skin mark. (Figure 3)

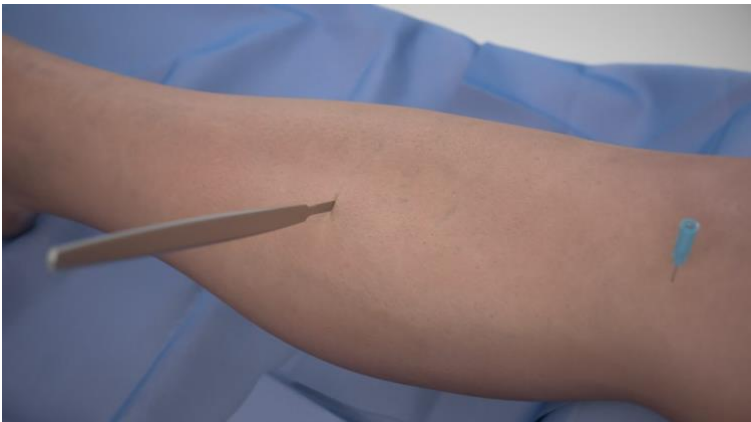


Figure 3

6. Using fluoroscopic guidance, advance the introducer needle assembly through the incision towards the marker needle using a low entry angle. (Figure 4)

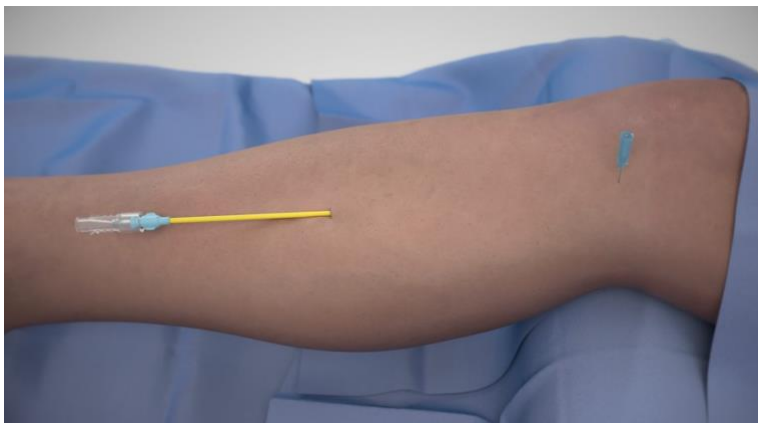


Figure 4

7. Remove the introducer needle stylet. (Figure 5)

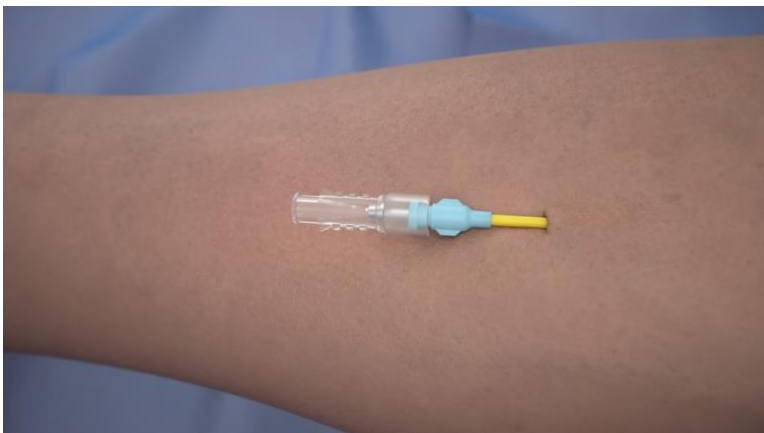


Figure 5

8. Advance the electrode array through the introducer cannula to the tip of the introducer cannula. (Figure 6)

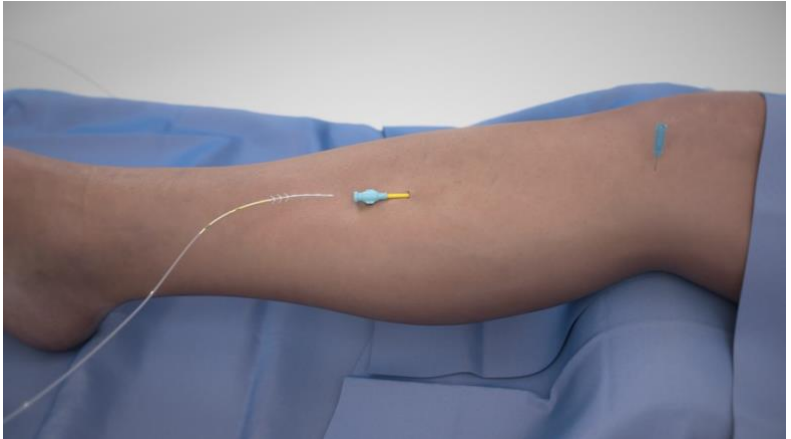


Figure 6

9. Confirm final electrode placement using fluoroscopy.

Procedural Tips:

Use ONLY the introducer or needle provided. Do not remove the introducer needle stylet from the introducer needle when driving into the tissue.

- *If resistance is encountered during the advancement of the Electrode Array with a bent stylet, exchange the bent stylet for a straight stylet and use short, firm movements to advance the device.*
