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

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

# TABLE OF CONTENTS

# GLOSSARY OF TERMS

| Term and Synonyms | Definitions |
|---|---|
| **Electrode** | Contact |
| **Electrode Array (Lead)** | An implanted catheter with electrodes that are placed in the epidural space |
| **Guidewire** | A flexible wire used to create a pathway in the epidural space for the Electrode Array to follow |
| **Incision** | Stab wound, cut down, surgical incision |
| **Introducer** | Needle, Introducer Assembly |
| **Needle (Introducer)** | A needle is used as the tunneling tool to clear a pathway between the Electrode Array incision and the receiver pocket |
| **Neurostimulator (Stimulator)** | Electrode Arrays plus a Receiver |
| **Receiver (Receiver Stylet, RF Stylet)** | An RF conductor that receives wireless signal during stimulation |
| **Stylet (Steering Stylet)** | Stiff wire that can be inserted into the Electrode Array body to aid in steering and positioning |
| **Transmitter** | Wearable Antenna Assembly, WAA, Battery |

# HOW TO USE THIS MANUAL

This manual describes the Freedom Neurostimulator implant procedure and the methods to optimally implant the device. Refer to the Product Safety Sheet for important safety information, contraindications, warnings, precautions, and adverse events.

## 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 or Freedom-4A Stimulator), receiver, and an externally worn transmitter (Wearable Antenna Assembly (WAA)) to power the device. The System is implanted only following a successful trial period with the Freedom 8A/4A 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.

# 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 or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.
- **Pregnancy –** Safety and effectiveness of the 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 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 SCS 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. step-down transformers or high voltage power lines)
- **Implanted cardiac systems –** Patients who have 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. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the 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 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, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

Patients that suspect the Freedom SCS System is being affected by EMI should:

- Immediately move away from the equipment or object.
- The external WAA should be removed from the vicinity of the patient.

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

- High-power amateur transmitters/antennas or citizen band (CB) radio or Ham radio used for private recreation, communication, and wireless experimentation
- Electric arc welding or resistance welding equipment used for melting and joining metals or plastics
- Industrial electric induction furnace/heater or electric arc furnace/heater used for melting metals and plastics
- High-voltage areas identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)

- Microwave transmitters identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Television and radio towers identified by fenced areas, restricted access signs, and caution signs (safe if outside the fenced area)
- Linear power amplifiers used for increasing the power output of radio transmitters, wireless communication applications, audio equipment or other electronic equipment
- Radio telemetry equipment used for tracking location of vehicles, equipment or animals

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

**Magnetic Resonance Imaging (MRI) – The Freedom-8A Electrode Arrays with Receiver are MR Conditional.** An MRI examination with the Freedom-8A Electrode Array with Receiver may be safely performed under certain conditions.

**Magnetic Resonance Imaging (MRI) – The Freedom-4A Electrode Array with Receiver is MR Unsafe.** Since the Freedom-4A Electrode Arrays with 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 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 power off; then the device can be powered 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 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 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 SCS 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 the Freedom SCS 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 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 WAA) 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 effect at farther distances. RFID emitters can be hidden or portable and not 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 SCS System. Use of TENS could cause the device to turn off or intermittent/increased stimulation.

**Electrocautery** – If electrocautery tools are used near the Freedom SCS System then the insulation can be damaged. The Freedom SCS 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 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. 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 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 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 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 has not been established for dental drills or ultrasonic probes within the vicinity of the Freedom SCS 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 SCS 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 SCS 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 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. 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 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 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 be placed overtop a thin layer of clothing or material at all times.

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

**Stimulation Frequencies –** Stimulation between 1,500 Hz and 10,000 Hz has not been evaluated for safety, effectiveness and perception of paresthesia in any 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 the diagnosis and treatment of chronic intractable pain and should be 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 –** Patients should be instructed before undergoing medical tests or procedures, to contact the clinician to determine if the procedure could cause damage to the patient or to the System.

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

**Use the WAA as directed –** Patients should be instructed to use the WAA only as explained by the clinician or as discussed in the User Manual. Using the WAA in any other manner could result in harm.

**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.

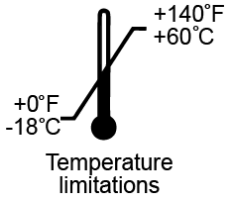
**Do not dismantle the WAA –** Patients should be instructed to not dismantle or tamper with the device. Tampering with the device could result in harm. If the device is not working properly, a Stimwave representative should be contacted for assistance.

