CURONIX

Infrapatellar Saphenous Nerve (IPS)

Surgical Technique

Freedom® Peripheral Nerve Stimulator (PNS) System

Indications

- Chronic intractable pain of the peripheral nerve origin as the sole mitigating agent or as an adjunct to other modes of therapy used in a multidisciplinary approach.*

Contraindications*

- Poor surgical risks
- Pregnancy
- Inability to operate the system
- Exposure to shortwave, microwave, or ultrasound diathermy
- Occupational exposure to high levels of non-ionizing radiation
- Implanted cardiac systems

* *The Freedom PNS System is not intended to treat pain in the craniofacial region. Refer to Instructions For Use (IFU) for all contraindications and warnings.*

Patient Positioning and Draping

The patient should be supine with their targeted knee flexed at approximately 30 degrees over a bolster. If an angled position is not possible, the knee can be straightened **(Figure 1)**.

Procedure 1: Implantation of Electrode Array

1. Using A/P fluoroscopy, confirm the location of the IPS by placing a marker needle from anterior to posterior at the medial tibial flare **(Figure 2)**.

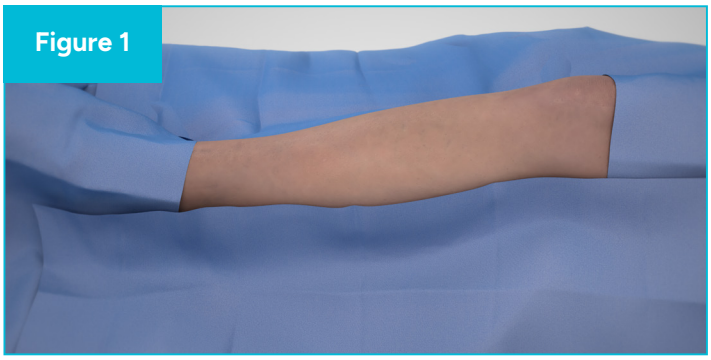
2. Transition to lateral fluoroscopy and advance the marker needle until the tip is halfway across the tibia. Ensure the femoral condyles are in line to confirm an accurate midline placement **(Figure 3)**.

3. Place the electrode array on the sterile skin using the marker needle as a guide in the A/P view. Holding the tip of the electrode array in place, extend the electrode array inferiorly along the medial aspect of the tibia while observing the first channel marker **(Figure 4)**.

4. Place a mark at the first channel marker band (proximal to the electrodes) using a sterile marker, signifying the first incision site **(Figure 4)**.

5. Place another mark approximately 1 cm past the receiver marker band to estimate the location of the pocket **(Figure 4)**.

Figure 1



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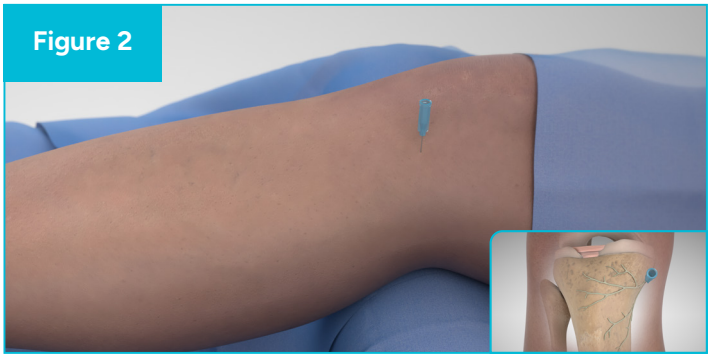

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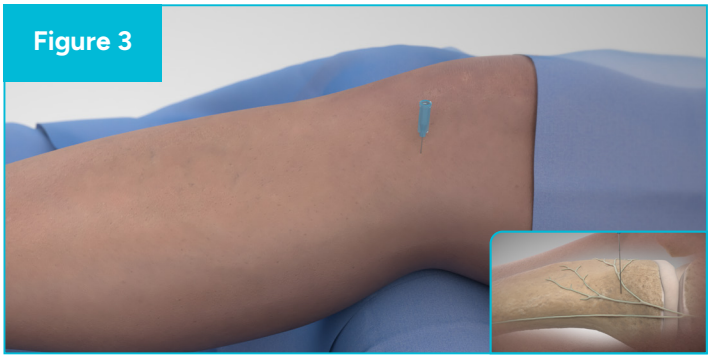

