CURONIX

FREEDOM® SPINAL CORD STIMULATOR SYSTEM

IMPLANTATION OF NEUROSTIMULATOR

INSTRUCTIONS FOR USE

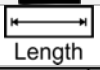
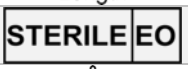
Caution: Federal law restricts this device to sale by or on the order of a physician.

FREEDOM SCS RECEIVER KIT

FR4A-RCV-A0	FR8A-RCV-A0
FR4A-RCV-B0	FR8A-RCV-B0
FR4A-SPR-A0	FR8A-SPR-A0
FR4A-SPR-B0	FR8A-SPR-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 the package
	Consult instructions for use
	Do Not Reuse
	Do Not Resterilize
	Do not use if the 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

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
SCS	Spinal Cord 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).
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 Spinal Cord Stimulator (SCS) System is used for spinal cord stimulation to provide therapeutic relief or chronic, intractable pain of the back and/or lower limbs including unilateral or bilateral pain. The therapy utilizes pulsed electrical current to create an energy field that acts on nerves near the spinal column. The System is comprised of an implantable stimulator (Freedom-8A), receiver, and an externally worn Transmitter Assembly to power the device. The System is implanted only following a successful trial period with the Freedom 8A Trial Lead.

INDICATIONS FOR USE

The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

The Freedom-8A Trial Kit is only used in conjunction with the Freedom-8A Receiver Kit.

The Freedom-4A Trial Kit is used for either the Receiver Kit Freedom-4A Stimulator or the Receiver Kit Freedom-8A Stimulator.

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 Transmitter 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 –** Spinal cord 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 SCS System for use during pregnancy and nursing have not been established.
- **Inability to operate System –** Spinal cord stimulators should not be used on patients who cannot understand or operate the System.
- **Exposure to shortwave, microwave, or ultrasound diathermy –** Diathermy should not be operated near a patient implanted with a Freedom SCS System or when wearing the Transmitter Assembly. 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 include 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 with implanted cardiac systems should not use the Freedom SCS System. 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 Transmitter Assembly. This may cause the external device to turn on, off, or to reset to the 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. 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 SCS System is being affected by EMI should:

- Immediately move away from the equipment or object.
- The external Transmitter Assembly 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 furnaces/heaters or electric arc furnaces/heaters 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 SCS Freedom-8A Electrode Arrays with Connected Receiver are MR Conditional. An MRI examination with the Freedom-8A Electrode Array with a connected Receiver may be safely performed under certain conditions.

Magnetic Resonance Imaging (MRI) – The SCS Freedom-4A Electrode Array with Connected Receiver is MR Unsafe. Since the Freedom-4A Electrode Arrays with a 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 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%. Freedom 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 the patient's body and powered off; then the device can be powered on. Before resuming therapy, confirm the device indicators/lights are operating correctly. If the device does 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 patients with a Neurostimulator. X-rays from the scan could cause unintended shocks or malfunctions of the Freedom SCS 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 the X-ray beam does not dwell over the Freedom SCS 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 turned on.
- Proper stimulation must be confirmed and 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 the Freedom SCS System. The 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 SCS 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 SCS 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 SCS System (implanted device and Transmitter Assembly) can be affected by separation distances between the Freedom SCS System and the RFID emitter of less than 3m (~10 ft). More powerful RFID emitters might cause an effect at farther distances. RFID emitters can be hidden or portable and not 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, they turn off the Transmitter, promptly move away from the area and remove the Transmitter Assembly from their body. When possible, it is best to avoid RFID emitters or turn off and 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 turn off the Transmitter Assembly, remove it from their body, then 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 SCS System. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

Electrocautery – Using electrocautery tools near the Freedom SCS System may cause damage to the insulation, causing the Freedom SCS System to potentially 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 Freedom SCS System.
    - Full-length operating room table ground pads should not be used.
- After electrocautery, confirm the Freedom SCS System is working as intended.

High-Output Ultrasonics / Lithotripsy – Safety has not been established for high-output ultrasonics or lithotripsy when implanted with the Freedom SCS System. The 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 Freedom SCS 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, harming the patient or nearby people.