**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.

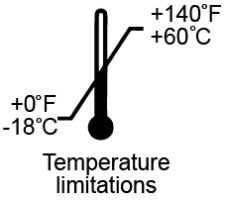
**Use of another patient's WAA –** Patients should be instructed to never use another patient's WAA. The therapy programmed is a unique prescription for each patient. Use of another patient's WAA could result in overstimulation.

**Storage Temperatures –** The Freedom SCS 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 Receiver Kit
Storage Temperature




Wearable Antenna Assembly
Storage Temperature




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

**Interference during programming –** If interference is suspected during programming of the 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 and shut down the WaveCrest™ application.
- Check for sources of Bluetooth interference in the surrounding area.
- Remove or turn off the source of interference.
- Re-establish the Bluetooth® link with the 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 spinal cord stimulation systems and electronic equipment during flights. Refer all questions to airline personnel.

## ADVERSE EVENTS

Implantation of a Neurostimulation system is similar to any surgical procedure. The patients should understand that 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
- 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 experienced any problems. 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 slipping from the implant site.

# DEVICE SPECIFICATIONS

The Freedom SCS System Neurostimulator is composed of an Electrode Array (Lead) and a Receiver; both components have a protective plastic casing. The Receiver receives energy wirelessly from the WAA and couples the energy to the Electrode Array providing a variety of programming options.

**Table 1. Freedom-4A/8A Electrode Array (s) Specifications**

| | | |
|---|---|---|
| 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 the procedure to gain access to the epidural space and familiar with the product labeling.

## Preparing for Procedure

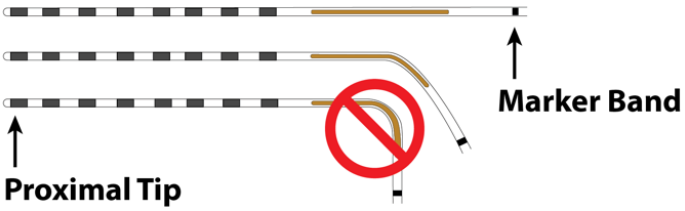
Before opening the device package, verify the package integrity, model number, and use-by date. This product is provided sterile. Do not use the product if the package is damaged. Do not use the product if the date has expired. Contact Stimwave for any questions regarding packaging and expiration dates.

Caution:

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

- Use only the cannula and needle supplied in the kit.
- Use a shallow needle-insertion angle (45 degrees or less) when inserting or withdrawing the cannula and 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 replacing 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 proximal tip to distal end of Electrode Array. Handle the Receiver with care.




# Implantation of the Electrode Array

**Steps:**

1. Place the tip of the Electrode Array on the prepared sterile skin at the approximate vertebrae level where the first electrode will be placed in the epidural space.
2. Mark the incision site using a skin marker at the first marker band on the skin (see Figure 1).

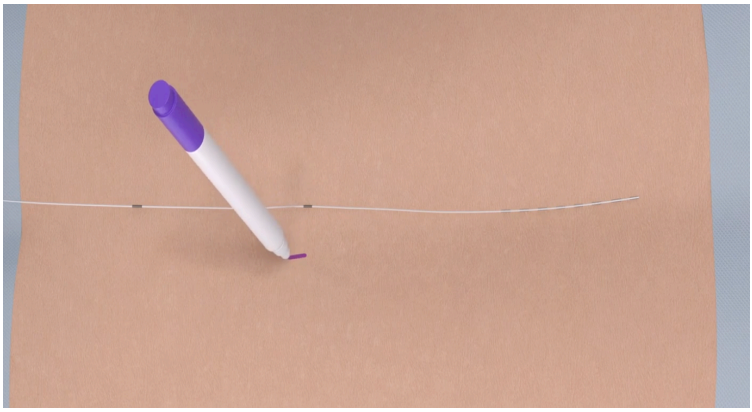


**Figure 1**

1. As necessary, perform “Time Out” or any other pre-op procedures.
2. Prepare the incision and needle entry sites by administering local anesthetic. Apply as needed through procedure (see Figure 2).