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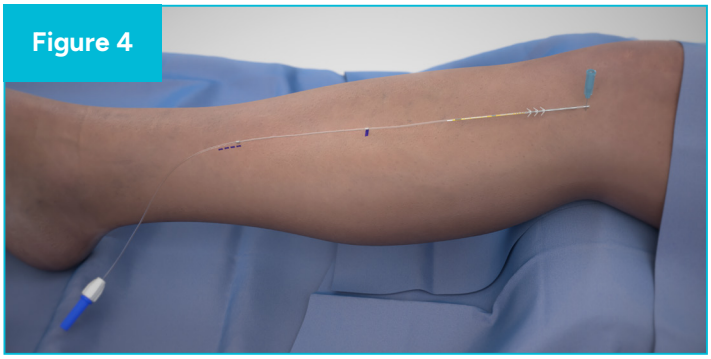
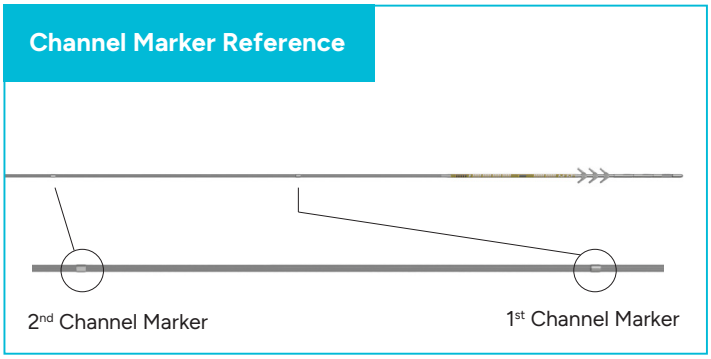


Channel Marker Reference



6. Prepare the entry incision site by administering a local anesthetic superficially and deeply along the proximal needle tract and as needed throughout the procedure.

7. Make a small stab incision at the skin mark **(Figure 5)**.

8. In the A/P view, advance the introducer needle assembly superiorly through the incision towards the needle marker and tibial flare using a low entry angle. Once the introducer needle assembly trajectory is confirmed along the medial tibia in A/P, switch to the lateral fluoroscopy view (**Figure 6)**.

9. Using the tip of the marker needle as the target, guide the introducer needle assembly to the final position, bisecting the tibia **(Figure 7)**.

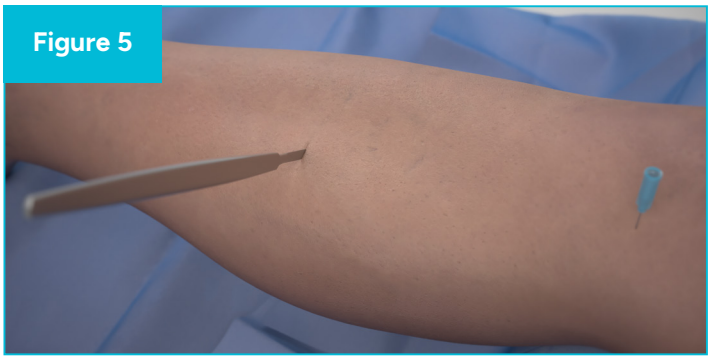
10. Remove the introducer needle stylet **(Figure 8).**

11. Advance the electrode array through the introducer cannula to the tip of the introducer cannula **(Figure 9)**.*

12. Once confirmed in lateral view, switch to A/P view to confirm final electrode array placement **(Figure 10)**.

* Do not attempt to force the electrode array through the soft tissue. If resistance occurs during the advancement of the electrode array through the tissues, remove the electrode array and use a guidewire to clear the obstruction at the distal end of the needle. If resistance continues during the advancement of the electrode array with the bent stylet (blue handle), exchange the bent stylet for the straight stylet (green handle) and use short, firm movements to advance the device. Circuitry should be positioned under the tissue when the first electrode reaches its target.