Bone Growth Stimulators – Safety has not been established for bone growth stimulator systems near the Freedom SCS 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 for dental drills or ultrasonic probes near the Freedom SCS System has not been established. The 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 near the Freedom SCS System. The use of electrolysis may result in damage to the device or harm to the patient.

Laser procedures – Safety has not been established for lasers near the Freedom SCS System. The 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 with the Freedom SCS 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 SCS System. A System malfunction 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 the use of the Freedom SCS System on aircrafts. Use of the Freedom SCS 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 occur.

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

Painful Stimulation – If the patient experiences painful stimulation, the amplitude on the Transmitter Assembly 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 SCS 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 diagnosing and treating chronic intractable pain and familiar with using the Freedom SCS System. Implanting clinicians should be experienced in spinal 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 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. Use only the device and accessories directly from the Manufacturer; use of third-party accessories may damage the device and is prohibited.

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.

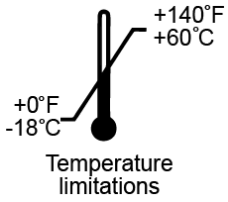
Do not dismantle the Transmitter Assembly – Patients should be instructed not to dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, a Curonix representative should be contacted for assistance.

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

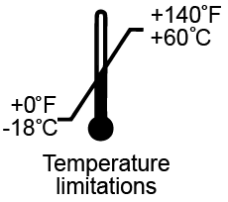
Use of another patient's Transmitter Assembly – Patients should be instructed to never use another patient's Transmitter Assembly. The therapy program is a unique prescription for each patient. Use of another patient's Transmitter Assembly could result in overstimulation or decreased stimulation.

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

Freedom Receiver 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 System should be turned OFF. Discuss these activities with the clinician.

Interference during programming – If interference is suspected during the 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 the 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 Transmitter Assembly through pairing.
- Resume programming in 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 not to dive below 13 meters (45 feet) of water or enter hyperbaric chambers above 1.5 atmospheres absolute (ATA). These conditions can damage the device. Patients 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 using medical Spinal cord 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 heals. 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
- Leakage of cerebrospinal fluid
- Epidural hemorrhage, hematoma, or paralysis

Therapeutic use of the Freedom SCS System incurs the following risks:

- Undesired change in stimulation, including uncomfortable chest wall stimulation
- 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 SCS 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. Specifications for the Freedom SCS Electrode Array(s)

FR4A-A1			
FR4A-B1			
FR8A-A1			
FR8A-B1			
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
Anchor		SandShark Anchor 	
Maximum recommended implant depth		6 cm	6 cm
Implant period		Permanent	Permanent

Table 2. Receiver Specifications

Receiver	
Length	47 cm
Diameter	0.35 mm
	
Maximum recommended implant depth	6 cm
Implant period	Permanent

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	No
Guidewire	Stainless Steel	Yes
Tuohy Needle	Stainless Steel	Yes
Stylets		
Handle	Polypropylene, Polycarbonate	Yes
Wire	Stainless Steel with Polytetrafluoroethylene (PTFE)	Yes
Anchor		
SandShark	Carbothane-Barium Sulfate	Yes

PACKAGE CONTENTS

Freedom SCS Permanent Kits

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

- (1) Electrode Array
- (1) Receiver
- (2) Steering Stylet
- (1) Tuohy Needle
- (1) Guidewire

Freedom SCS Permanent Kit

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

- (1) Electrode Array
- (2) Receiver
- (2) Steering Stylet
- (1) Tuohy Needle
- (1) Guidewire

INSTRUCTIONS FOR IMPLANTATION

Implanting clinicians should be experienced in procedures that gain access to the epidural space, spinal cord stimulators, ultrasound and/or fluoroscopy, and Freedom product labeling.

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

PREPARING FOR PROCEDURE

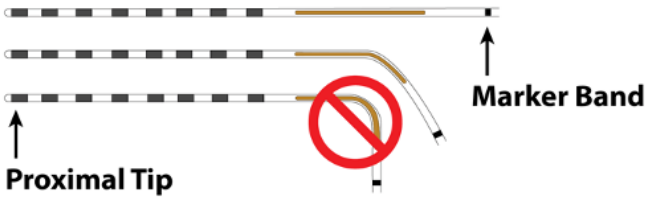
Before opening the device package, verify the package integrity, model number, and use-by date. This product is provided sterile. Do not use the product if the package is damaged. Do not use the product if the date has expired. Contact Curonix for any questions regarding packaging and expiration dates.