- *A 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 implanted. Measurements and skin marking may be performed before the procedure.*

PROCEDURE 2: POCKET CREATION & CONNECTION OF ELECTRODE ARRAY TO RECEIVER

Notes:

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

CONNECTION OF ELECTRODE ARRAY TO RECEIVER

Steps:

1. Remove the steering stylet from the Electrode Array. (Figure 1)

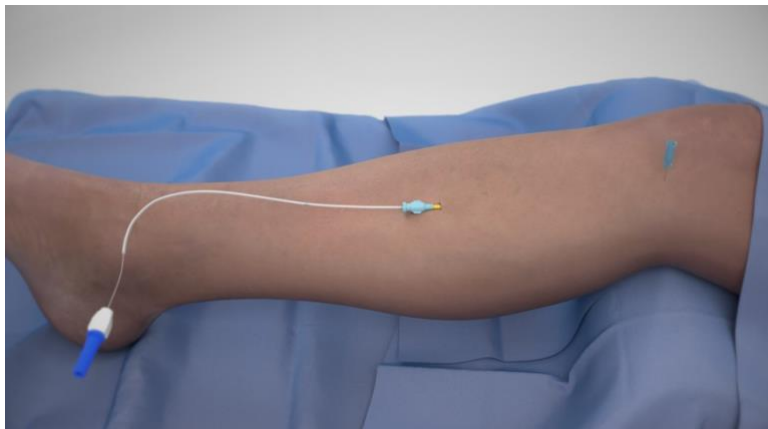


Figure 1

2. Connect the electrode array to the Receiver. (Figure 2)

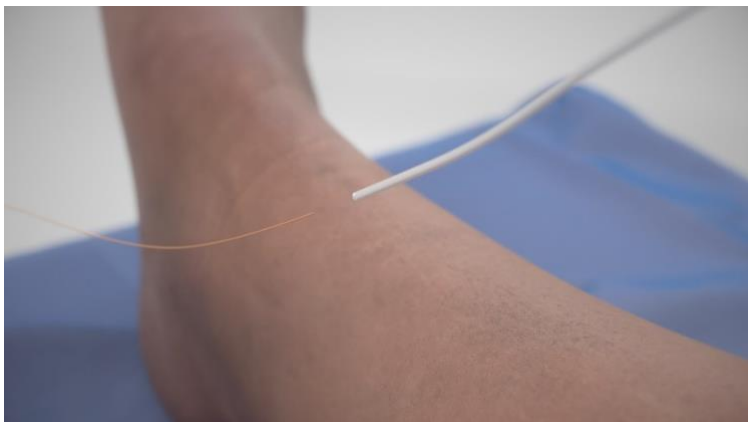


Figure 2

3. The receiver is fully connected when it reaches the tip of the electrode array. Check for a complete connection of the receiver to the electrode array to ensure the functionality of the total neurostimulator.
4. Gently retract the introducer cannula under intermittent or live fluoroscopy, exposing the neurostimulator's final position. (Figure 3)