Figure 5



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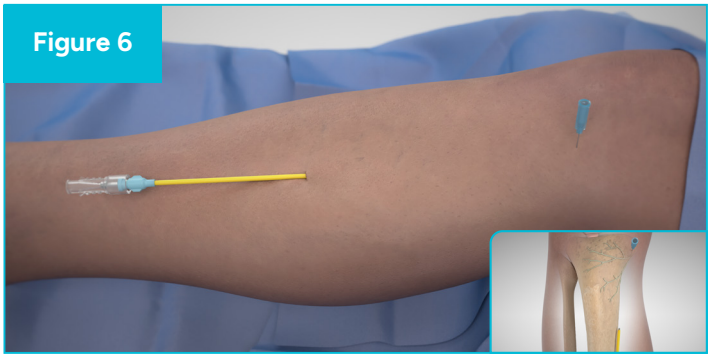

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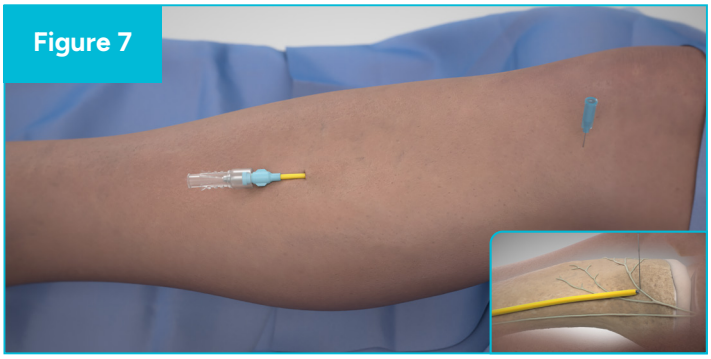

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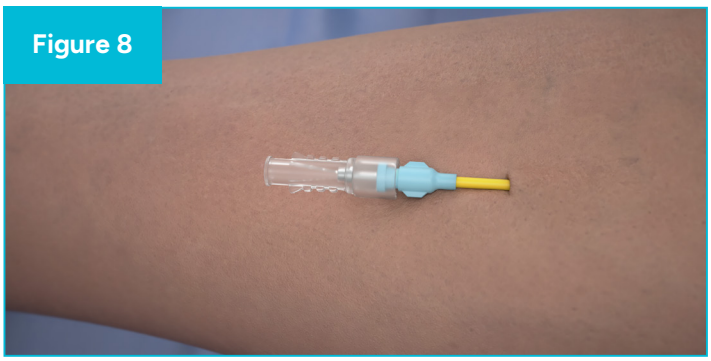

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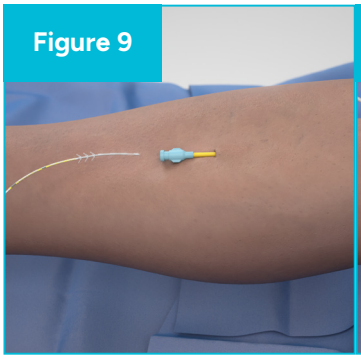

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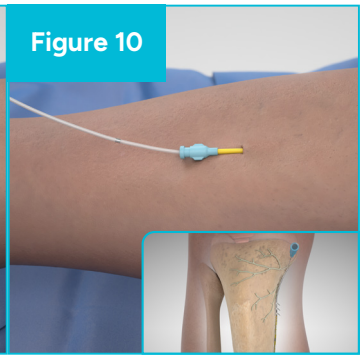


Procedure 2: Pocket Creation & Connection of Electrode Array to Receiver

1. Remove the steering stylet from the electrode array **(Figure 1)**.

2. Connect the electrode array to the receiver. The receiver is fully connected when it reaches the tip of the electrode array. Check for complete connection of the receiver to the electrode array to ensure functionality of the total neurostimulator **(Figure 2)**.

Optional: Prior to connecting the receiver, cut the proximal end of the electrode array at an angle to create a more prominent target of the central lumen to facilitate receiver insertion better. Magnifying loops are beneficial.

3. Gently retract the introducer cannula under intermittent or live fluoroscopy, exposing the neurostimulator's final position **(Figure 3)**.

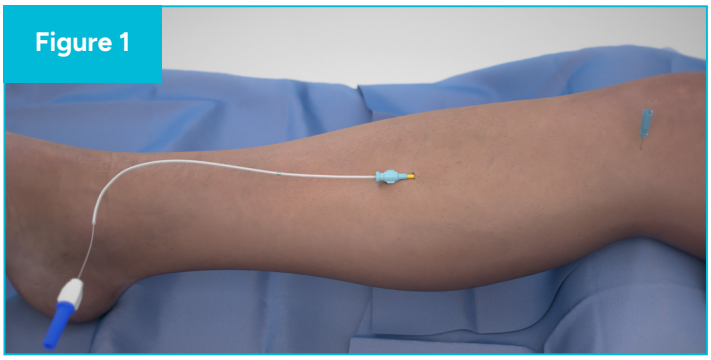
Intraoperative Stimulation Testing

4. Place the wireless transmitter assembly into a sterile Curonix cover.

5. Position the blue antenna with the black side down, lengthwise, between the two silver marker bands along the neurostimulator. After testing, document the neurostimulator position in the patient's chart that provided appropriate stimulation coverage **(Figure 4)**.