 CAUTION:

To reduce the risk of damage to the product that might result in intermittent or loss of stimulation:

- Use only the needle(s) supplied.
- Use a shallow needle-insertion angle (45 degrees or less) when inserting or withdrawing the needle into or out of the epidural space.
- 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.

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 the proximal tip to the distal end of the Electrode Array. Handle the Receiver with care.



PROCEDURE 1: IMPLANTATION OF THE ELECTRODE ARRAY

Steps:

1. As necessary, perform “Time Out” or any other pre-op procedures.
2. On the prepared sterile skin, place the proximal tip of the Electrode Array at the approximate vertebrae level where the first (E0) electrode will be placed in the epidural space.
3. Place a mark at the first channel marker band (proximal to the electrodes) using a sterile marker, signifying the first incision site. (Figure 1)

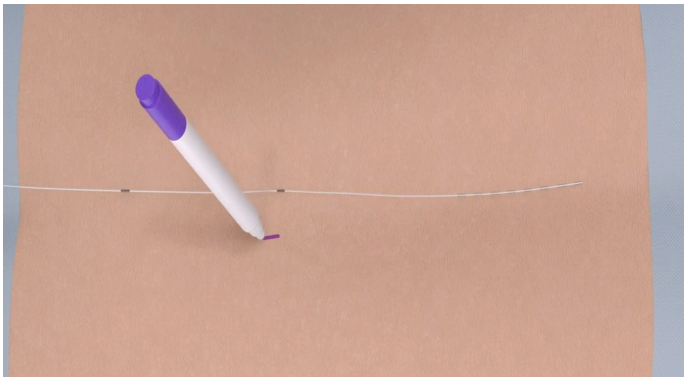


Figure 1

4. Prepare the entry site by administering a local anesthetic superficially and deeply along the needle tract and as needed throughout the procedure. (Figure 2)

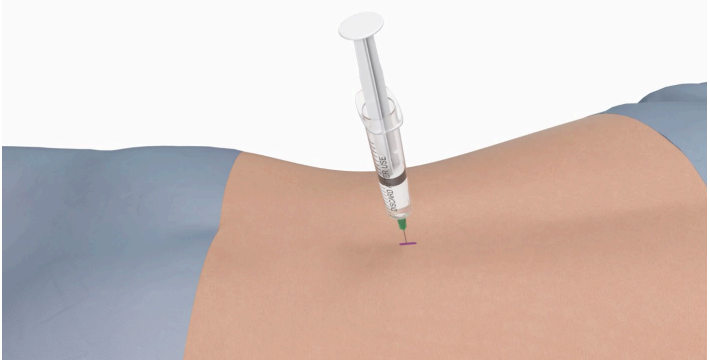


Figure 2

5. If necessary, make small incision at the needle-entry site to the depth of the subcutaneous fascia.
6. Use a paramedian approach lateral to the midline to insert the needle assembly into the epidural space. Use a shallow angle until you encounter resistance from the ligamentum flavum.
7. Under fluoroscopy verify that the needle location is in the correct position.
8. Confirm entry into the epidural space using the loss-of-resistance technique with air or sterile saline.
9. If desired, insert the guide wire through the needle; advance the guide wire no farther than 1 cm to 3 cm past the needle tip.
10. Slowly insert the electrode array through the needle and advance to the location that has the proposed optimal starting location (see Figure 3). Use fluoroscopy to visualize the location (anterior-posterior and lateral views).

