Expanding the Practice of Peripheral Nerve Stimulation with a Novel, Battery-free Micro-implantable Neurostimulation System

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AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
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Disclosure

- Consultant/Independent Contractor: Abbott, Avanos, Averitas Pharm, Biotronik, Boston Scientific, Nalu, Nevro, PainTeq, Saluda, SPR Therapeutics, Vertos Medical
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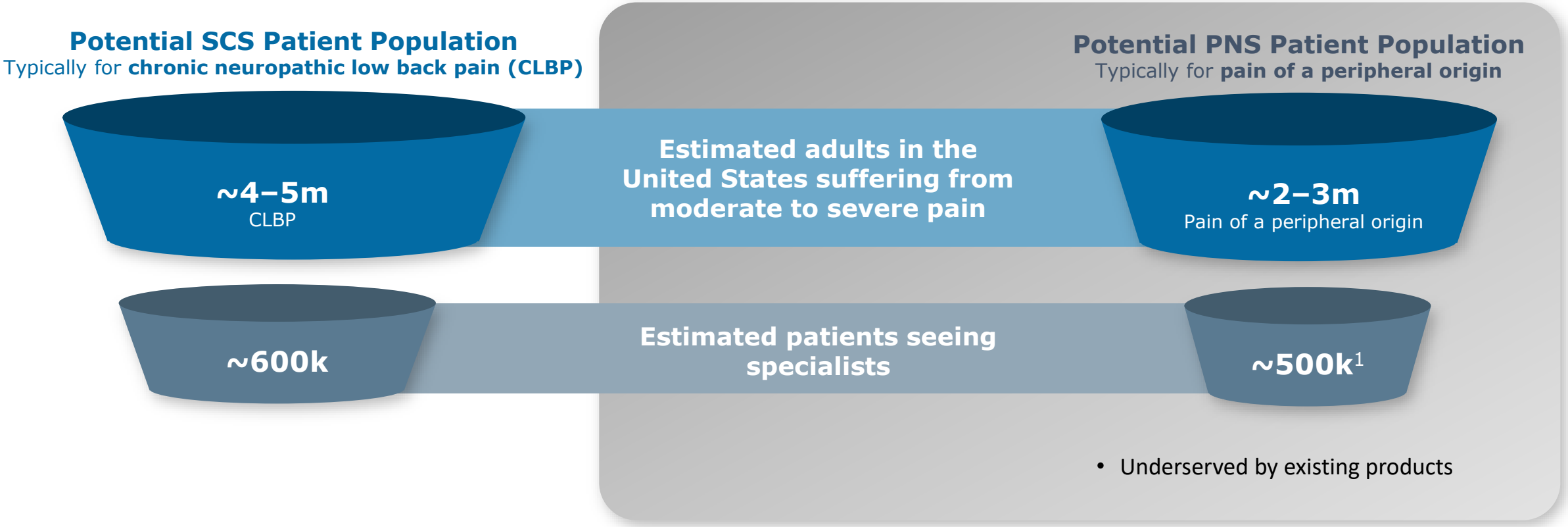
- Advisory Board: Abbott, Saluda
- Equity: Nalu, National Spine and Pain Centers

Underpenetrated patient populations

Estimated Patient Population

~13–16m

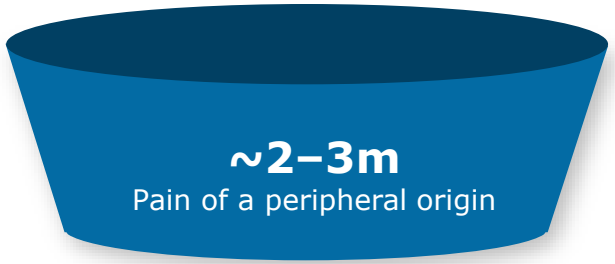
estimated US adults in 2019 with chronic, moderate to severe, neuropathic pain