6. With the receiver fully connected, cut the excess portion of the receiver flush with the lumen to decrease the possibility of the receiver disconnecting from the electrode array **(Figure 5)**.

Figure 1



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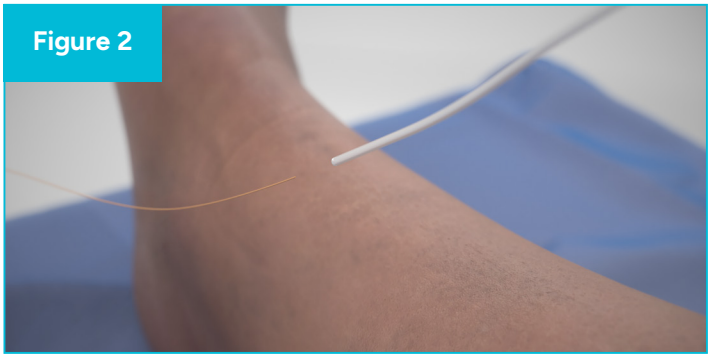

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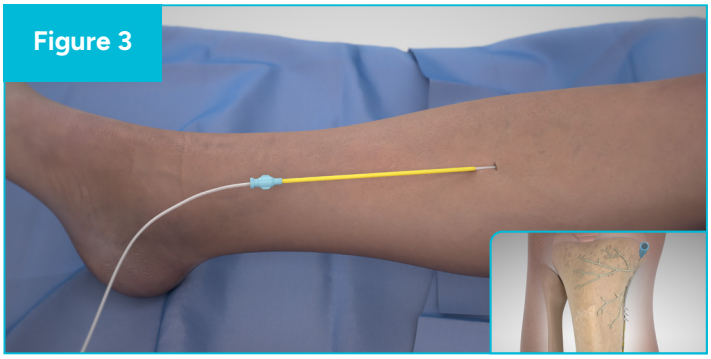

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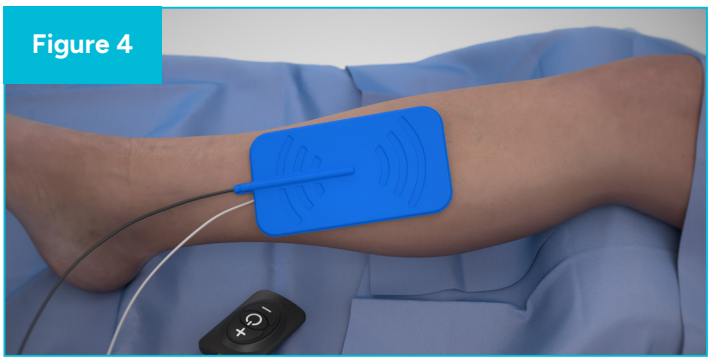

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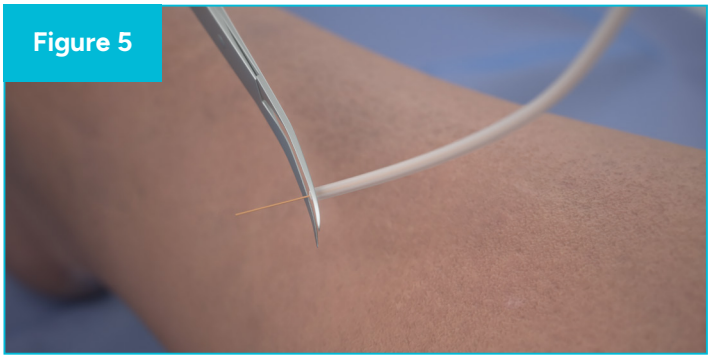


Procedure 2: Pocket Creation & Connection of Electrode Array to Receiver Continued

7. To identify the location of the second incision for the pocket creation, utilize a sterile marker, re-mark the skin after the second marker band or approximately 10 cm from the first incision. The remarking is an assurance that the pocket will be within close proximity to the original measure during the first step of the surgical process **(Figure 6)**.

