PNS Innovative Technology

Dr. Alaa Abd-Elsayed

ASIPP – May, 2022

Disclosures

PNS Market – 100,000 Patients Annually

50 Million U.S. Chronic Pain Sufferers

+25 Million Peripheral Chronic Pain Sufferers

+1 Million Patients with Chronic Pain

+100 K Est. Annual PNS Patients

PNS

10 Million Back Pain Sufferers

1 Million Willing/Able to Accept IPG

No IPG

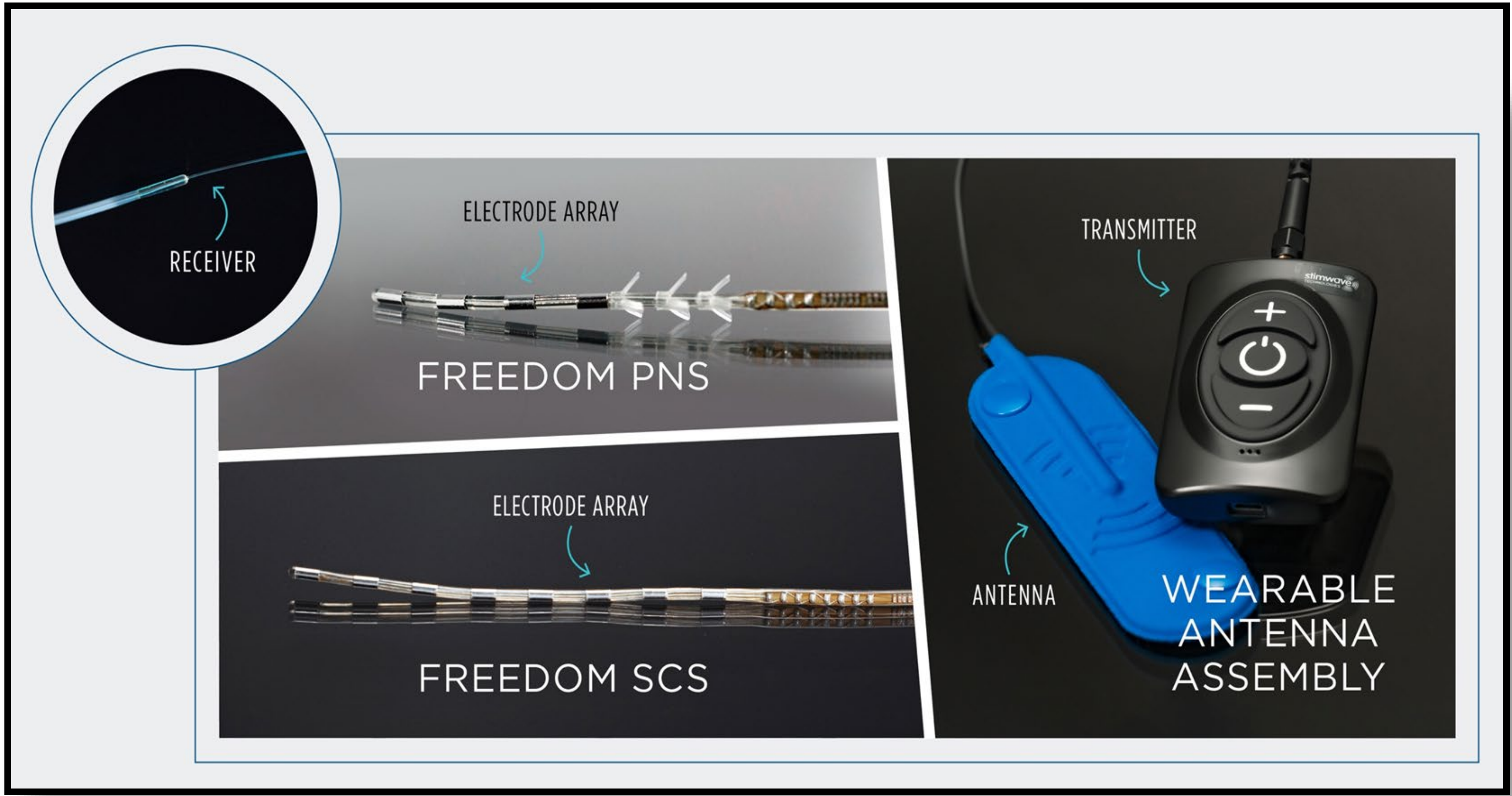
80K Annual SCS Procedures

+22k

SCS

Treating Underserved Pain Patients With PNS + SCS

Freedom System Overview



Freedom PNS Indications & Contraindications

Indications – Pain Management

- Adults
- Severe intractable chronic pain – peripheral nerve origin
- As the sole mitigating agent
- As an adjunct to other modes of therapy used in a multidisciplinary approach

Contraindications – Patient

- 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

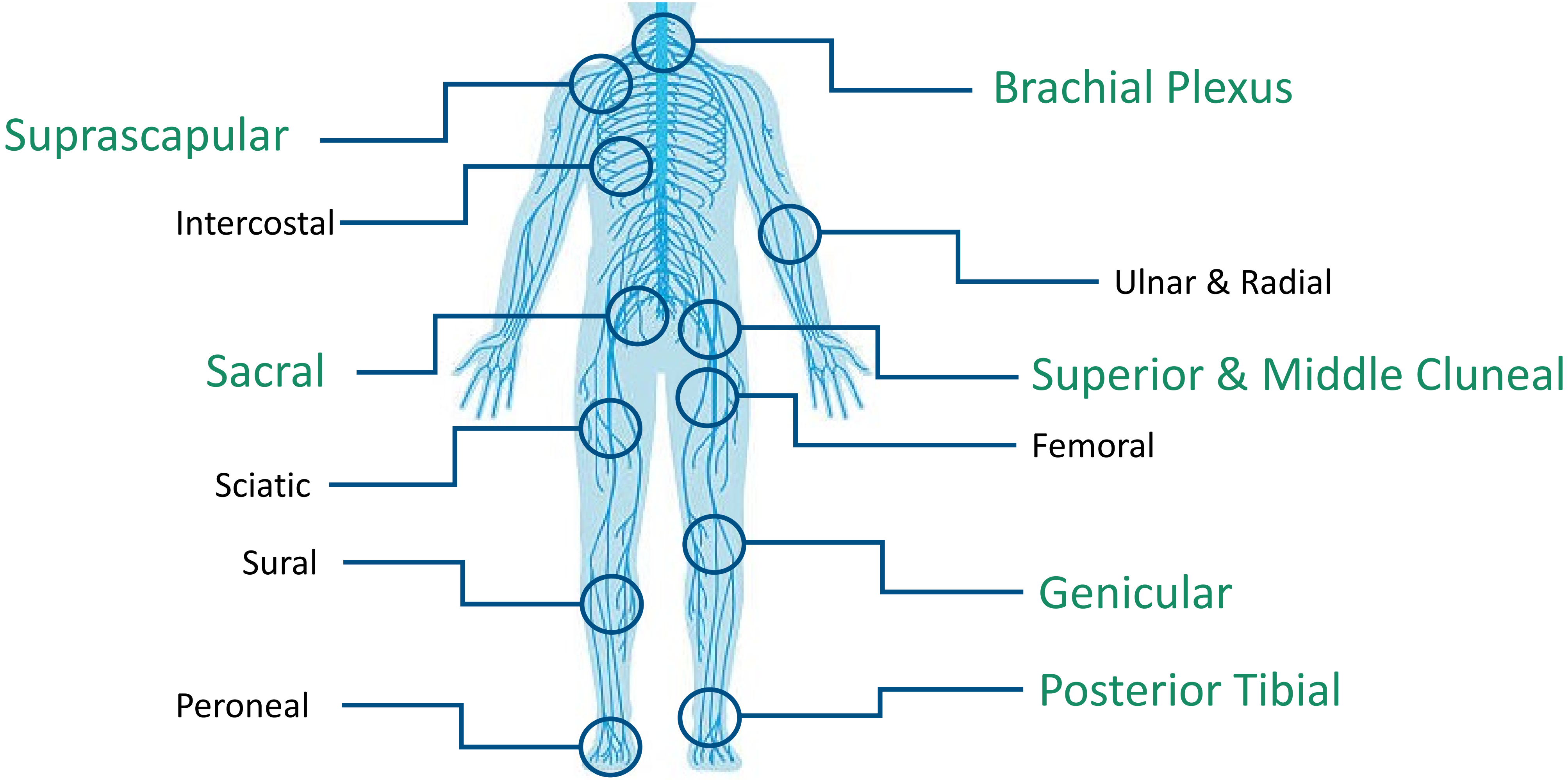
Note: See IFU for a complete description of indications and contraindications