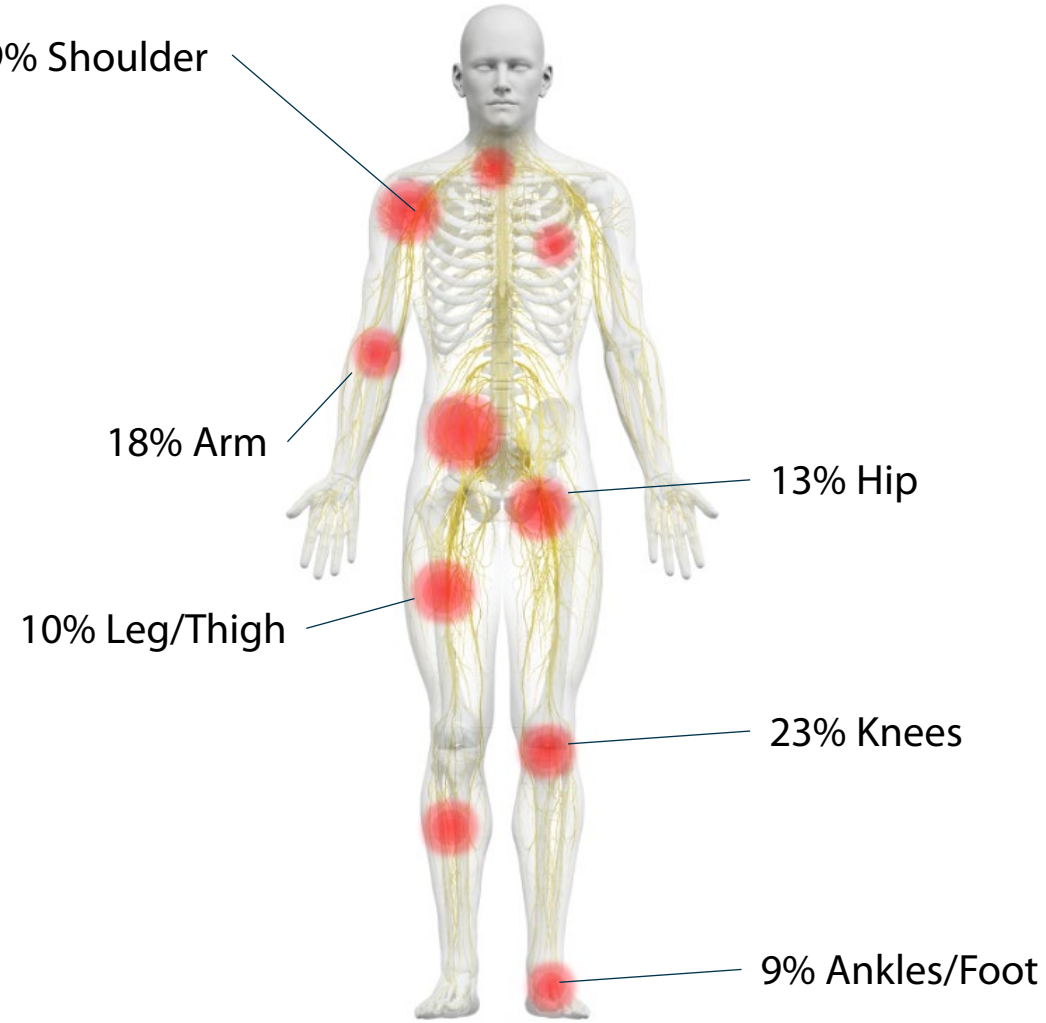


1. Nalu Medical S-1 SEC Filing: https://www.sec.gov/Archives/edgar/data/1647424/000119312521211837/d102511ds1.htm

Anatomical sites for chronic pain of a peripheral origin

Potential PNS Patient Population
Typically for **pain of a peripheral origin**