8. Infiltrate local anesthetic along the mark and surrounding tissues in preparation for the second incision.

9. Make an incision, about 2 cm **(Figure 7)**.

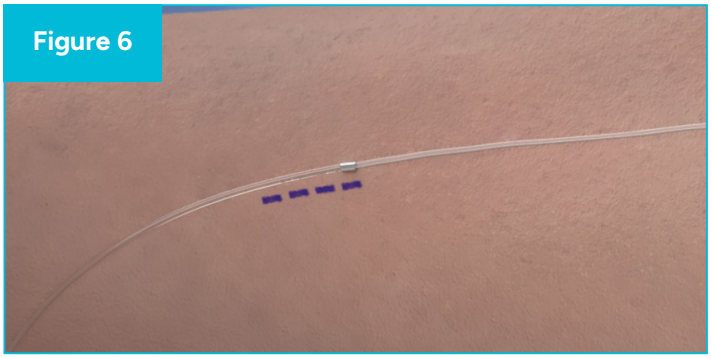
10. Using blunt dissection through the incision, create a subcutaneous receiver pocket **(Figure 8)**.

11. Infiltrate local anesthetic from the pocket to the initial introducer entry site.

12. With the stylet in place, advance the introducer from the second incision receiver pocket to the first incision electrode array entry site **(Figure 9)**.

13. Remove the introducer needle stylet. Feed the tip of the receiver and electrode array through the distal end of the introducer cannula back into the subcutaneous receiver pocket **(Figure 10)**.

Figure 6



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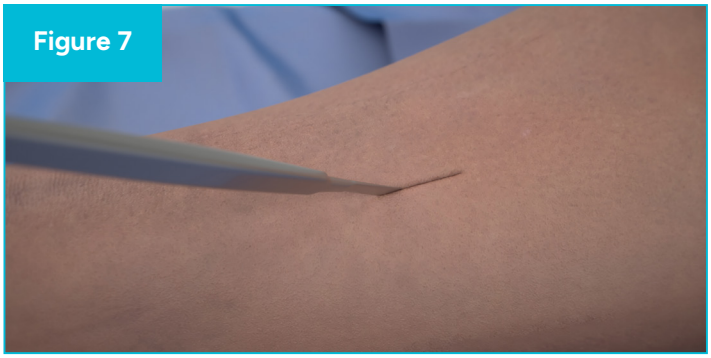

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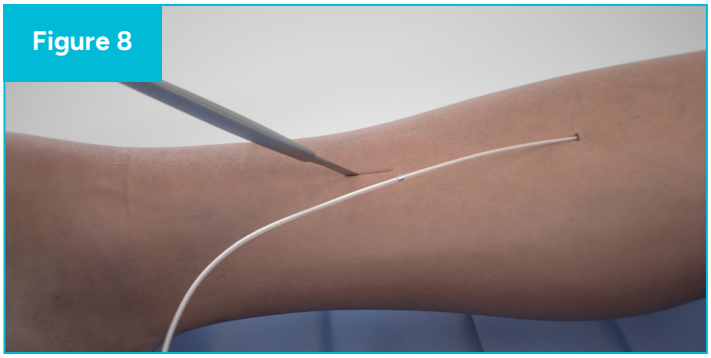

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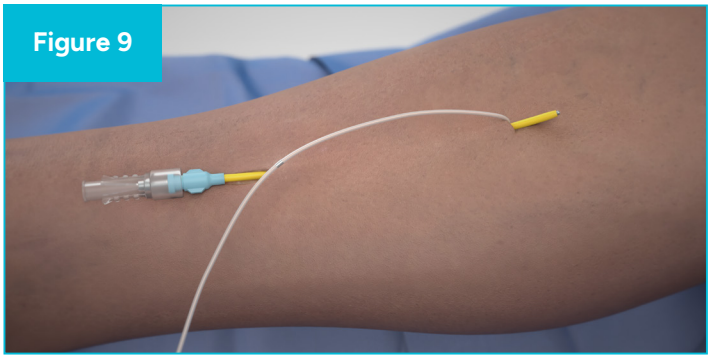

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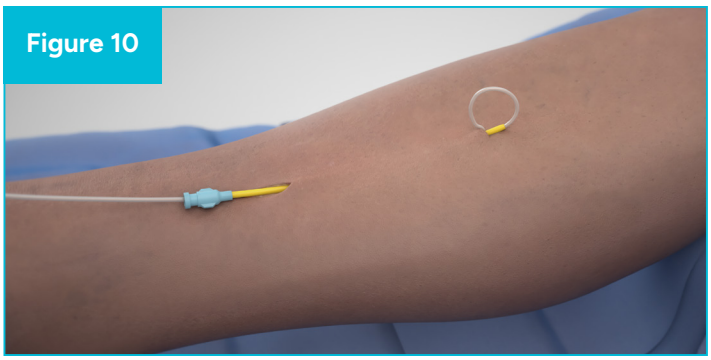


Procedure 2: Pocket Creation & Connection of Electrode Array to Receiver Continued

14. Ensure there is no slack at the first incision entry site before withdrawing the introducer from the subcutaneous receiver pocket **(Figure 11)**.