PNS Patient Profiles

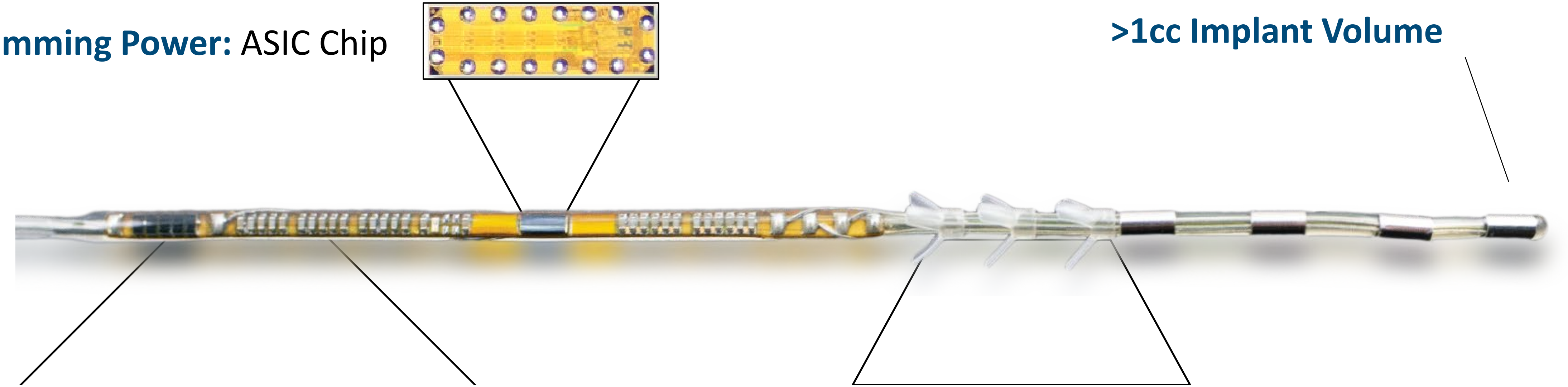
- Successful Nerve Block
- High MRI Burden
- Active Patients
- Patient’s w/Low BMI

- Post Surgical Chronic Pain
- Failed SCS
- IPG Concerns
- Patient's w/Comorbidities

Common Peripheral Nerves/Nerve Bundles



Separate Electrode Array & Receiver



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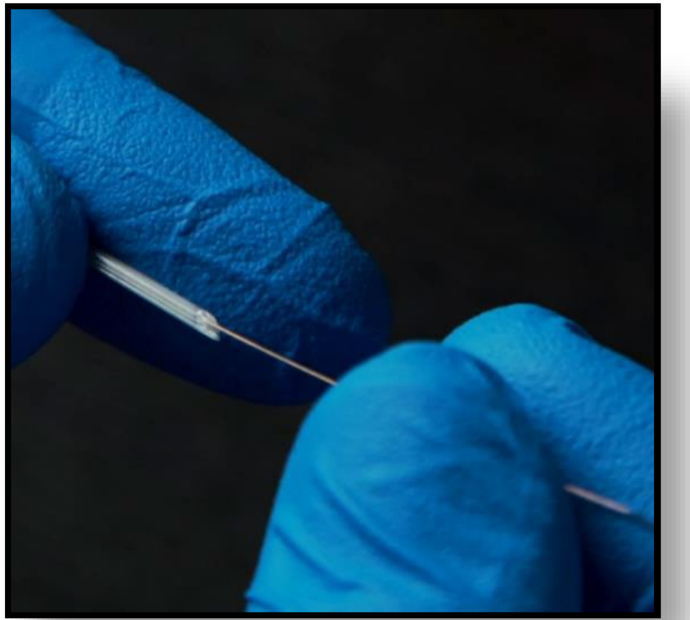
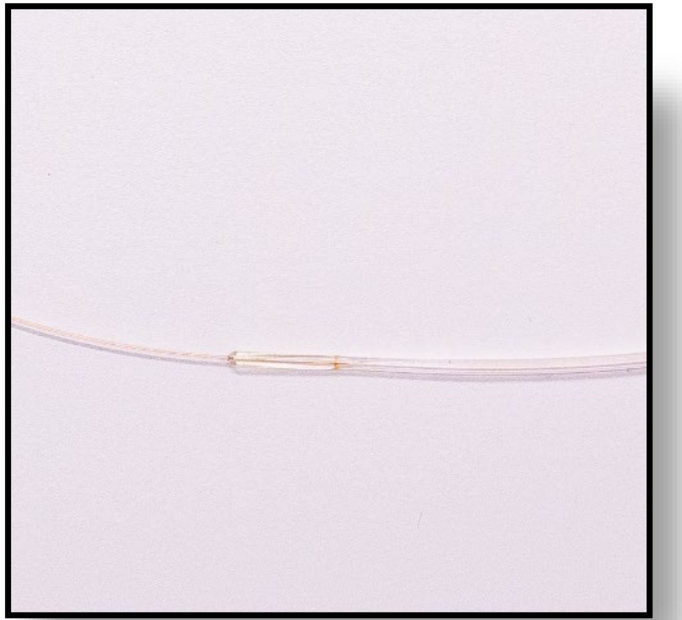
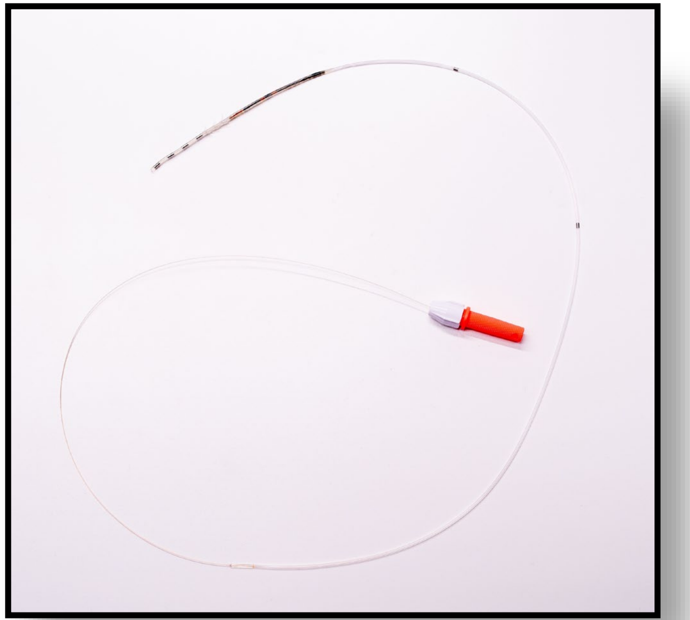






Full-Body MRI Safety Conditions

- Patients' treatment continuum
- No limitations on head or limb coils

Specifications	Freedom PNS			Freedom SCS	
Conditions*	**STQ4**	**FR4A**	**FR84**	**FR4A**	**FR8A**
1.5T Full Body	Yes	Yes	No	No	Yes
3T Full Body	No	No	No	No	Yes

*Further conditions apply. See MRI information at stimwavefreedom.com

Greater Patient Comfort – Freedom with Wearables

SCS & Cluneal

PNS

HF–EMC Wireless Energy Transfer

Dr. Alaa Abd-Elsayed

Rapidly Growing Body of Evidence

Lessons Learned

- **Patient Selection is Key**
  - Targeted nerve application in PNS
  - Diagnostic injections in PNS
- **Appropriate Surgical Technique**
  - Proper placement, targeted nerve proximity
  - Prevent migration for long term effectiveness
- **Customized Patient Programming Required**
  - Variability at the pain site, patient
  - Evolving patient needs over time
- **Wearable Technology Impacts Outcomes**
  - Flexibility & comfortable a improves patient's experience & impacts outcomes
  - Range & adaptation is critical for long-term engagement

Body of Evidence

		Publications	RCT	Case Series
Posters	SCS	7	1	6
	PNS	42	1	41
Publication *(accepted included)*	SCS	14	2	12
	PNS	16	0	16
White Papers *(Scientific)*	SCS	9	N/A	N/A
	PNS	2	N/A	N/A
	Total	**90**	**4**	**65**

Stimwave Freedom Clinical Trials

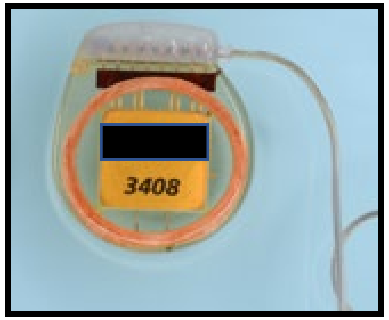
Knee	F&A	Low Back	Shoulder	SCS

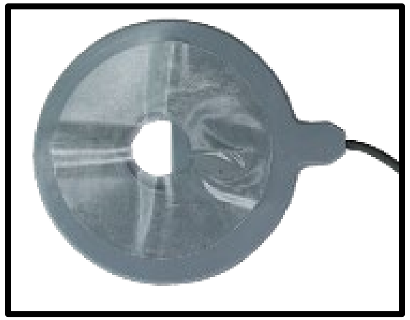
Note: A pules rate of 1,500 Hz was used in some studies, Stimwave is only permitted to provide SCS therapy at frequencies below 1,500 Hz