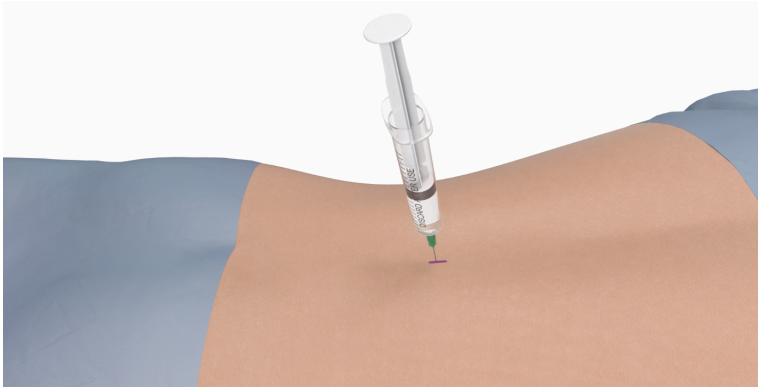


**Figure 2**

# PLACING AN ELECTRODE ARRAY

***Notes:***

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

**Steps:**

1. If necessary, make an incision at the needle-entry site to the depth of the subcutaneous fascia.
2. 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.
3. Under fluoroscopy verify that the needle location is in the correct position.
4. Confirm entry into the epidural space using the loss-of-resistance technique with air or sterile saline.
5. 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.
6. Slowly insert the device 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**

# Implantation of Receiver

## Subcutaneous Receiver Pocket

**Steps:**

1. Approximately 10 cm from the Electrode Array entry site incision, mark the skin to prepare for a Receiver subcutaneous pocket incision.
2. After administering local anesthetic, make a 2-inch vertical incision (see Figure 4) for the Receiver subcutaneous pocket.
3. The pocket is made to house and fixate the Receiver.
4. As needed, use electrocautery to obtain hemostasis.

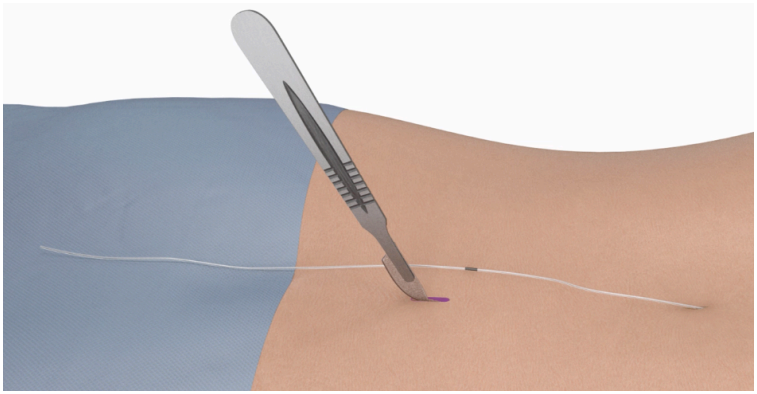


**Figure 4**

## Coupling the Receiver with the Electrode Array

**Steps:**

1. Remove the steering stylet from the Electrode Array.
2. Insert the Receiver into the central lumen of the Electrode Array.
3. Continue advancing the Receiver until it reaches the end of the Electrode Array and there is only 2 cm extruding from the end of the Electrode Array body, the final position of the Receiver.
4. Remove the handle from the proximal end of the Receiver and confirm that it has advanced as far as possible.