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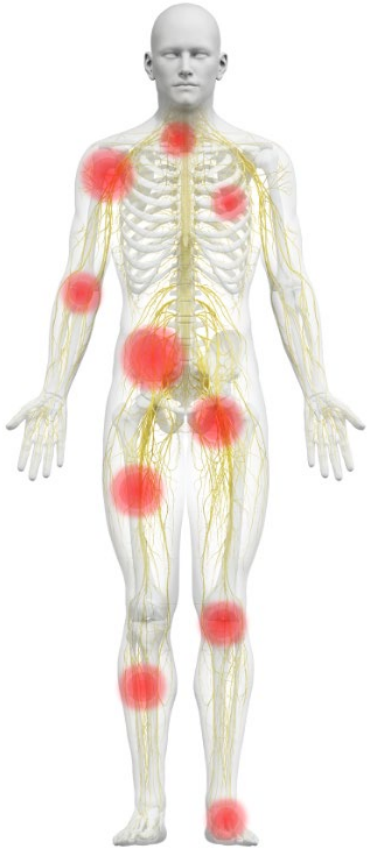
Limitations w/Certain Existing PNS Technologies



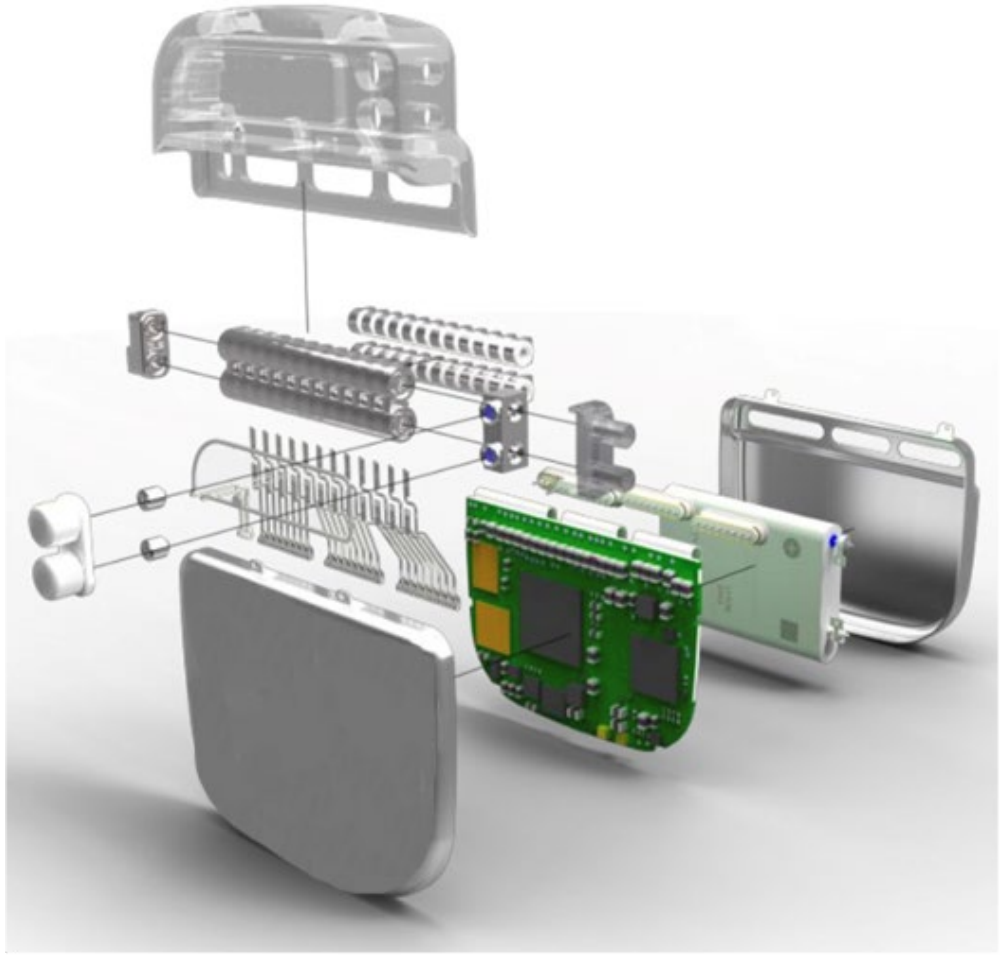
Limited capabilities

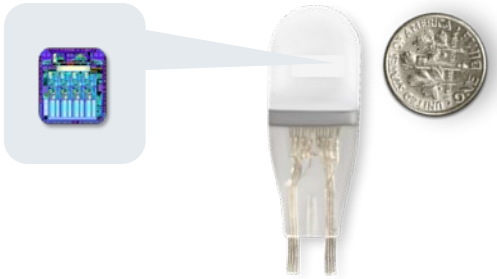
Limited system configurations

No trial

Limited longevity (<60 days)