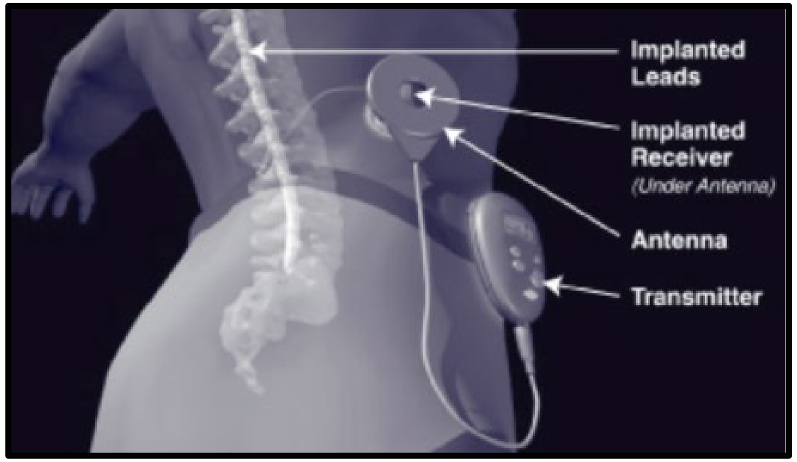
Historical Receiver Technology Overview

Neuromod Technology & Limitations

- **Implanted Lead (electrode array)**
- **Copper Coil Receiver – Hard Shell**
  - Pocket pain in select patients
  - Limited therapy to SCS due to implant size
- **External Transmitter – Limited Programming Capabilities**
- **Antenna – Sticky Patient Fixation**
  - Required precise external alignment
  - Intermittent Therapy resulting from a limited range of power transfer



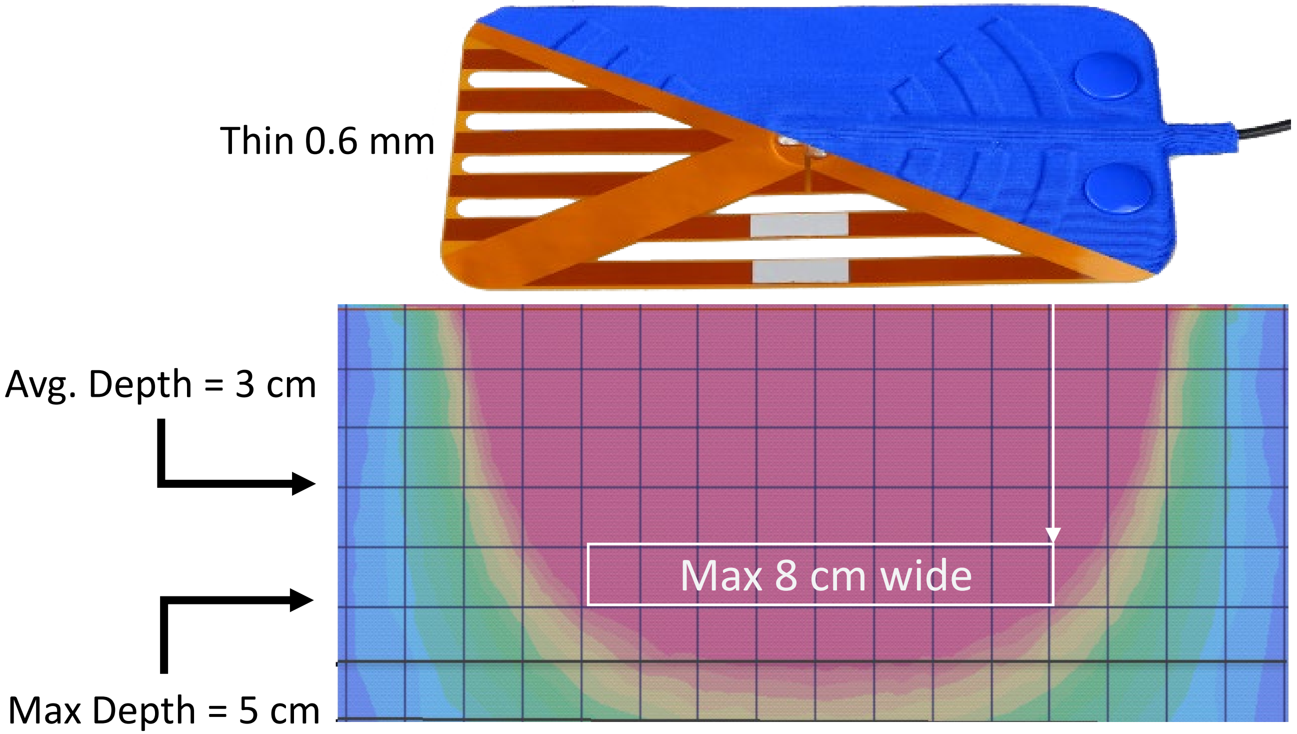




HF-EMC: Maximizing Depth & Range

HF-EMC Powered Dipole Antenna

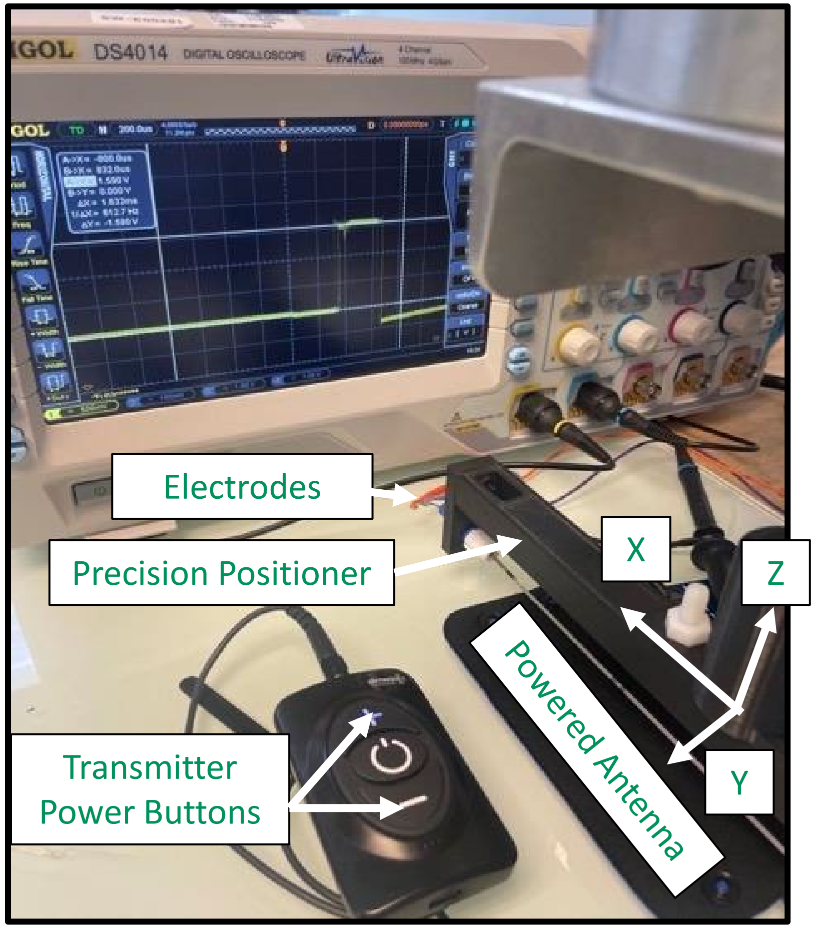
(Near Field + Far Field)



Radiation Plot (W) @ 915 MHz

A. Yakovlev, et al, "Implantable biomedical devices: Wireless powering and communication," in IEEE Communications Magazine, vol. 50, no. 4, April 2012