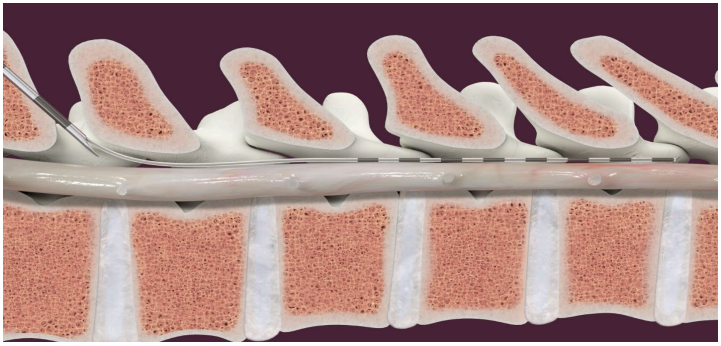


Figure 3

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.*
- *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.
2. Connect the electrode array to the Receiver. (Figure 1)

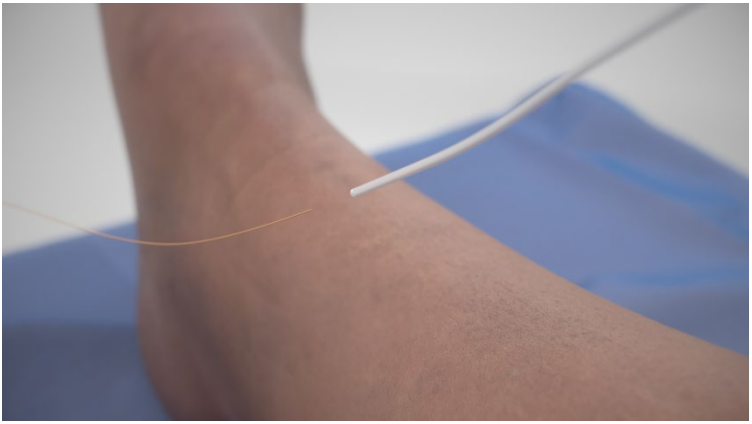


Figure 1

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 needle under intermittent or live fluoroscopy, exposing the neurostimulator's final position.

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

Steps:

After the Electrode Arrays are in the desired location in the epidural space, perform intraoperative testing:

1. Place the Transmitter Assembly 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.
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. Include a fluoroscopic image of the device position.
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 2)

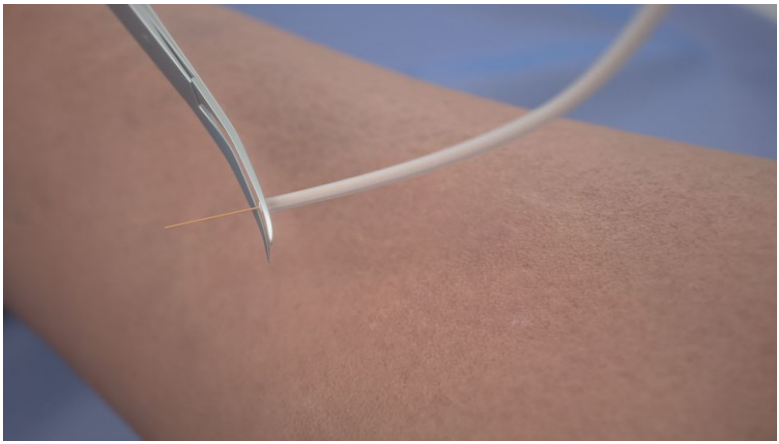


Figure 2

Procedural Tips:

- *This procedure requires a Transmitter Assembly (packaged separately). Refer to the Instructions for Use of the Transmitter Assembly.*
- *The metal needle **blocks** the energy from the Transmitter Assembly. The needle must be removed before intraoperative testing.*

- *If paresthesia response is not obtained, change the electrode array and programming settings as necessary.*

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 mark the skin after the second marker band or approximately 10 cm from the first incision.
2. Infiltrate local anesthetic along the mark and surrounding tissues in preparation for the second incision.
3. Make an incision, about 2 cm. (Figure 4)

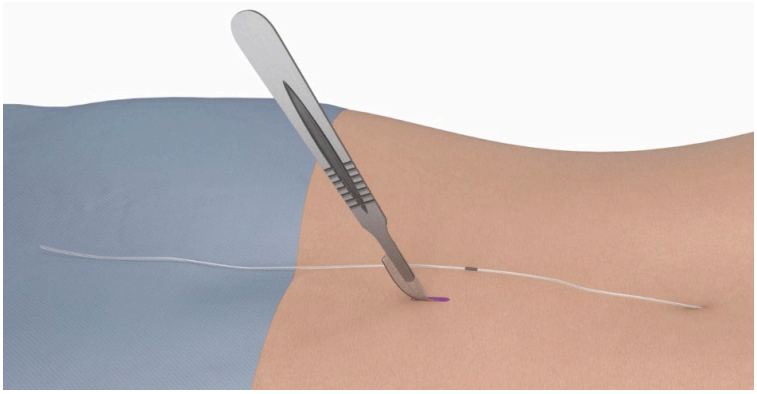


Figure 4

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.