Microelectronics & Advanced Stimulation



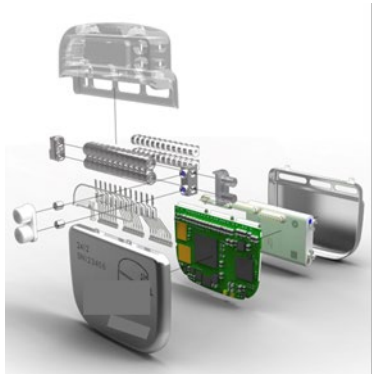


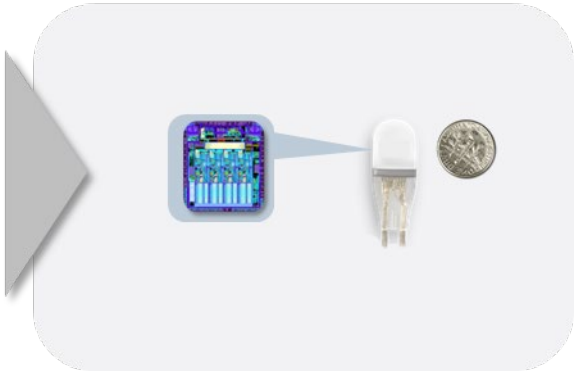
2021 R&D 100 WINNER

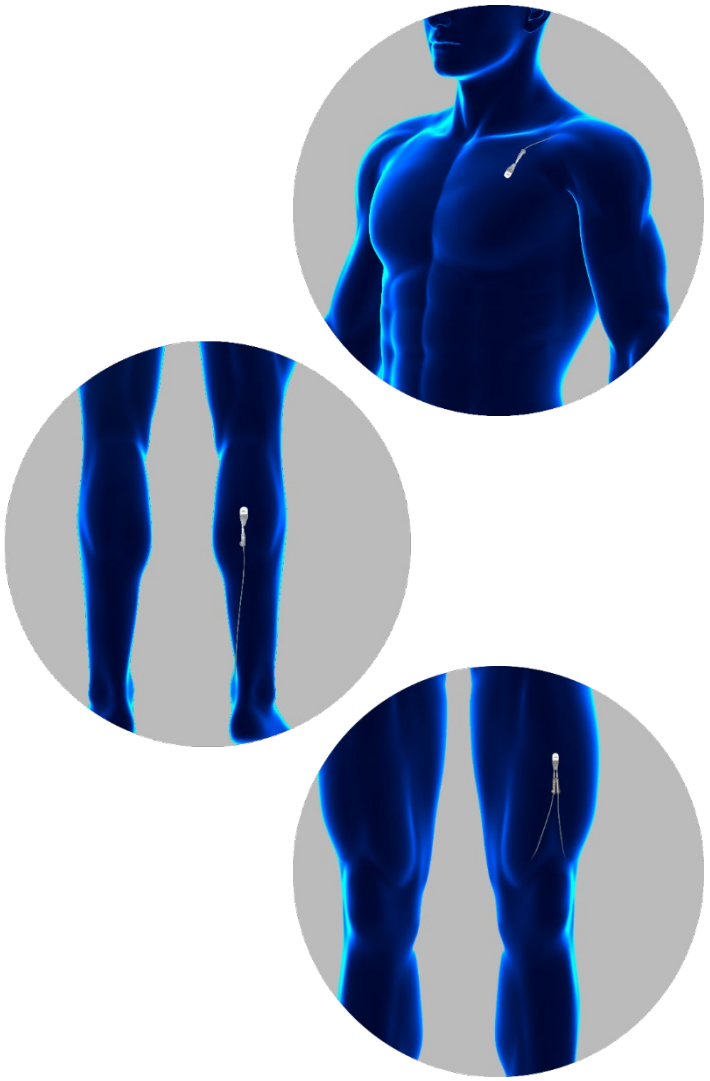
2021 MEDTECH VISIONARIES AWARD WINNER

2021 GOLD WINNER MEDICAL DESIGN EXCELLENCE AWARDS

micro-IPG – Bringing SCS capabilities to PNS







SCS systems