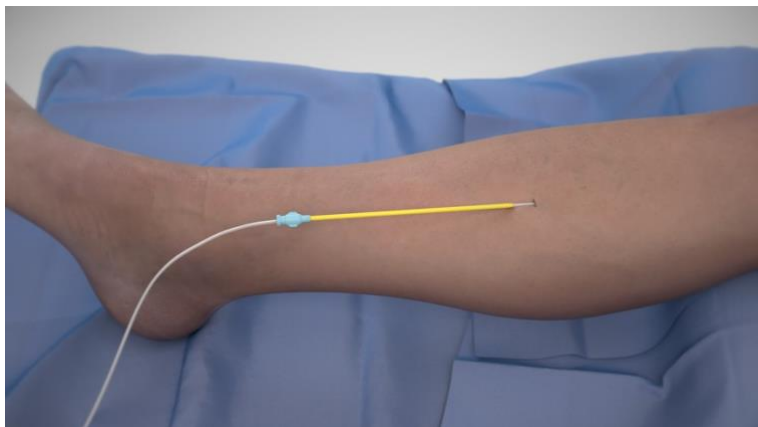


Figure 3

INTRAOPERATIVE TESTING

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 WAA over the implant.
- When placing the neurostimulator in close proximity to the targeted nerve, ensure during intra-operative testing that the paraesthesia does not cause discomfort, as the patient may be more susceptible to uncomfortable or unexpected stimulation.

Steps:

1. Place the WAA in a sterile drape or sterile fluoroscope bag.
2. Position the blue antenna with the black side down, lengthwise, between the two silver marker bands along the neurostimulator. (Figure 4).

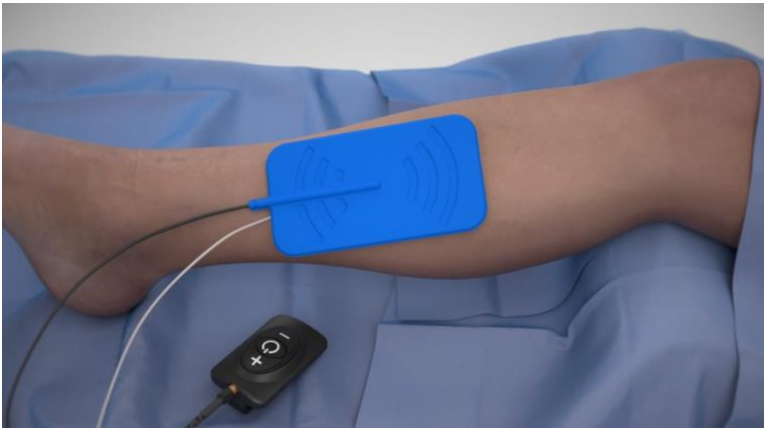


Figure 4

3. 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.
4. After testing, document the neurostimulator position in the patient's chart that provided appropriate stimulation coverage.
5. With the receiver fully connected, cut the excess portion of the receiver flush with the lumen to decrease the possibility of the receiver disconnecting from the electrode array. (Figure 5)

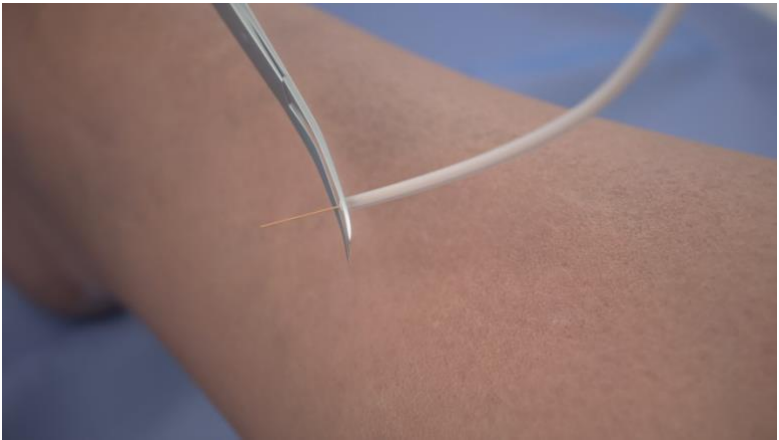


Figure 5

Procedural Tips:

- *This procedure requires a WAA (packaged separately). Refer to the Instructions for Use of the WAA.*
- *Metal stylets can block the energy from the WAA. 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.*

CREATING A SECOND INCISION FOR SUBCUTANEOUS RECEIVER POCKET

Steps:

1. To identify the location of the second incision for the pocket creation, utilize a sterile marker to re-mark the skin after the second marker band or approximately 10 cm from the first incision. The remarking is an assurance that the pocket will be within close proximity to the original measure during the first step of the surgical process. (Figure 1)