The Power of HF-EMC & Separate Receiver

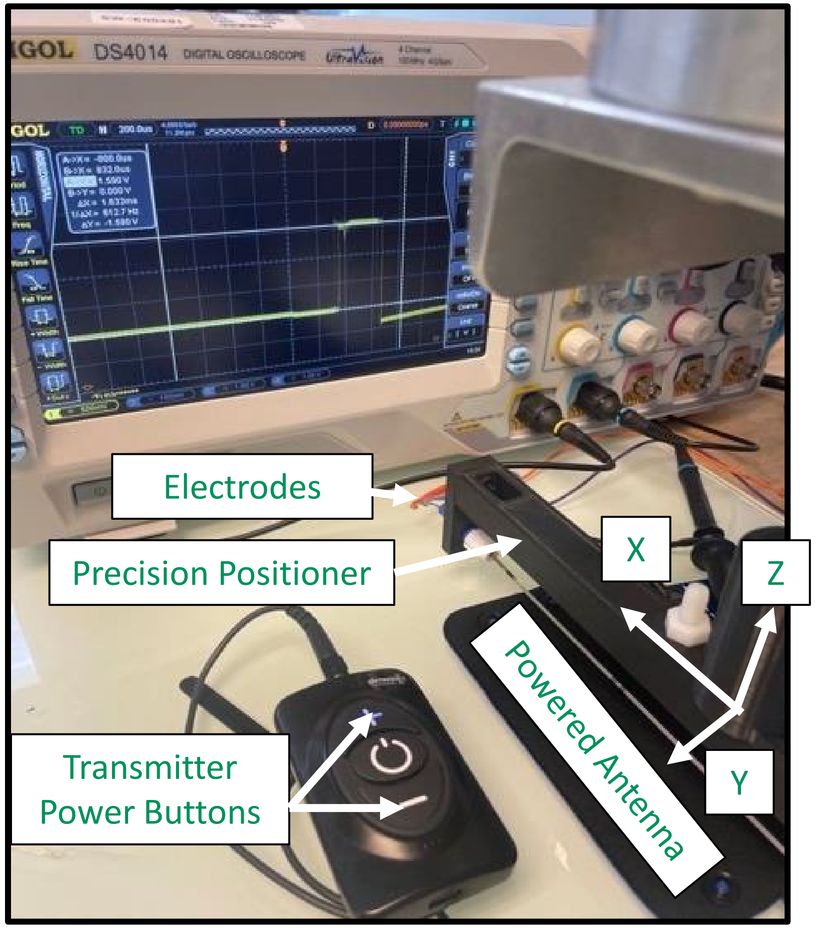


Additional Separate receiver note is shown in the test setup

Static Test Conditions:

- Amplitude (power output of stimulator measured at Electrode Array tip): 3.0 mA (optimum therapy)
- Rate: 60 HZ
- Width: 300 micro sec
- Constant distance between Electrode Array/separate receiver and Antenna: Z = 3.0 cm
- Electrode Array and separate receiver held constant at center-point of Antenna: Y = 0 .0 cm

The Power of HF-EMC & Separate Receiver



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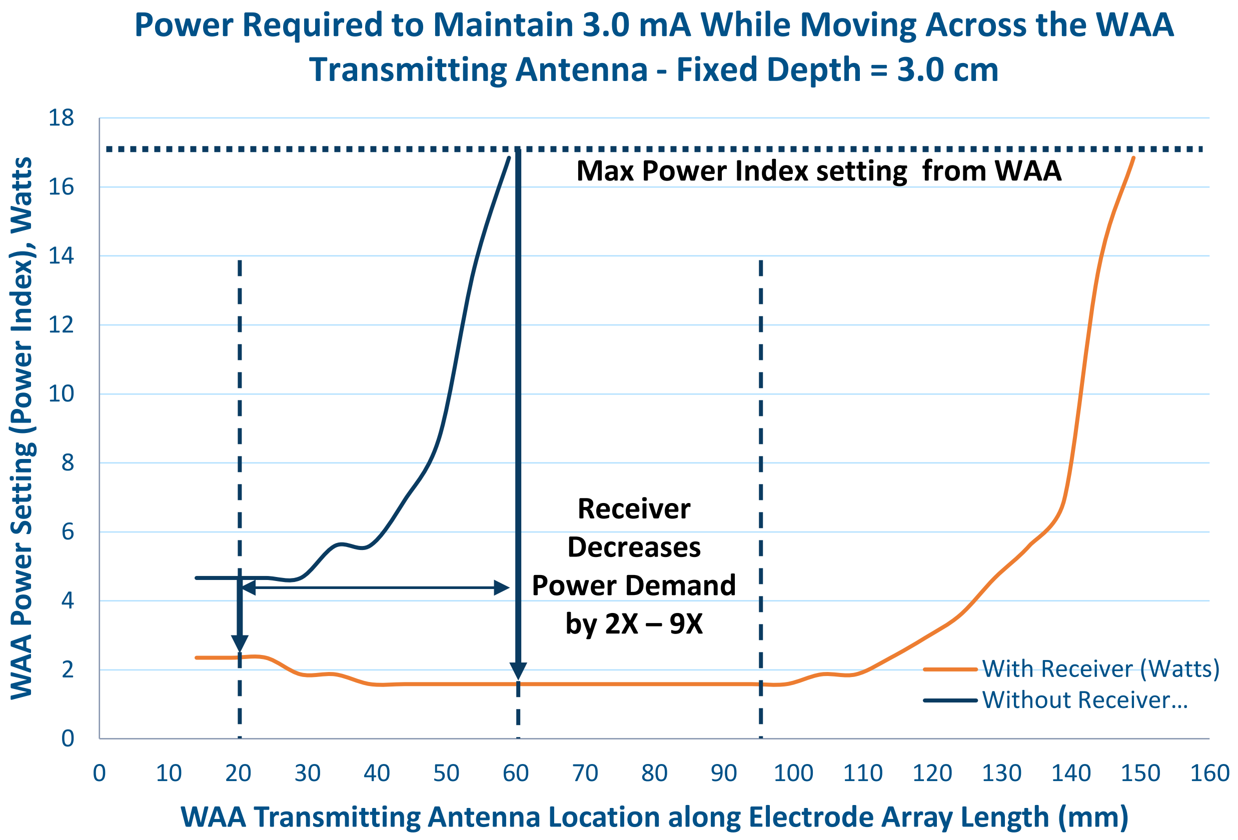
Dynamic Test Conditions:

- Along X – Axis, electrode array & separate receiver is moved along precision positioner
- Concurrently, the transmitter is adjusted to maintain the power output of the electrodes at 3.0 mA
- Test is repeated with and without separate Receiver Component
  (old technology versus new current technology)

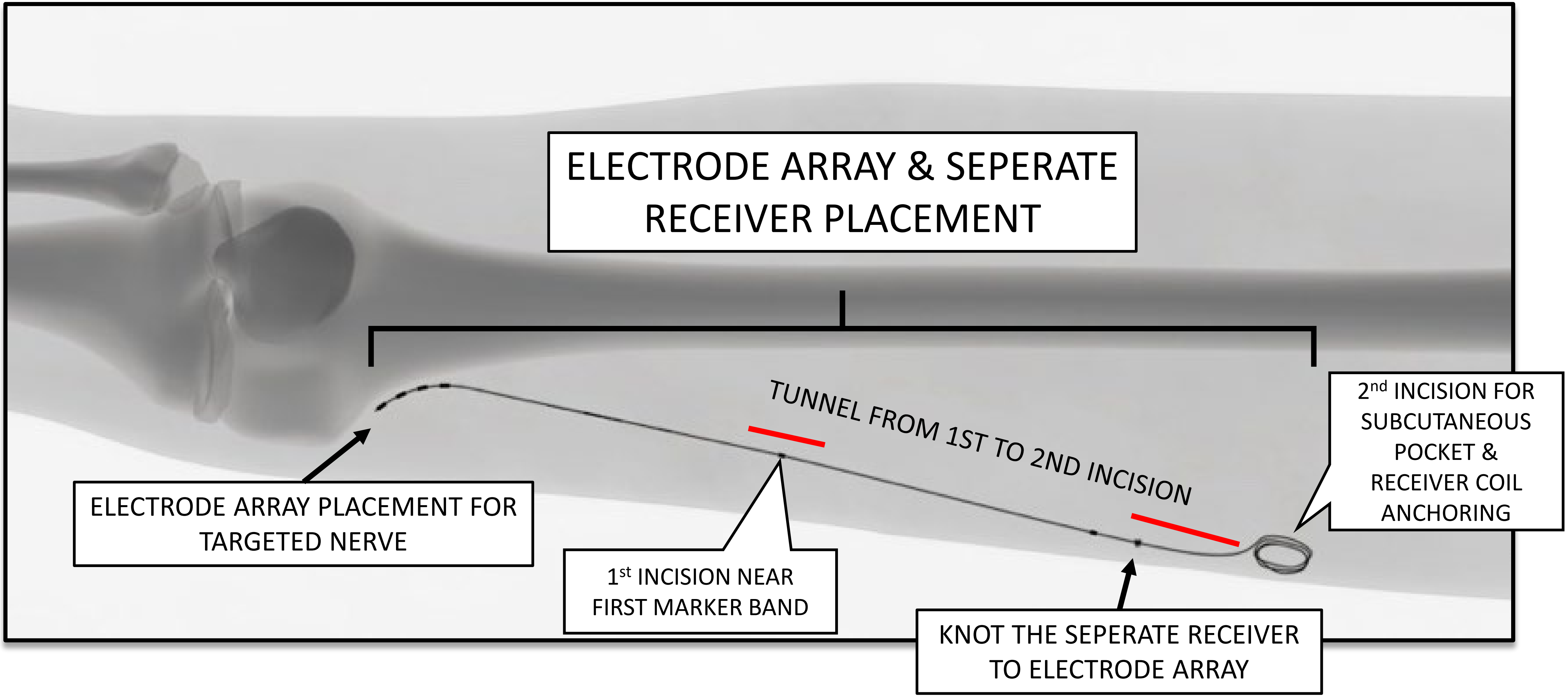
The Power Advantage - Separate Receiver Technology