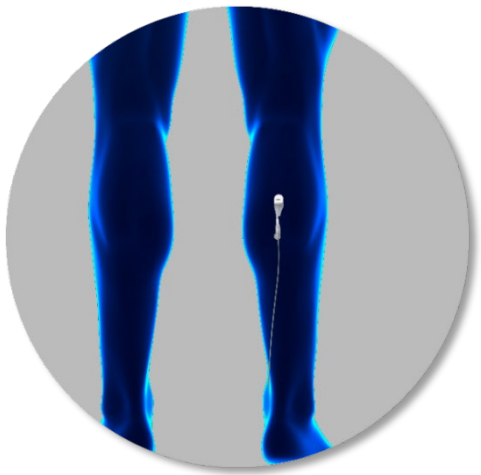
- IPG
- Broad capabilities
- Multiple lead configurations
- Full trial
- Impedance measurements
- Longevity

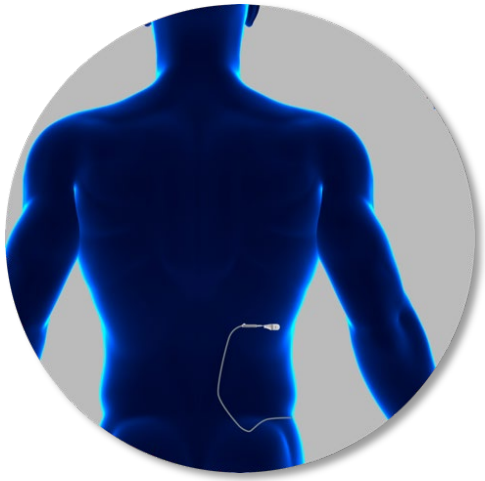
PNS systems

- Small size
- Can be placed near target nerve

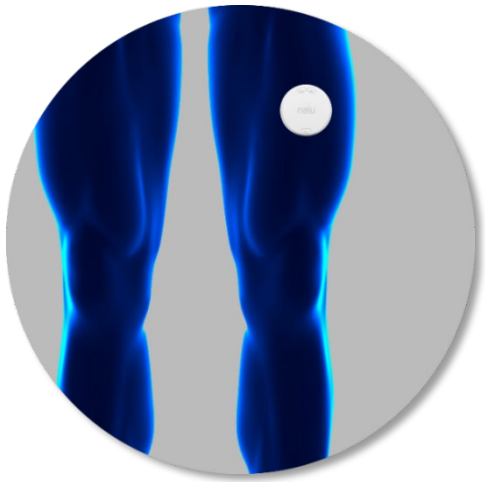
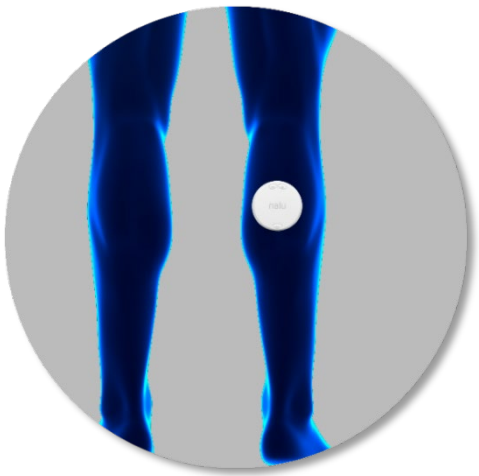
micro-IPG - Peripheral Nerve Stimulation Examples