ANCHORING THE NEUROSTIMULATOR

Notes:

- *Repeat the steps below for each additional Electrode Array.*
- *The SandShark Injectable Anchor System is packaged separately. Refer to the Instruction for Use of the SandShark Injectable Anchor System.*

Steps:

1. Remove the needle without moving the position of the Electrode Array.
2. Load the SandShark Anchor using the Loading Base. Slowly twist the Injectroducer to load the SandShark Anchor on to the Injectroducer.
3. Once loaded, straighten the SandShark Anchor so that it can pass through the dermal layers and through the first incision site. (Figure 5)

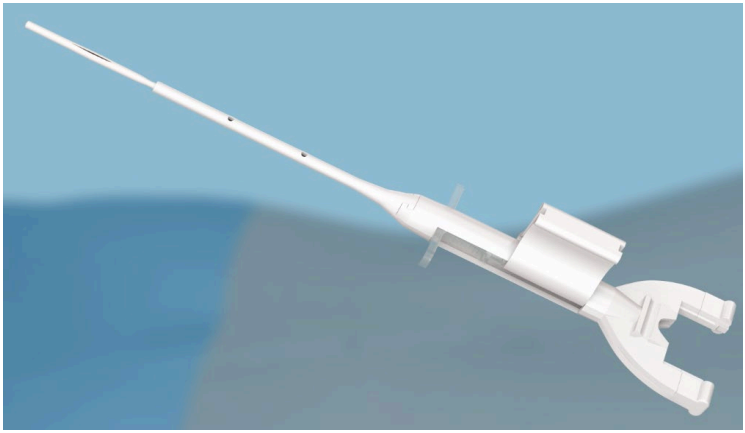


Figure 5

4. Insert the tail of the Electrode Array through the distal mouth of the Injectroducer. (Figure 6)

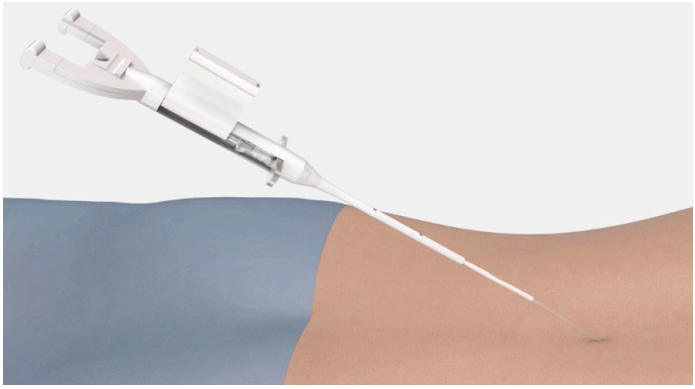


Figure 6

5. Advance the Injectroducer such that the SandShark Anchor is beneath the fascia and posterior to the ligamentum flavum.
6. To prepare for deployment, place the locking clip on the proximal tail of the Injectroducer, securing the excess Stimulator tubing underneath the locking clip.
7. Verify with an AP and lateral view X-ray that the electrodes have not shifted from the original target location.
8. Deploy the SandShark Anchor by pulling back on the handle. (Figure 7)

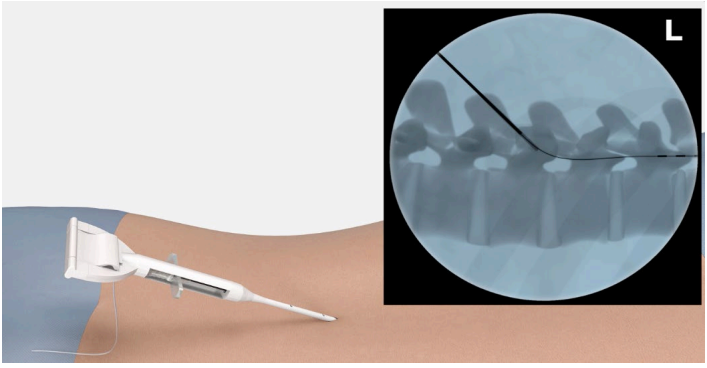


Figure 7

9. Remove the locking clip and pull the Injectroducer out slowly, verify final placement of SandShark Anchor with another lateral X-ray. (Figure 8)