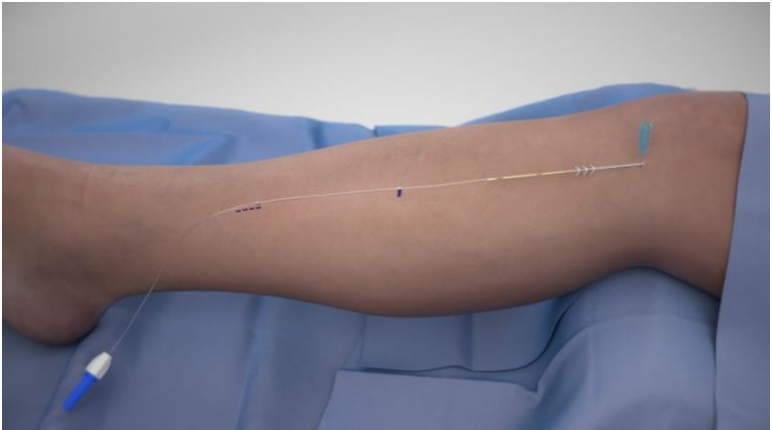


Figure 1

2. Infiltrate local anesthetic along the mark and surrounding tissues in preparation for the second incision.
3. Make an incision, about 2 cm. (Figure 2)

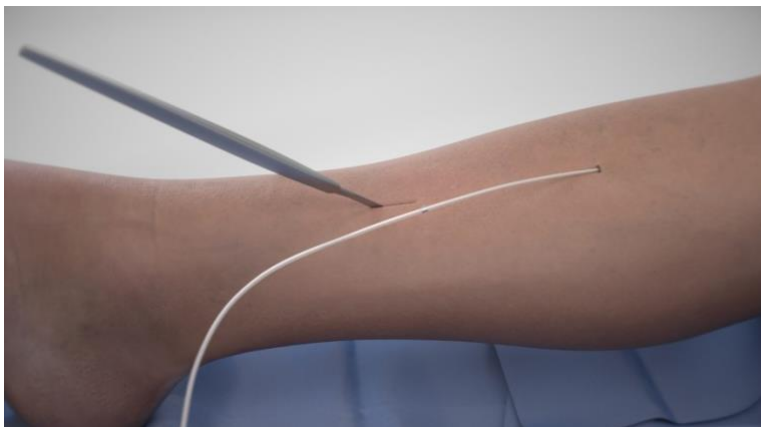


Figure 2

4. Using blunt dissection through the incision, create a subcutaneous receiver pocket. The subcutaneous pocket is made to house and permanently fixate the Receiver coil.
5. As needed, use electrocautery to obtain hemostasis and irrigate with antibiotic solution.

TUNNEL THE CONNECTED RECEIVER AND ELECTRODE ARRAY

Steps:

1. Infiltrate local anesthetic from the pocket to the initial introducer entry site.
2. With the stylet in place, advance the introducer from the second incision receiver pocket to the first incision electrode array entry site.
(Figure 1)