Internal micro-IPG

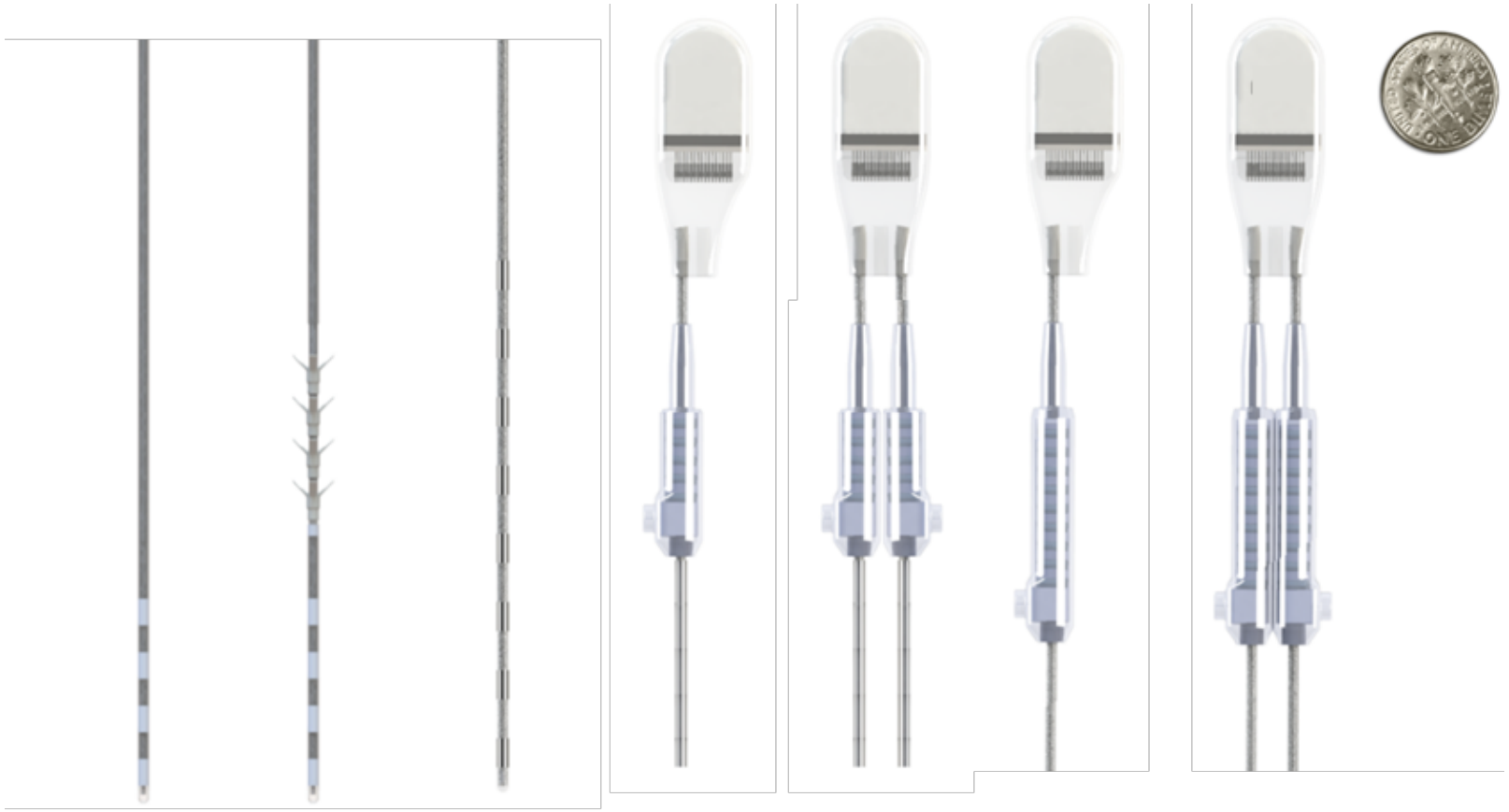


External wearable

These images are provided for illustrative purposes only.
Exact placement of the IPG and Therapy Disc are determined independently by physicians.