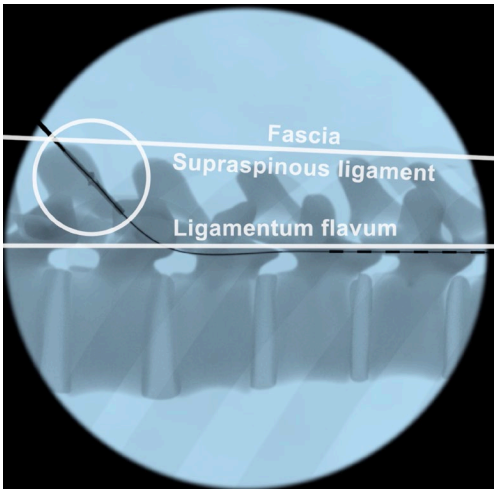


Figure 8

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).

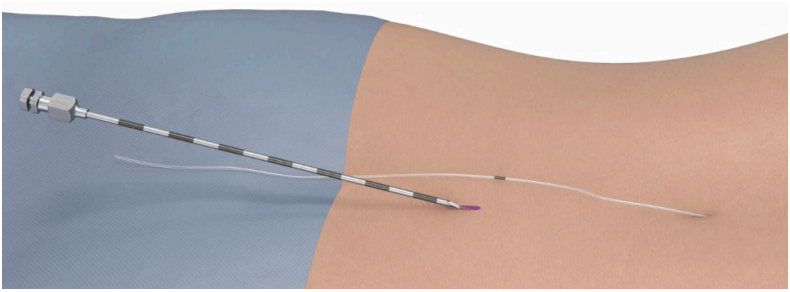


Figure 1

3. Remove the needle.
4. Feed the tip of the receiver and electrode array through the distal end of the needle back into the subcutaneous receiver pocket. (Figure 2)

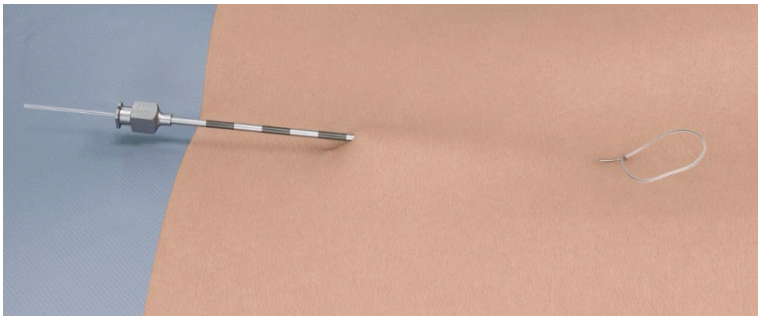


Figure 2

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

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.

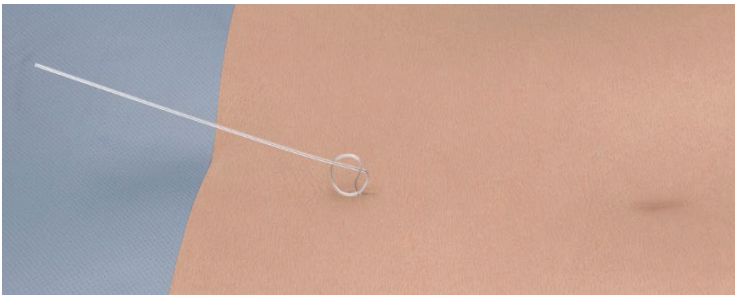


Figure 1

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.