15. Irrigate the pocket with an antibiotic solution.

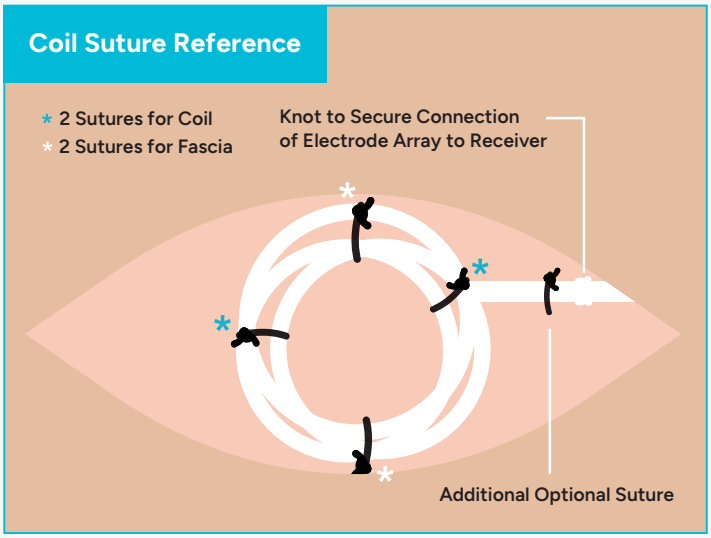
16. Secure the connection of the electrode array to receiver by tying a knot after the receiver marker band **(Figure 12)**.

17. After the knot, coil the remaining receiver portion into a small diameter coil. Tie two nonabsorbable sutures to permanently form the receiver coil **(Figure 13)**.

18. Tuck the end of the receiver coil underneath the coil to avoid protruding edges. This may further mitigate pocket complications associated with erosion **(Figure 14)**.

19. Using a non-absorbable suture, suture the receiver coil to the fascia at two locations, ensuring it is flat in the pocket **(Figure 14)**.

Coil Suture Reference



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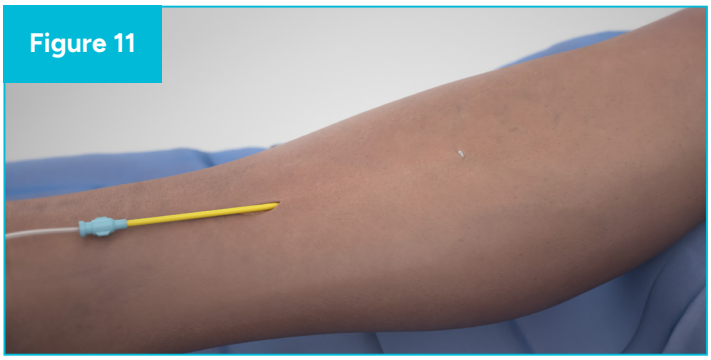

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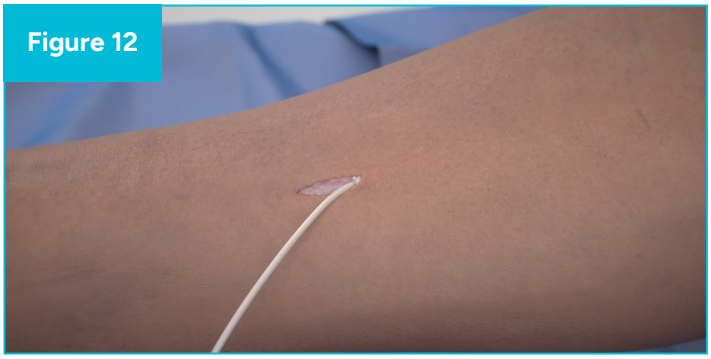