Results – Separate Receiver Component

- Flexibility Through Broad Range
  - Extended wearable antenna range for patients 13.5 cm
  - “Perfect” antenna placement is not required to achieve continuous therapy
  - Broad range makes treating peripheral locations more feasible (e.g., ankle, scapula, etc.)
- Extended Battery Life – Decreases power demand of antenna by at least 2x (up to 9x)

Freedom PNS Neurostimulator: HF-EMC Technology



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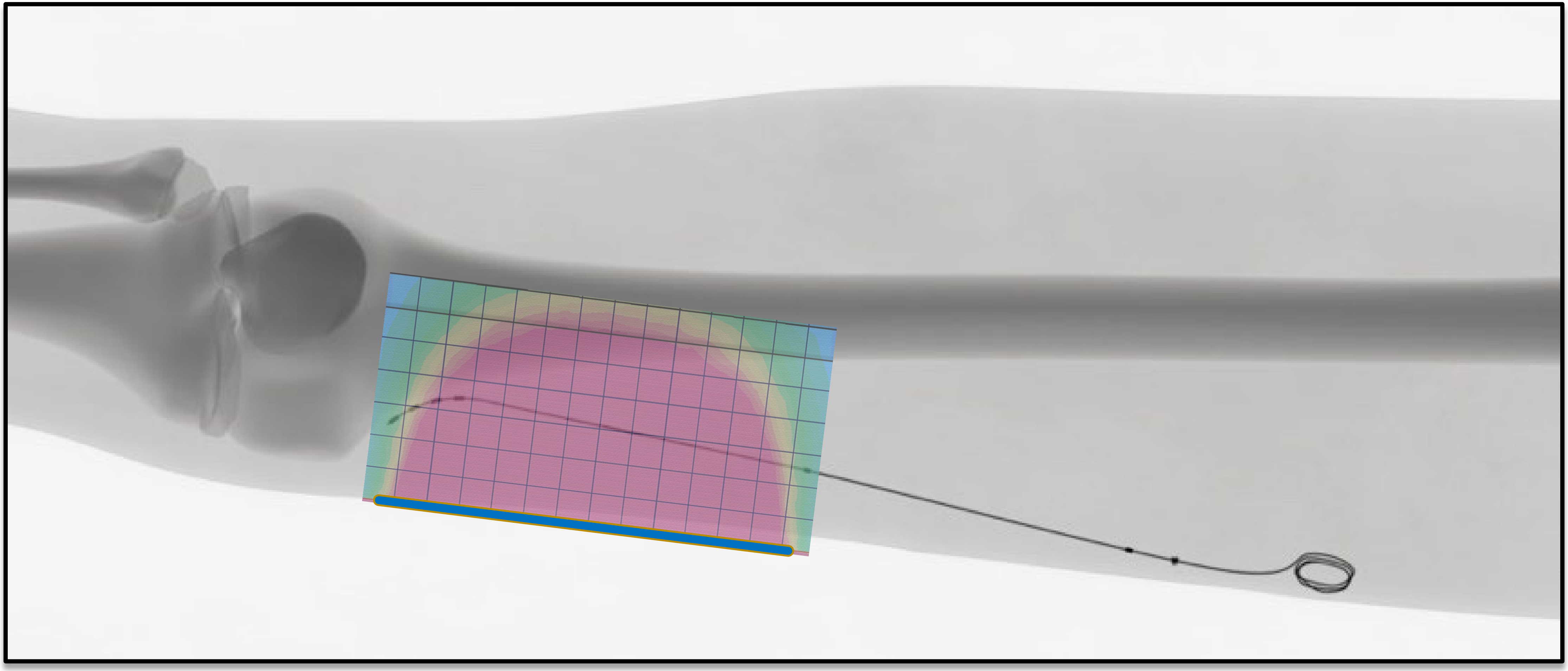

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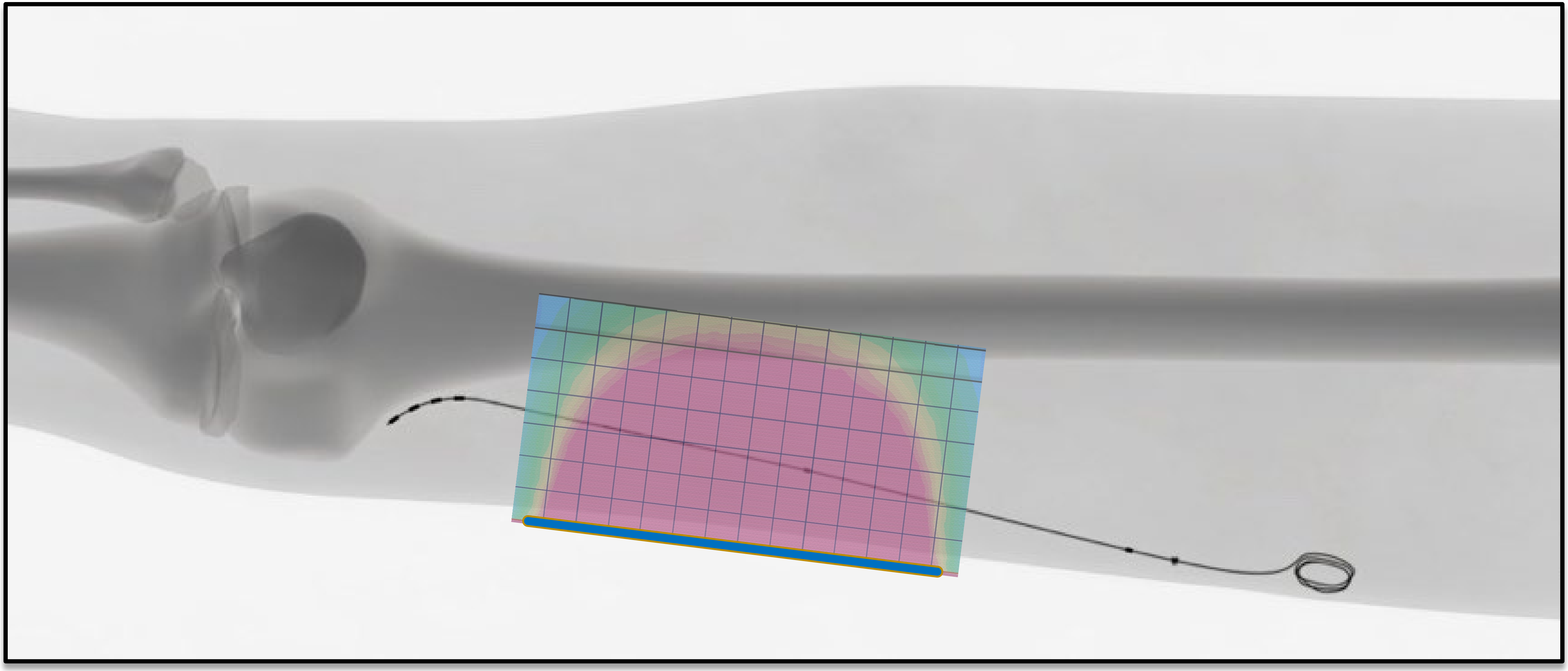