4. Using a non-absorbable suture, suture the receiver coil to the fascia at two locations, ensuring it is flat in the pocket. (Figure 2 & 3)

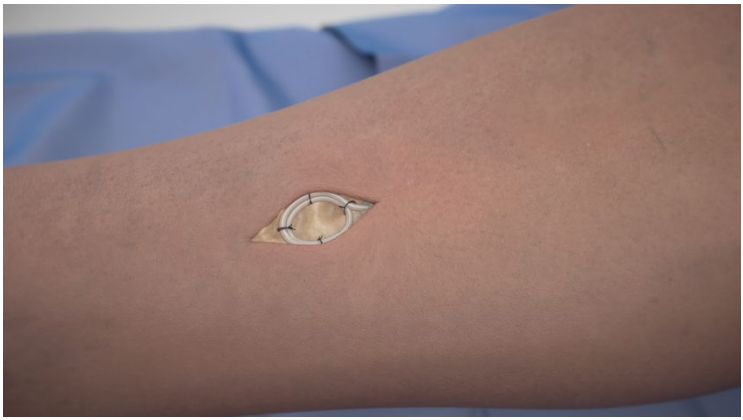


Figure 2

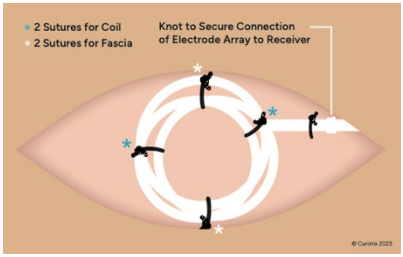


Figure 3

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. (Figure 4)

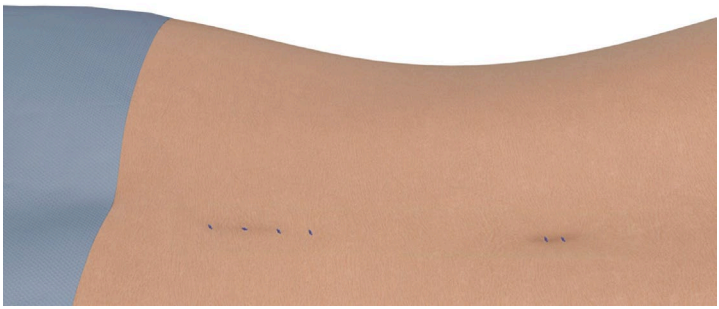


Figure 4

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 Transmitter Assembly 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. Implant the second device parallel to the first. (Figure 1)
3. Repeat steps for anchoring the Electrode Array.
4. Repeat the steps for Pocket Creation & Connection of the Electrode Array to the Receiver
5. Close the incisions using standard surgical techniques and apply dressings.

Notes:

- *If resistance is encountered during 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.*

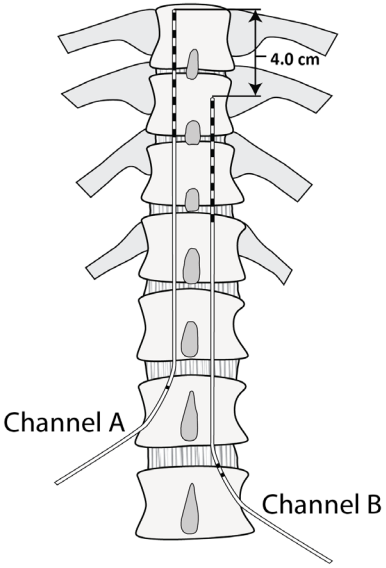


Figure 1

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. If applicable, cut sutures free of any tissue structures or scarring.
5. Remove the device by slowly pulling on the exposed end.
6. After removing the device, verify that all components are intact and that all implanted materials (including sutures) are accounted for.
7. 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 Curonix for information on returning the devices for safe disposal.

MRI SAFETY INFORMATION

MRI CONDITIONS FREEDOM-8A SCS (FR8A) NEUROSTIMULATOR

Non-clinical testing demonstrated that the Freedom SCS FR8A Neurostimulator (Electrode Arrays with connected Receiver) is MR Conditional. A patient with the SCS Freedom FR8A Neurostimulator can be safety scanned in an MR system meeting the conditions defined in the table below, per the location of the device implant. Under the scan conditions defined, patients can be scanned continuously for thirty (30) minutes with a wait time cooling period of thirty (30) minutes between scans. No other components of the Freedom SCS System (e.g., Transmitter Assembly, Wearable Accessory, charger, stylets, introducer assembly) may be taken into the MR system room. Refer to the MRI Instructions for Use (05-20500) for specific scan locations and parameters.