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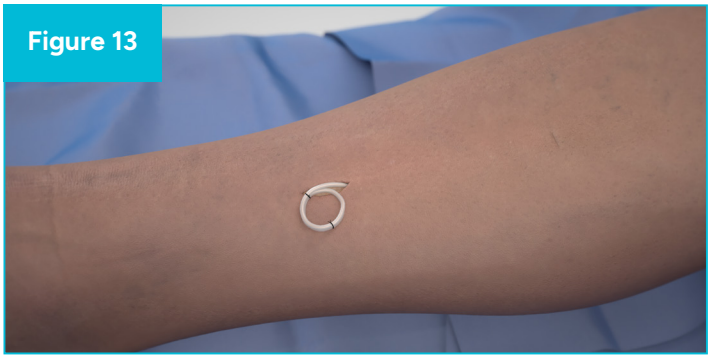

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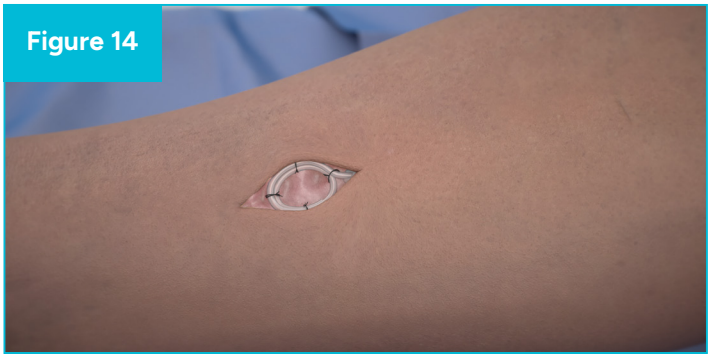


Final Neurostimulator Placement

Closing the Incisions

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

Placing Additional Electrode Arrays/Receivers

The implantation of an additional electrode array and separate receiver is required for some patients. Follow these instructions if an additional Freedom PNS device is indicated.

Preparation: For customized programming, ensure the additional electrode array is labeled “Channel B.”

Channel A Electrode Array

- The first neurostimulator implanted is considered Channel A. This neurostimulator has one band marking unique to a Channel A designation.
- If another Channel A is implanted, it will receive the same programming parameters as the first neurostimulator.

Channel B Electrode Array

- A Channel B neurostimulator can be programmed independently of a Channel A neurostimulator. This neurostimulator is distinguishable from Channel A by two band markings on the electrode.
- Additional Channel A and B devices may be used but cannot be programmed separately from the two main channels.

Only one transmitter assembly is required for the patient to receive simultaneous but separate stimulation in the Channel A and Channel B devices. The Channel A and B receivers must be in proximity of each other in a parallel direction to ensure the single transmitter assembly delivers energy to both devices.

Surgical Technique

Repeat the steps for the implantation of the electrode array. Implant the second device parallel to the first. Repeat the steps for pocket creation and connection of the electrode array to the receiver. Close the incisions using standard surgical techniques and apply dressings.

For Countries Performing Trial Procedures

Follow these instructions to complete the trial procedure after implantation of electrode array and connection of electrode array to receiver.

Secure the connection of the electrode array to receiver by tying a knot after the receiver marker band.

Using steri-strips, mastisol/benzoin and/or sutures, fixate device so that the area between the channel marker band and receiver marker band remains straight.

Secure under sterile dressing.

Device Explant Procedure

1. Use fluoroscopy to visualize the most distal marker band to the neurostimulator on the implanted device **(Figure 1)**.

2. After anesthetizing the incision site, make an incision at the pocket site to reopen the pocket **(Figure 2)**.

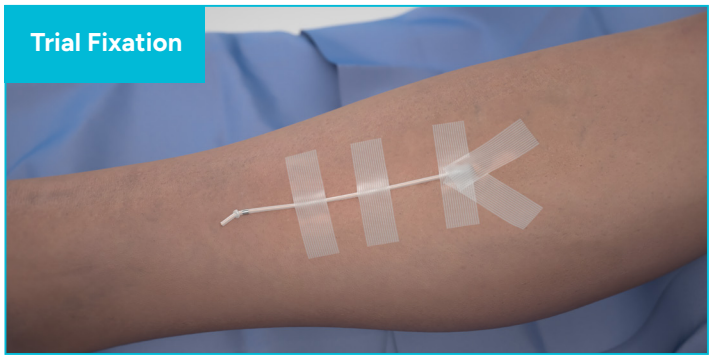
3. Using sharp and blunt dissection, release the coil from any scarring and cut the remaining sutures **(Figure 3)**.