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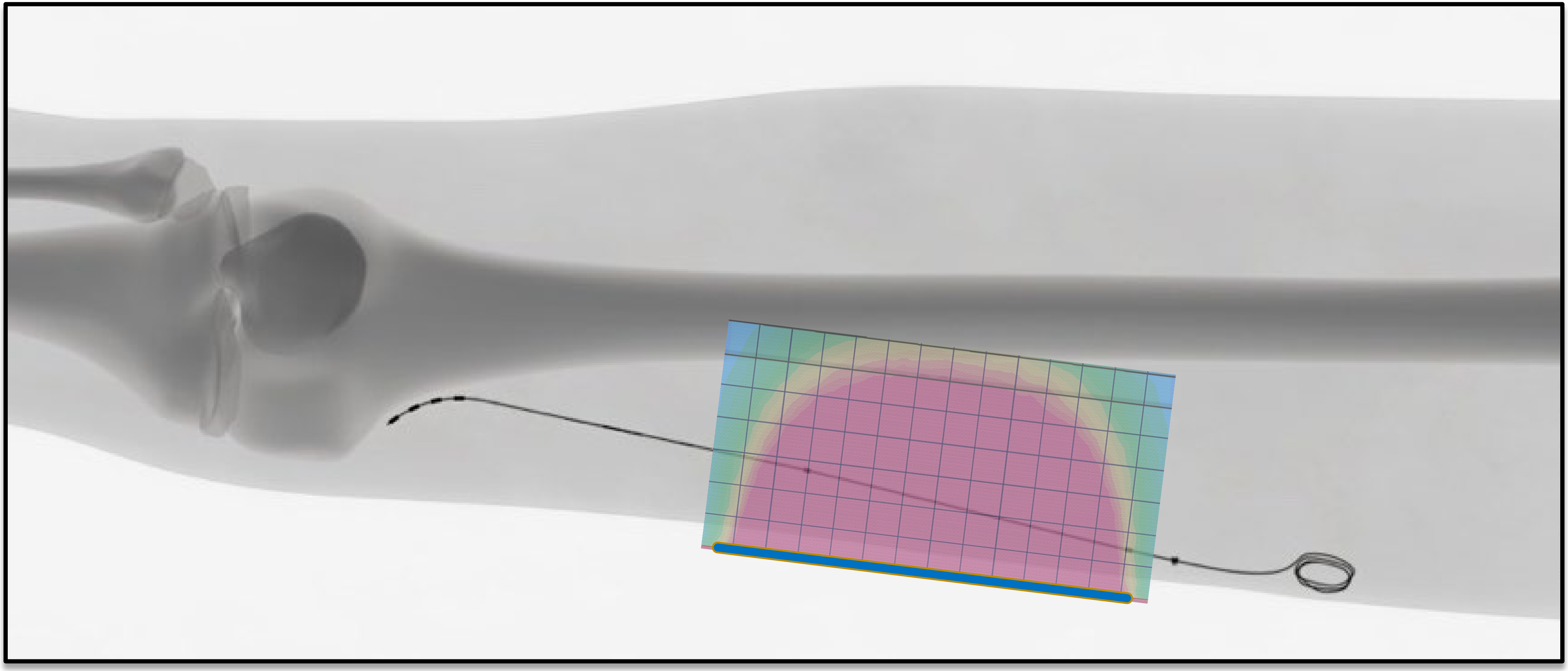

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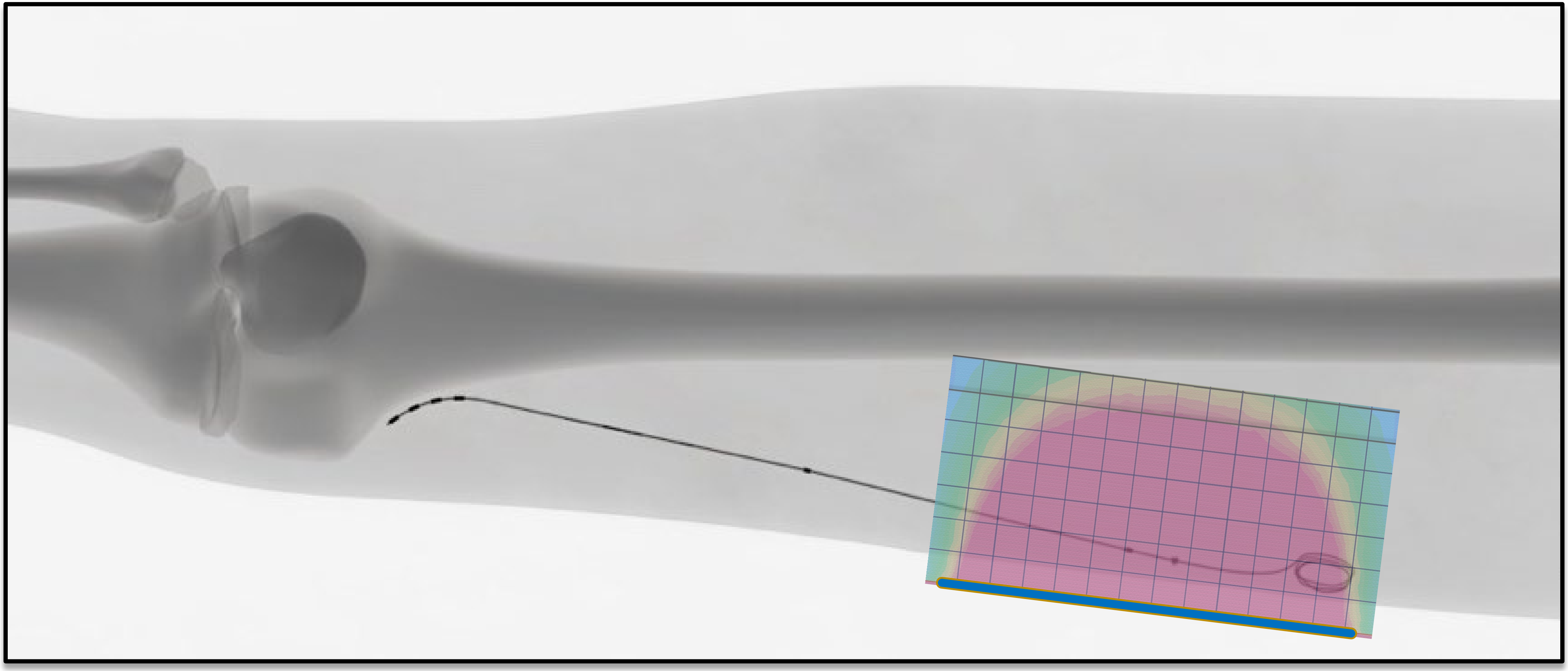


Freedom Neurostimulator: HF-EMC

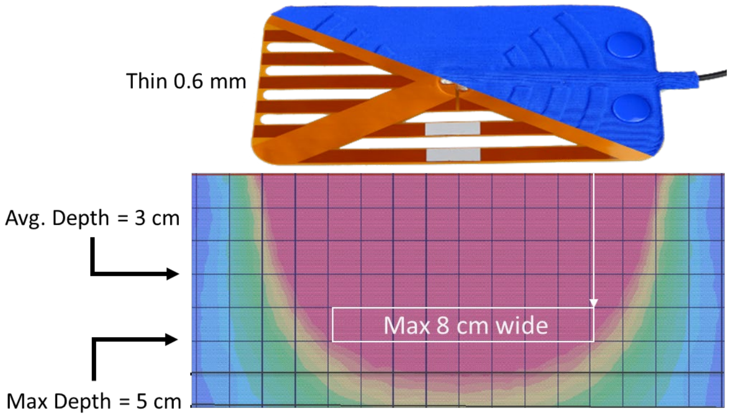
- Greater Range & Depth = HF-EMC + Separate Receiver
- 14 hrs. of Therapy/ Charge: Lithium-Ion Battery
- Versatility: Broad Programming Capabilities
- Designed for an Optimal Patient/Physician Experience

Summary – HF-EMC Power

- Continuous Broad Coverage – Depth & Range
- Proven Technology – Clinical Data & Bench Testing
- **Powerful Technology that Powers Receiver Through Clothing**
- **Patient Wearables Customized for Comfort**

HF-EMC Powered Dipole Antenna

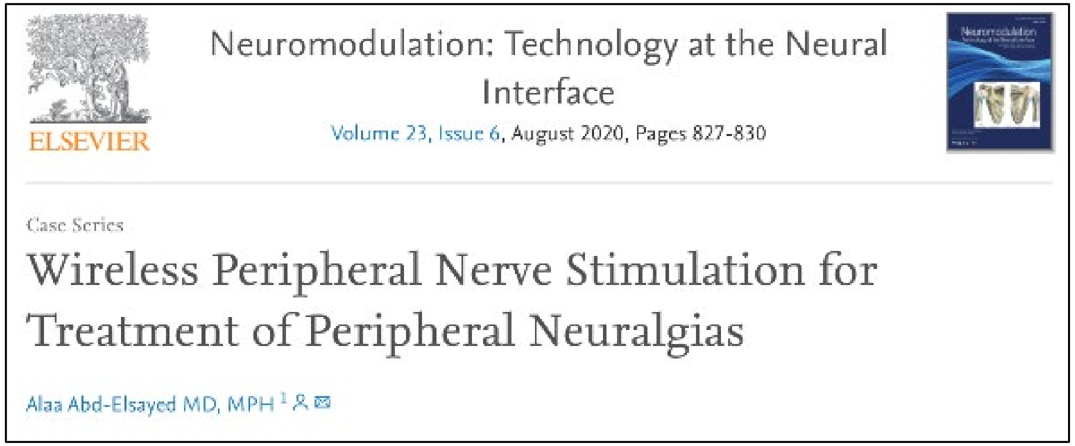
(Near Field + Far Field)



Radiation Plot (W) @ 915 MHz

Recent Data Publications

Wireless Peripheral Nerve Stimulation for Treatment of Peripheral Neuralgias


ELSEVIER
Neuromodulation: Technology at the Neural Interface
Volume 23, Issue 6, August 2020, Pages 827-830

Case Series

Wireless Peripheral Nerve Stimulation for Treatment of Peripheral Neuralgias

Alaa Abd-Elsayed MD, MPH [1]