Specifications	Permanent Freedom PNS		Permanent Freedom SCS
Conditions	**4-Contact Electrode Array (With Tines)** STQ4-RCV-A0, STQ4-RCV-B0, STQ4-SPR-B0, FR4A-RCV-A0, FR4A-RCV-B0, FR4A-SPR-B0  Close-Up View	**8-Contact Electrode Array** FR8A-RCV-A0, FR8A-RCV-B0, FR8A-SPR-B0  Close-Up View	**8-Contact Electrode Array** FR8A-RCV-A0, FR8A-RCV-B0, FR8A-SPR-B0  Close-Up View
1.5T Full Body	MR	MR	MR
3T Full Body	MR	MR	MR

NOTE: *This information applies only to a single implanted Freedom FR8A Neurostimulator (Electrode Arrays with connected Receiver).*

The Freedom SCS System components are labeled as follows:

MR Conditional Component	MR Unsafe Components
Freedom SCS FR8A Neurostimulator (Electrode Arrays with connected Receiver). A patient with the Freedom SCS FR8A Neurostimulator (Electrode Arrays with 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.	• FR4A SCS Neurostimulator • FR8A Trial Lead • FR4A Trial Lead • Transmitter Assembly • Wearable Accessory • iPad Programmer • USB Battery Charger • Needle • Introducer • Guidewire • Steering Stylet

⚠ WARNING:

Remove the Transmitter Assembly and wearable accessory 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 Transmitter Assembly and/or the MR system.

The Transmitter Assembly **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 Curonix 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 SCS System for the MRI procedure. Acceptable MR conditions to ensure patient safety can then be used.

IMPORTANT MRI SAFETY INFORMATION

Magnetic resonance imaging (MRI) may be safely performed under certain conditions on a patient with a Freedom Stimulator System. However, the Transmitter Assembly unit (i.e., the external transmitter and antenna components of this neuromodulation system) MUST NOT be present in the MRI 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.

PREPARATION FOR AN MRI

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

1. Remove the Transmitter Assembly (the external component of the system) and Wearable Accessory from the patient before allowing the patient to enter the MRI system room.
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 System (SCS/PNS) is unknown.
3. Instruct the patient to immediately inform the MRI system operator (i.e., the MRI technologist) of any discomfort, stimulation, shocking, or heating, or other unusual sensation occurs during the examination.
4. The patient should be conscious during the MRI examination in order to inform the MRI system operator of any problem.
5. Verify with the MRI system operator that all proposed MRI conditions comply with the requirements specified in the Instructions for Use. If any MRI parameter is not met and cannot be modified, do not perform the MRI procedure.

As an MRI 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 to inform the MRI system operator of any discomfort, stimulation, shocking, or heating during the examination. 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.

After confirmation, remove the patient from the MRI system room and have the patient complete the following for the Freedom System (SCS/PNS):

1. Place the Transmitter Assembly in the Wearable Accessory and over the implanted stimulator.
2. Turn on stimulation by powering on the Transmitter Assembly and adjusting to identified Power Index.
3. Confirm proper stimulation and check that indicator lights are operating as expected.
4. Turn off the Transmitter Assembly if it is suspected that the external components (Transmitter Assembly) or internal stimulator is not

functioning properly or if any discomfort, stimulation, shocking, or heating occurs.*

*If any of these event(s) occurs, turn off the Transmitter Assembly and contact your local Curonix representative.

FREEDOM TRIAL STIMULATOR SYSTEMS FOR SCS

The Freedom Trial Stimulators (FR4A-TRL-A0, FR4A-TRL-B0, FR8A-TRL-A0, FR8A-TRL-B0) are MR Unsafe due to the lack of fixation of the device during the trial period.

CONTACT INFORMATION

MANUFACTURER

Curonix LLC
1310 Park Central Boulevard South
Pompano Beach, Florida 33064
United States

Telephone: +1.800.965.5134
www.curonix.com