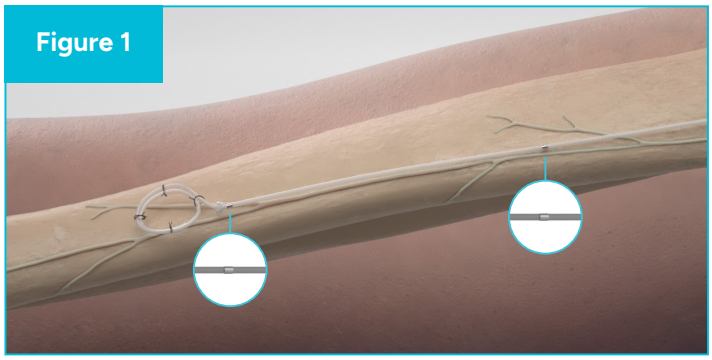
4. Remove the device by slowly pulling on the exposed end **(Figure 4)**.

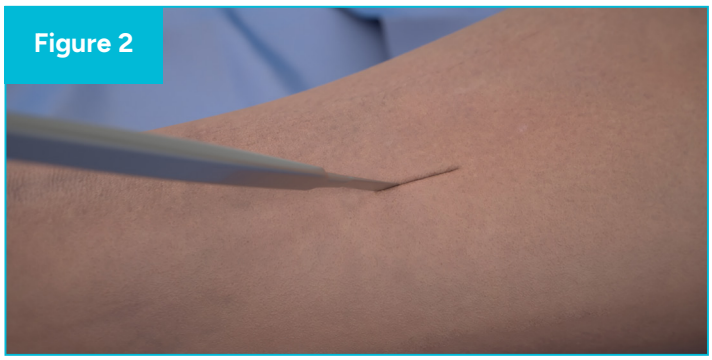
5. After removing the device, verify that all components are intact and that all implanted materials (including sutures) are accounted for.

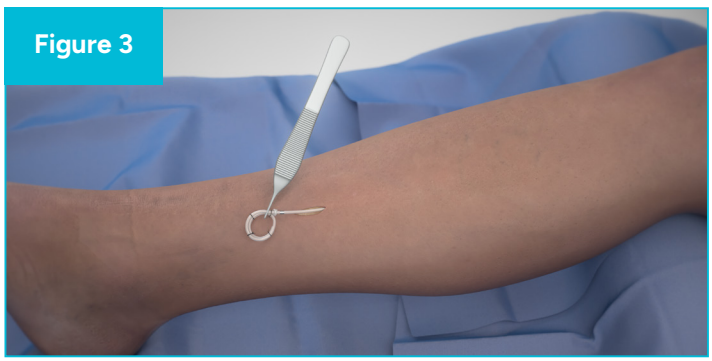
6. Close the incisions using standard surgical techniques and apply dressings.

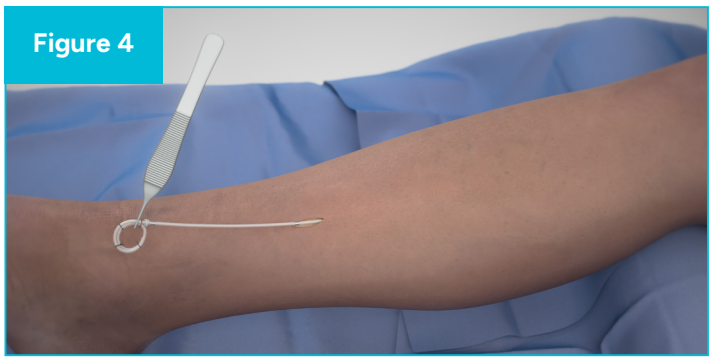
Explanted devices are not to be re-sterilized or re-implanted. Dispose of the used device(s) according to local laws and regulations. Alternatively, contact Curonix for information on returning the devices for safe disposal.











Notes

Notes

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Individual results may vary. Curonix LLC is a manufacturer of medical devices and does not practice medicine. Only a physician can determine what treatment is appropriate. The contents of this document do not constitute medical, legal, or any other type of professional advice. For more information on risks, warnings, and possible adverse side effects refer to the Instructions for Use provided with the device or available in various languages on Curonix.com.

The Transmitter Assembly may be identified as the Wearable Antenna Assembly (WAA) in certain jurisdictions.