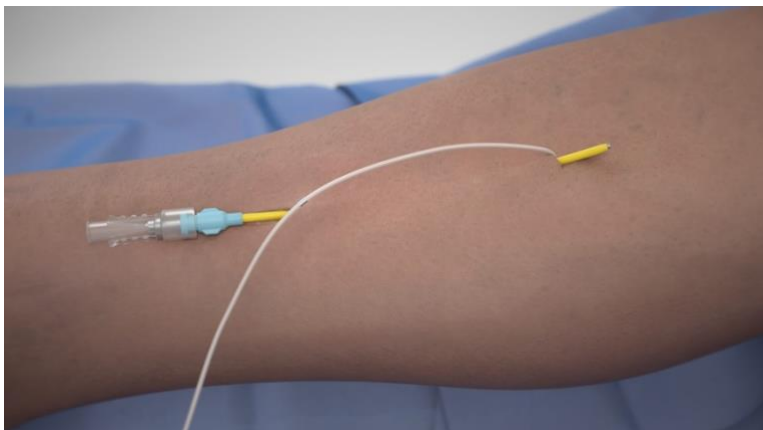


Figure 1

3. Remove the introducer needle stylet. (Figure 2)

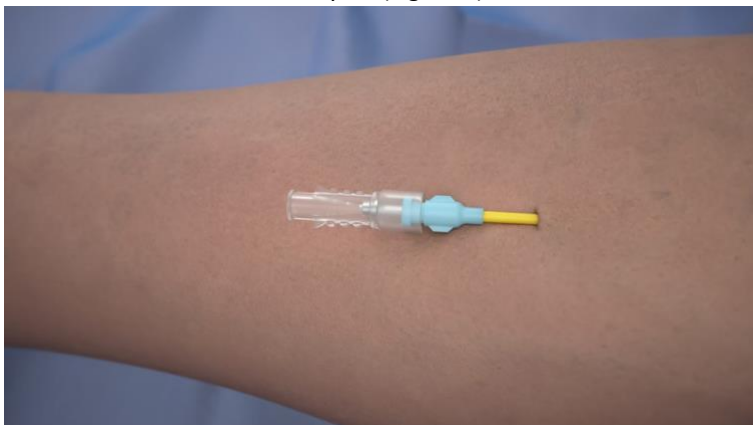


Figure 2

4. Feed the tip of the receiver and electrode array through the distal end of the introducer cannula back into the subcutaneous receiver pocket. (Figure 3)

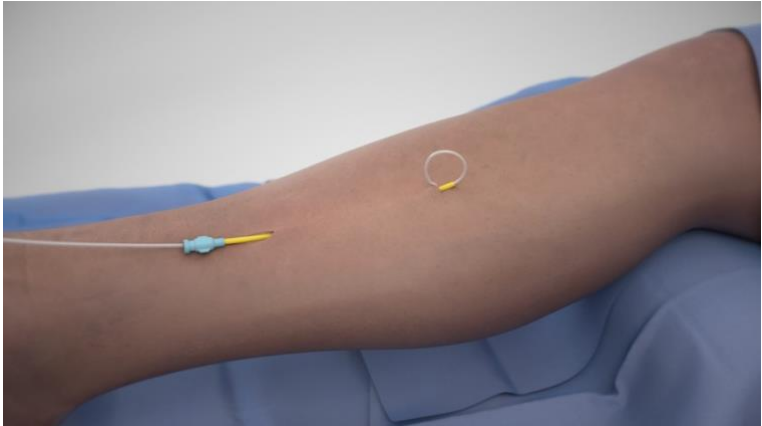


Figure 3

5. Ensure there is no slack at the first incision entry site before withdrawing the introducer from the subcutaneous receiver pocket. (Figure 4)

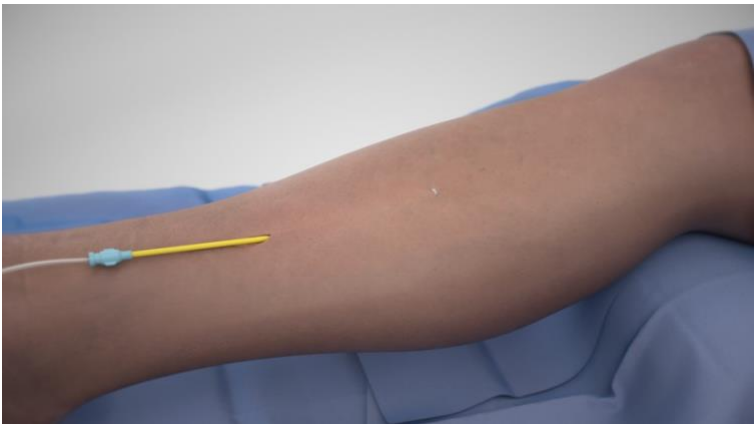


Figure 4

COIL AND FIXATE THE CONNECTED RECEIVER

Steps:

1. Secure the connection of the electrode array to the receiver by tying a knot after the receiver marker band. (Figure 1) The knot must be proximal to the marker bands.