AUTHORS: Alaa Abd-Elsayed

Background: Peripheral neuralgia is a common cause of chronic pain. Treatment might be challenging, and the condition can be resistant to commonly used treatment modalities for chronic pain. **We present five cases of peripheral neuralgia who were successfully treated using wireless peripheral nerve stimulation.**

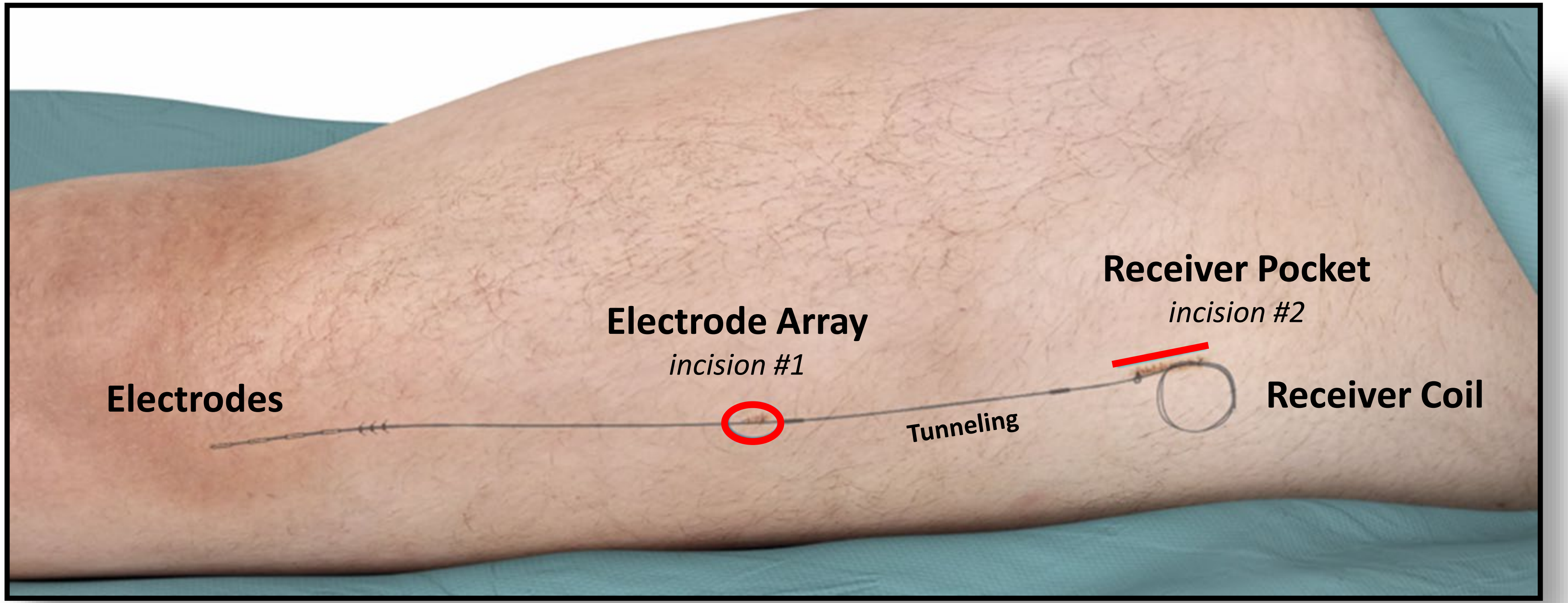
Materials and methods: This was a retrospective case series that includes a description of five patients who underwent wireless peripheral nerve stimulator therapy for the treatment of peripheral neuralgia.

Results: The patients in this case series underwent peripheral nerve stimulator placement for the treatment of superior cluneal, sural, ilioinguinal and genitofemoral neuralgias. **Patients reported a decline in their Numerical Rating Scale (NRS) pain scores from a mean of 6.4 before the procedure to a score of 1 following implant**. The change in pain scores was found to be statistically significant ($p < 0.05$).

Conclusions: We present five patients with peripheral neuralgias resistant to other treatment modalities who received excellent pain relief following implantation of a peripheral nerve stimulator.

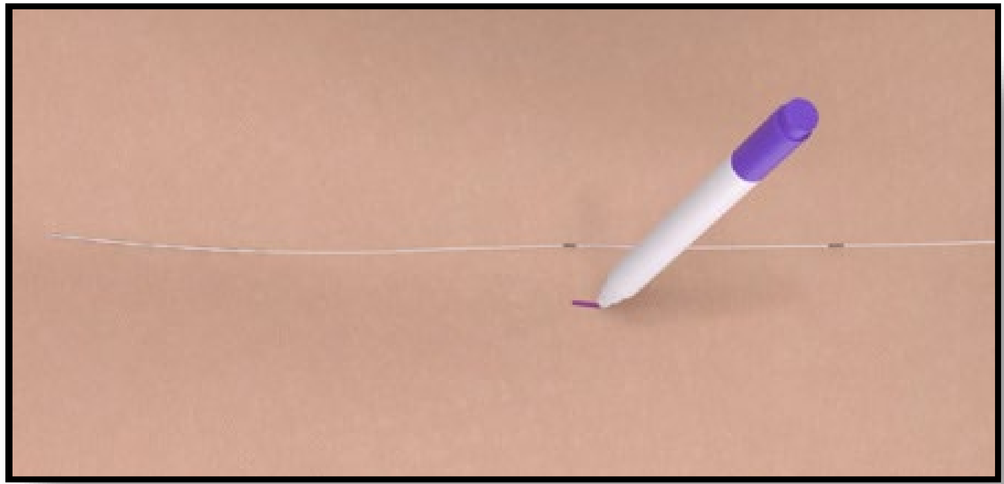
Freedom PNS Technique

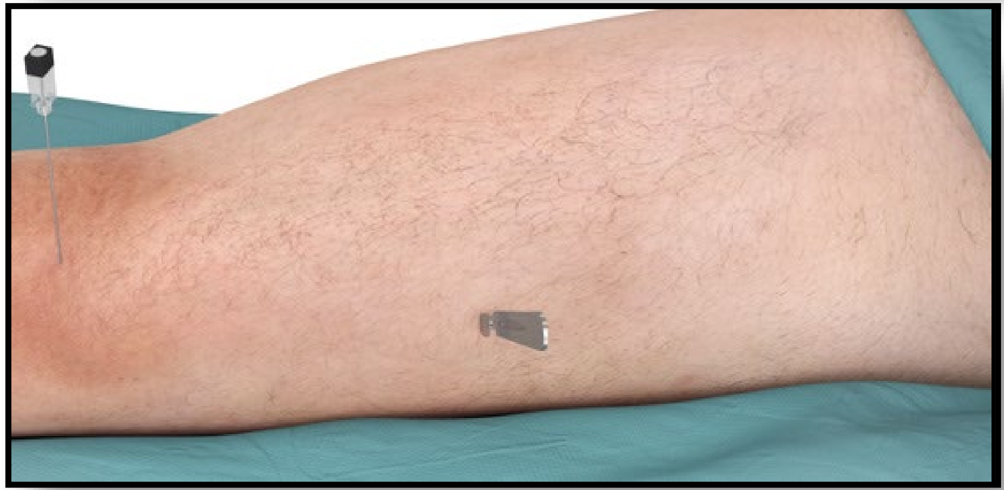
Freedom PNS Surgical Technique Summary



Electrode Array – Locating the 1st Incision

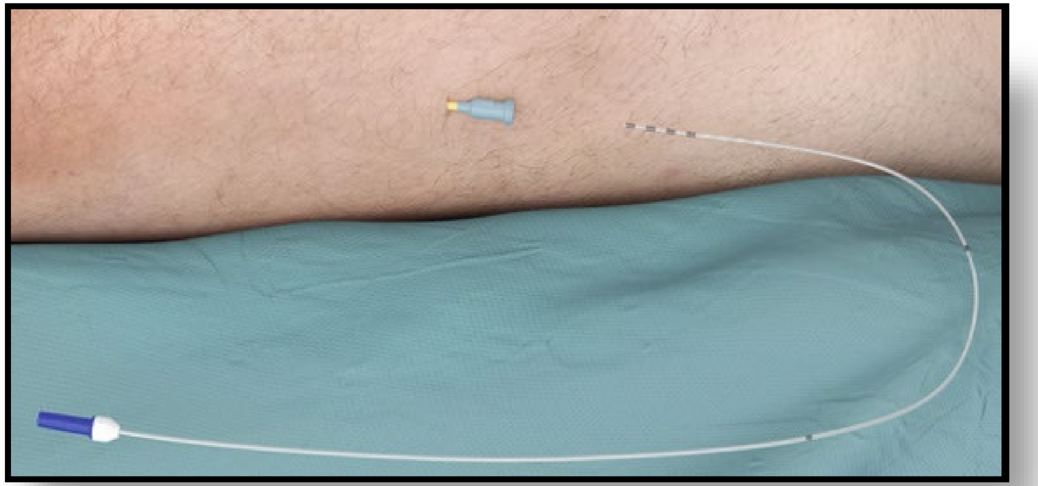
- On top of the skin, place the tip of the electrode array where the first electrode will be placed.
- Holding the tip of the electrode array firmly on the skin, extend the array along the plane of the skin.
- Mark the location of the first marker band on the electrode array (distal from tip of the array). This mark will be the first incision location.
- Make a puncture incision at the marker band.