# ANCHORING THE ELECTRODE ARRAY

***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 needle entry-site (see Figure 5).

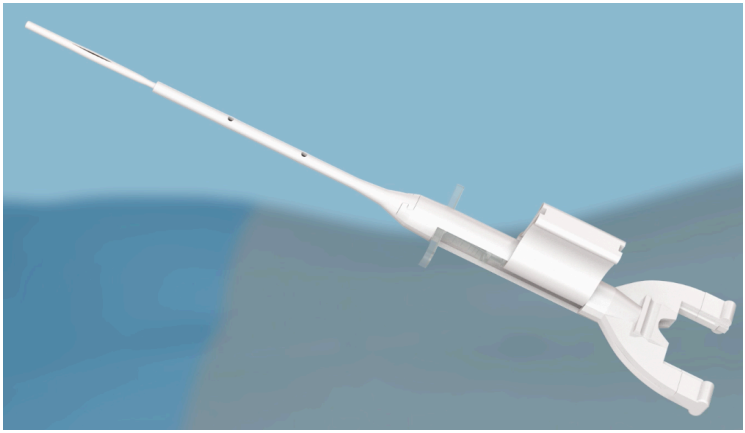


**Figure 5**

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

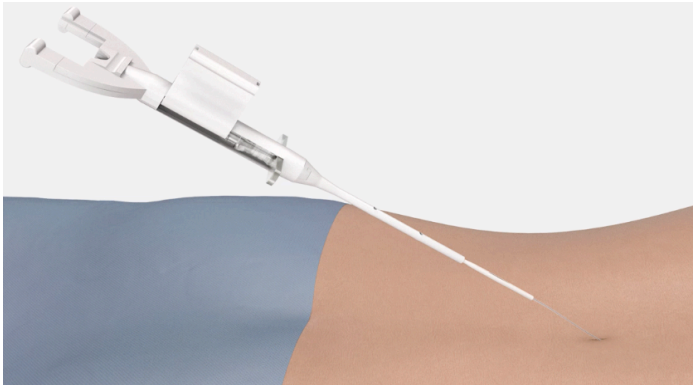


**Figure 6**

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 (see Figure 7).

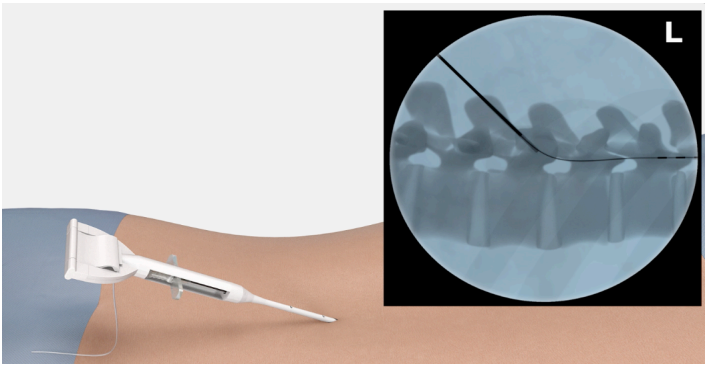



**Figure 7**

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

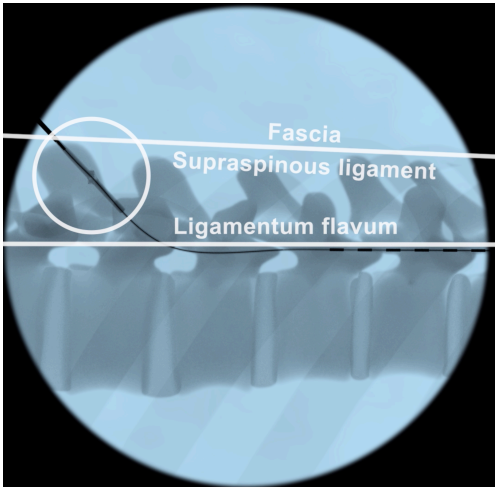



**Figure 8**

# RECEIVER TUNNEL

***Notes:***

- *Repeat the steps below to tunnel and fixate each Receiver*

**Steps:**

1. Advance the needle from the subcutaneous Receiver pocket to the electrode array entry site (see Figure 9).

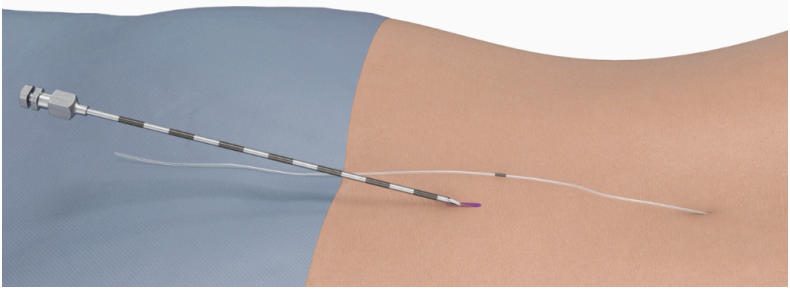


**Figure 9**

2. Take the proximal tip of the Electrode Array and Receiver and thread it through the distal tip of the needle to the subcutaneous Receiver pocket (see Figure 10).