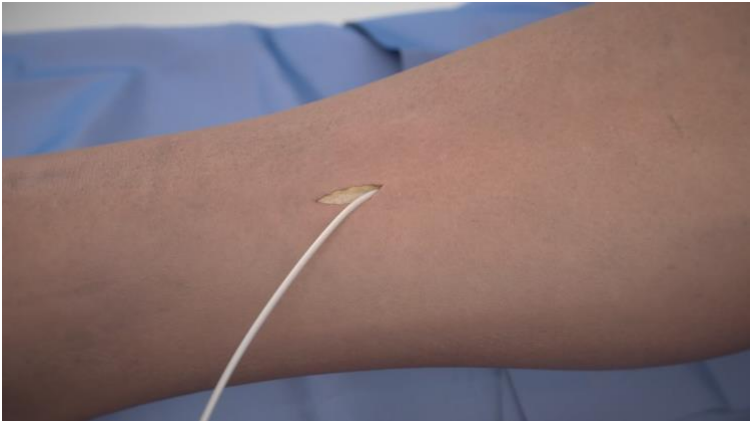


Figure 1

2. Coil the remaining receiver portion after the knot into a small diameter coil.
3. Tie two non-absorbable sutures to permanently form the receiver coil. Tuck the end of the receiver coil underneath the coil to avoid protruding edges. This may mitigate potential pocket complications associated with erosion. (Figure 2)

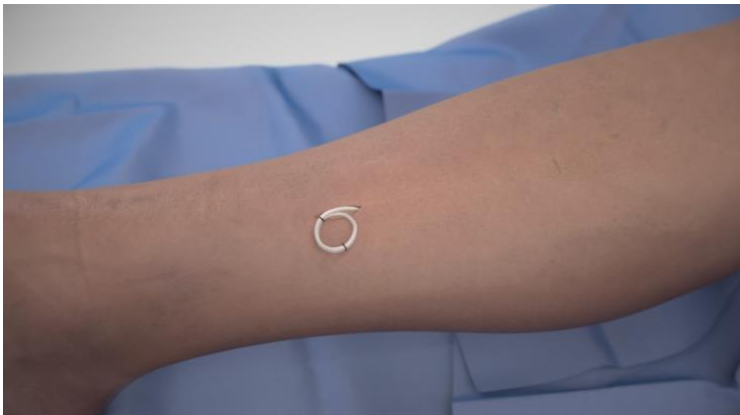


Figure 2

4. Using a non-absorbable suture, suture the receiver coil to the fascia at two locations, ensuring it is flat in the pocket. (Figure 3 & 4)



Figure 3

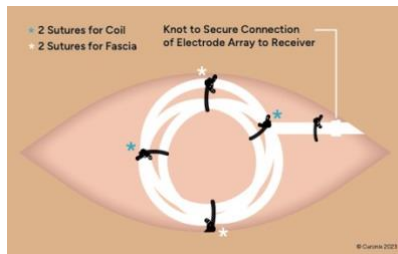


Figure 4

5. Close the incisions using sterile skin closures and apply dressings. Closures are usually done in two steps, with absorbable sutures for the deeper layer and either nonabsorbable or absorbable sutures for the superficial layer. Apply dressings as needed.

PLACING ADDITIONAL ELECTRODE ARRAYS WITH CONNECTED RECEIVER

Notes:

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

Steps:

1. Repeat steps for implantation of the Electrode Array.
2. Insert the second device parallel to the first.
3. Repeat the steps for Pocket Creation & Connection of the Electrode Array to the Receiver.
4. Close the incisions using standard surgical techniques and apply dressings.

Notes:

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

DEVICE EXPLANT PROCEDURE

Steps:

1. Use fluoroscopy to visualize the most distal marker band to the neurostimulator on the implanted device.
2. After anesthetizing the incision site, make an incision at the pocket site to reopen the pocket.
3. Using sharp and blunt dissection, release the coil from any scarring and cut the remaining sutures.
4. Remove the device by slowly pulling on the exposed end.
5. After removing the device, verify that all components are intact and that all implanted materials (including sutures) are accounted for.
6. Close the incision using standard surgical techniques and apply dressings.

DEVICE DISPOSAL

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

MRI SAFETY INFORMATION



MRI CONDITIONS FREEDOM PNS (FR4A/STQ4)

NEUROSTIMULATORS

Non-clinical testing demonstrated that the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver) is MR Conditional. A patient with the Freedom PNS FR4A/STQ4 can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla.
- Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 T/m).
- Neurostimulators/Leads Implanted in Upper Arm (e.g., located between elbow and shoulder):

- Scanning the upper arm region (i.e., radial and ulnar nerves near the implant) at 1.5Tesla/64MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg. This SAR is more restrictive than the Normal Operating Mode.
- Scanning any other region (e.g., lower arm, shoulder, head, torso, leg) at 1.5 Tesla/64MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).