Electrode Array Insertion

- Advance the introducer assembly through the incision and towards the peripheral nerve with imaging.
- Remove the dilator from the introducer.
- Advance the Electrode Array through the introducer – parallel to the target nerve.
- Remove the introducer to expose the electrodes.



Creating the Reciever Pocket – 2nd Incision

- Mark the skin ~10cm from the 1st incision.
- Make a second incision and create a subcutaneous pocket.
- The subcutaneous pocket is made to house and fixate the Receiver

Receiver/Electrode Array Connection

- Remove the steering stylet from the Electrode Array.
- Connect the separate Receiver to the Electrode Array.

Testing Stimulation Intraoperatively

1. Place the WAA in a sterile drape over the region directly above the most proximal implanted electrode.

2. Identify the most appropriate stimulation parameters.

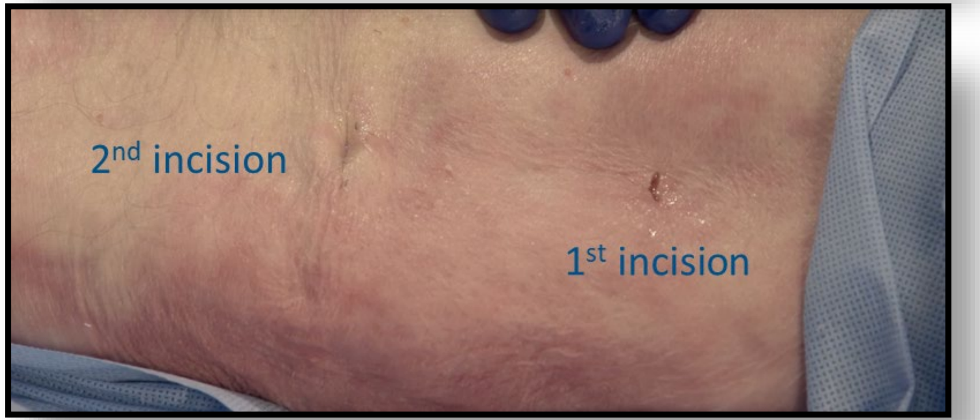
3. Record the stimulation settings and patient responses.

Receiver Tunneling

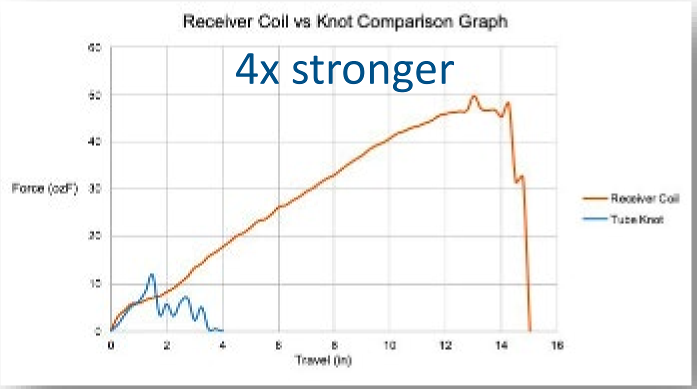
- Advance the introducer from the subcutaneous Receiver pocket to the electrode array entry site.
- Tunnel the electrode array and the connected receiver from the first incision to the second incision (receiver pocket).
- Withdraw the introducer from the subcutaneous Receiver pocket.

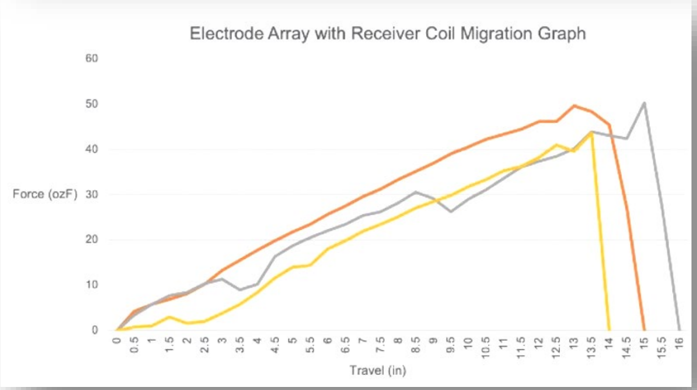
Receiver Coiling & Fixation

- Tie a knot to permanently connect the Electrode Array and separate the Receiver.
- Push the knot to the distal edge of the receiver pocket.
- Coil the Receiver after the marker band.
- Suture anchor the receiver coil to the fascia within the pocket at two or more locations (marker band).
- Close incision using sterile skin closures and dressings.

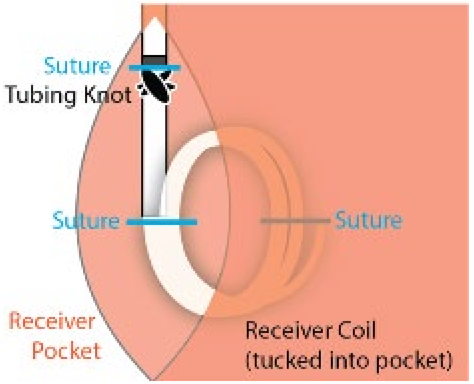


Proper Surgical Anchoring Strength Data





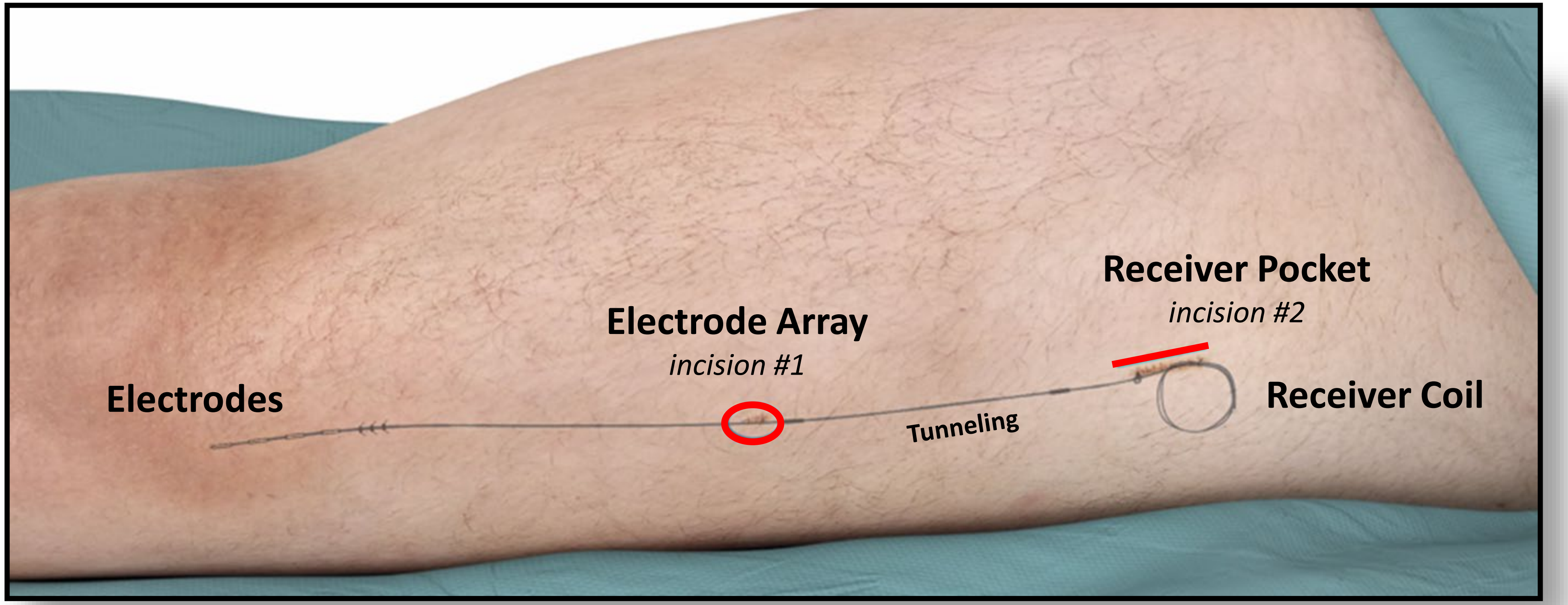
4X Stronger Fixation in Pocket



0.95% Migration Complaint Rate

Configuration	Minimizing Receiver Movement	Minimizing Neurostimulator Migration
Receiver Coil	X	✓
Knot	✓	X
Receiver Coil + Knot	✓	✓

Freedom PNS Surgical Technique Summary



Thank You!

Questions & Comments