3. Once there is no slack at the electrode array entry site, withdraw the needle from the subcutaneous Receiver pocket.

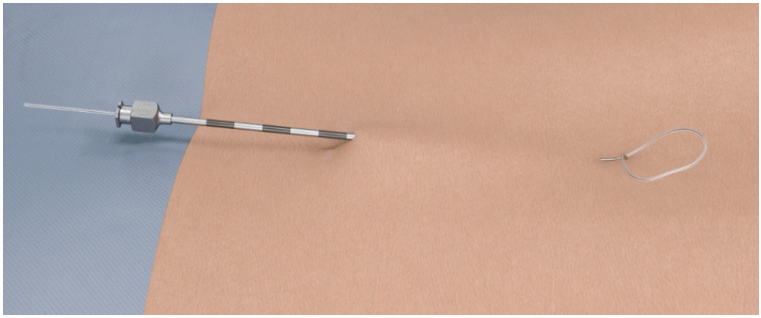


**Figure 10**

## COIL AND FIXATE THE RECEIVER

**Steps:**

1. Inside the subcutaneous Receiver pocket, establish hemostasis, and irrigate with antibiotic solution.
2. Tie a knot in the Electrode Array containing the Receiver and push the knot to distal edge of the subcutaneous Receiver pocket. Knot must be proximal of marker bands. (Figure 11).

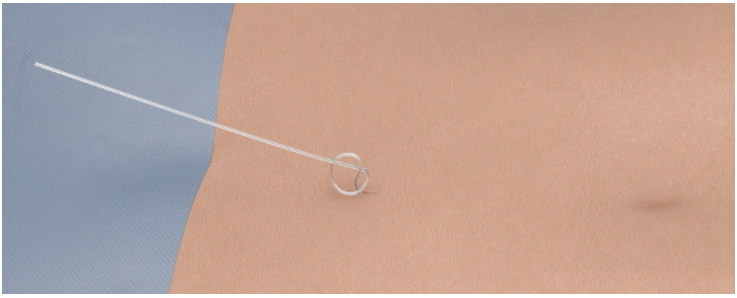


**Figure 11**

3. With the Electrode Array containing the Receiver now inside subcutaneous Receiver pocket, coil the remaining Receiver after the marker band into a 3 cm diameter coil.
4. Using non-absorbable suture, tie a square knot around the coil and into the fascia at two locations and at the marker band. Tuck the proximal tail into the suture loop to avoid any protruding edges (see Figure 12).

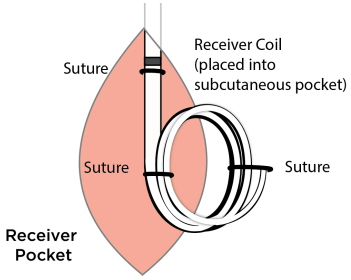



**Figure 12**

5. Ensure that the device is sutured securely in the subcutaneous Receiver pocket.
6. Close incisions using sterile skin closures and dressings (see Figure 13).

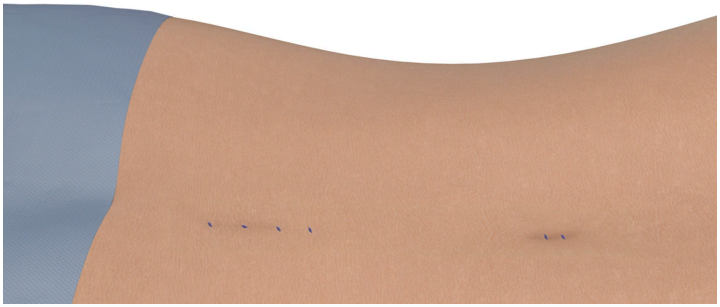


**Figure 13**

# PLACING ADDITIONAL ELECTRODE ARRAYS

***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. Implant the second device parallel to the first (see Figure 14).
3. Repeat steps for anchoring the Electrode Array.
4. Repeat steps for the implantation, coupling, coil and fixation of the Receiver.

***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.*

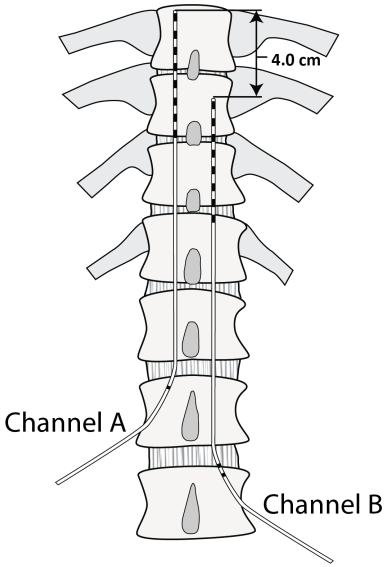



**Figure 14**

# TESTING STIMULATION INTRAOPERATIVELY

⚠ CAUTION:

To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensations), change parameter settings in small increments when approaching the patient's perception threshold. Decrease the amplitude before adjusting the program or location of the electrodes.