- Neurostimulators/Leads Implanted in Lower Arm, Low Back, Pelvis, Leg:
 - Whole Body Scans (i.e., near or far from the implant) at 1.5Tesla/64MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0W/kg (Normal Operating Mode).
- No other components of Freedom PNS System (e.g., WAA, battery charger, stylets, introducer assembly) may be taken into the MR system room.

Under the scan conditions defined above, the Freedom PNS FR4A and STQ4 Electrode Array with a connected Receiver are expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 15 mm from the Freedom PNS FR4A/STQ4 Electrode Array with connected Receiver when imaged with a gradient echo pulse sequence and a 1.5T MRI system.

NOTE: *This information applies only to a single implanted Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with Receiver).*

Magnetic Resonance Imaging (MRI) may be safely performed under specific conditions on a patient with the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver). In-vitro testing demonstrated that the Freedom PNS FR4A/STQ4 Neurostimulator (Electrode Array with connected Receiver) is MR Conditional. The Freedom PNS System components are labeled as follows:



MR Conditional Component



MR Unsafe Components

Freedom PNS FR4A/STQ4 Electrode Arrays with connected Receiver. A patient with the Freedom PNS FR4A and STQ4 Electrode Arrays with a connected Receiver may be safely scanned with MRI only under very specific conditions.

Scanning under different conditions may result in severe patient injury or device malfunction.

See the specific conditions for safe scanning given above.

- FR8A PNS Electrode Array with connected Receiver
- WAA
- Programmer
- USB Battery Charger
- Introducer
- Guidewire
- Steering Stylet

WARNING:

Remove the WAA from the patient before entering the MR system room. The strong magnetic field of the MR system could attract or otherwise damage the unit and may cause serious harm or damage to the WAA and/or the MR system.



The WAA **MUST NOT** be present in the MR system room at **ANY TIME**. Failure to adhere to the specific requirements described in this manual can result in tissue damage, severe injury, or death of the patient. Please use the contact

information found on the last page of this manual for additional information. Follow these instructions when preparing the patient for an MRI examination:

- Instruct patients to carry their current Medical Implant Card to every MRI appointment.
- Instruct patients to always provide the MRI personnel with their Medical Implant card. This indicates the manufacturer as Stimwave and identifies the implanted product model number(s) to be used to determine appropriate MR conditions.

The MRI system operators can use this information to obtain instructions to determine the eligibility of your Freedom PNS System for the MRI procedure. Acceptable MR conditions to ensure patient safety can then be used.

PREPARATION FOR AN MRI

The following steps are required before performing an MRI procedure on a patient with an implanted Freedom PNS System.

1. Remove the WAA (the external component of the System) from the patient before allowing the patient to enter the MR System.
2. Do not conduct an MRI procedure if the patient has any other implant or health condition that prohibits or contraindicates an MRI examination. If the patient has another implant, especially an electronically activated or “active” device, the safety of performing an MRI with the addition of Freedom PNS FR4A/STQ4 Electrode Arrays with Receiver is unknown.
3. Instruct the patient to immediately inform the MR system operator (i.e., the MRI technologist) if any discomfort, stimulation, shock, heating, or other unusual sensations occur during the examination.
4. The patient must be conscious during the MRI examination to inform the MR system operator of any problem.
5. Verify with the MR system operator that all proposed MRI conditions comply with the requirements specified in this manual. If any MRI parameter is not met and cannot be modified, do not perform the MRI procedure.

As an MR system operator, if you are unsure of your MRI system's capabilities, contact the manufacturer. If the MRI scan sequences do not

meet the conditions, then the pulse parameters must be adjusted so that they comply.


DURING AN MRI EXAMINATION

The patient should be conscious during the MRI procedure. Monitor the patient both visually and audibly. Check the patient between each MR imaging sequence. Discontinue the MRI examination *immediately* if the patient is unable to respond to questions or reports any problem.

POST-MRI REVIEW

After the MRI procedure, verify that the patient feels normal. Verify that the Freedom PNS FR4A/STQ4 Electrode Array with connected Receiver is functional by checking its response to the WAA.

CONTACT INFORMATION

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