***Notes:***

- *This procedure requires a WAA (packaged separately). Refer to the User Manual for use of the WAA.*
- *The metal needle **blocks** the energy from the WAA. The needle must be removed before intraoperative testing.*
- *If paresthesia response is not obtained, change the electrode array and programming settings as necessary.*
- *Repeat the steps below to tunnel each stimulator Electrode Array.*

**Steps:**

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

1. Using minimal force, carefully withdraw the insertion needle from the patient while holding the Electrode Array.
2. Place the WAA in a sterile drape or sterile fluoroscope bag over the region directly above the proximal Marker Bands.
3. Identify the 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, discomfort threshold, and area of paresthesia coverage.
4. In the patient's chart, document the position that provided appropriate stimulation coverage. Record the stimulation settings and patient responses. Include a fluoroscopic image of the device position.

# DEVICE EXPLANT PROCEDURE

**Steps:**

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

# DEVICE DISPOSAL

Explanted devices are not to be re-sterilized or re-implanted. Dispose of the used 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-8A (FR8A) NEUROSTIMULATOR

Non-clinical testing demonstrated that the Freedom-8A Neurostimulator (Electrode Arrays with Receiver) is MR Conditional. A patient with the SCS Freedom-8A Neurostimulator (Electrode Arrays with Receiver) can be safety scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla.
- Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 T/m).
- Whole Body Scans at 1.5Tesla/64MHz - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).
- Torso Scans at 3Tesla/128MHz - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 0.3 W/kg. This SAR limitation is more restrictive than the Normal Operating Mode.
- Head and Extremity Scans at 3Tesla/128MHz – Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).
- No other components of Freedom SCS System (e.g. Wearable Antenna Assembly, battery charger, needles, stylets, guidewire, trial lead) may be taken into the MR system room.

Under the scan conditions defined above, the Freedom-8A Neurostimulator is expected to produce a maximum temperature rise of less than 4ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact extends approximately 20-mm relative to the size and shape of the device when imaged using a gradient echo pulse sequence and a 3-Tesla/128-MHz MRI system.

***NOTE:*** *This information applies only to a single implanted Freedom-8A Neurostimulator (Electrode Arrays with Receiver).*

Magnetic Resonance Imaging (MRI) may be safely performed under specific conditions on a patient with the Freedom-8A Neurostimulator. In-vitro testing demonstrated that the Freedom-8A Neurostimulator are MR Conditional. The Freedom-8A SCS System components are labeled as follows:

| MR Conditional Component | MR Unsafe Components |
|---|---|
| Freedom-8A Neurostimulator (Electrode Arrays with Receiver).<br><br>A patient with the Freedom-8A Neurostimulator (Electrode Arrays with Receiver) may be safely scanned with MRI only under very specific conditions.<br><br>Scanning under different conditions may result in severe patient injury or device malfunction.<br><br>See specific conditions for safe scanning given below. | • Freedom-4A Electrode Array with Receiver<br>• Freedom-8A Trial Leads<br>• Freedom-4A Trial Leads<br>• Wearable Antenna Assembly<br>• Programmer<br>• USB Battery Charger<br>• Needle<br>• Introducer<br>• Guidewire<br>• Steering Stylet |

## ⚠ WARNING:

Remove the Wearable Antenna Assembly (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 Wearable Antenna Assembly (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 identification (ID) card to every MRI appointment.
- Instruct patients to always provide the MRI personnel their patient ID card. This indicates the manufacturer as Stimwave and identifies the model number of the product.

The MRI system operators can use this information to obtain instructions to determine the eligibility of the Freedom-8A SCS 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 prior to performing an MRI procedure on a patient who has an implanted Freedom-8A Neurostimulator.

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-8A Neurostimulator is unknown.
3. Instruct the patient to immediately inform the MR system operator (i.e., the MRI technologist) if any discomfort, stimulation, shocking, or heating, or other unusual sensation occurs during the examination.
4. The patient must be conscious during the MRI examination in order 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.

MR system operators that are unsure of the capabilities of the MRI system, must contact the MRI system 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-8A Neurostimulator is functional by checking its response to the WAA.

# CONTACT INFORMATION

## MANUFACTURER

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