Portfolio of Leads & Micro-IPGs



4-contact trial lead (PNS)

4-contact tined lead (PNS)

8-contact lead (SCS/PNS)

Single 4 IPG (PNS)

Dual 4 IPG (PNS)

Single 8 IPG (SCS/PNS)

Dual 8 IPG (SCS/PNS)

Menu of therapy options offered in the micro-IPG

Conventional therapies
(available today)

- Tonic
- Pulse dosing (high and low dose)
- Current steering (SCS)

Advanced therapies
(available today)

- Burst (multiple variations)
- Scheduling
- Paired Therapies
- Combination Therapies

micro-IPG therapies

- Current Steering (PNS)
- Ultra-long Pulse Width (up to 2000 µs)
- Pulsed stimulation patterns (PSP)

Potential for Software updates
subject to FDA review and 510(k) clearance

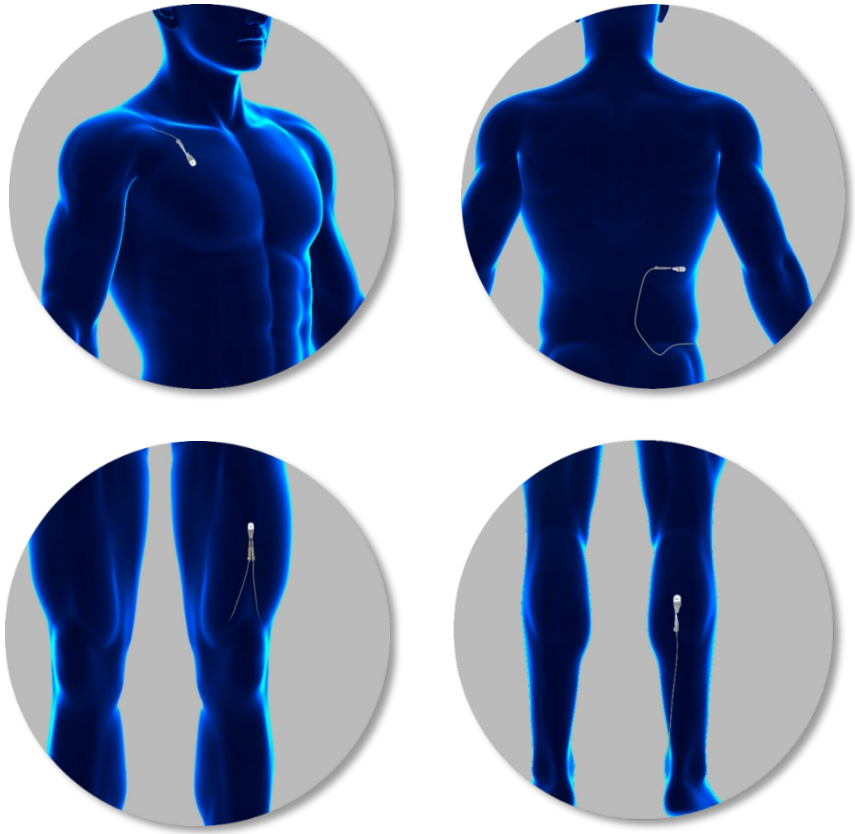
Expanding Options with PNS

The PNS patient – patient identification

- **Patient preference – small incision, no implantable battery**
  - Reluctance to undergo “surgery”
  - Fear of having implanted device and battery
  - Pocket pain
  - Need for battery replacement
  - Cosmetic outcome

- **Clinical factors**
  - History of spine surgeries
  - Co-morbidities
  - Anti-coagulants

- **Technical Implementation of a micro-IPG**
  - Dual lead capable, multi-contact leads w/current steering
  - Trial capability (up to 30 days)
  - Easily upgradeable stimulation capabilities (SCS capabilities in a PNS form factor)



Ultrasound Targets

Lower Extremity

- Femoral
- Sciatic
- Saphenous
- Tibial
- Common Peroneal

Truncal Area

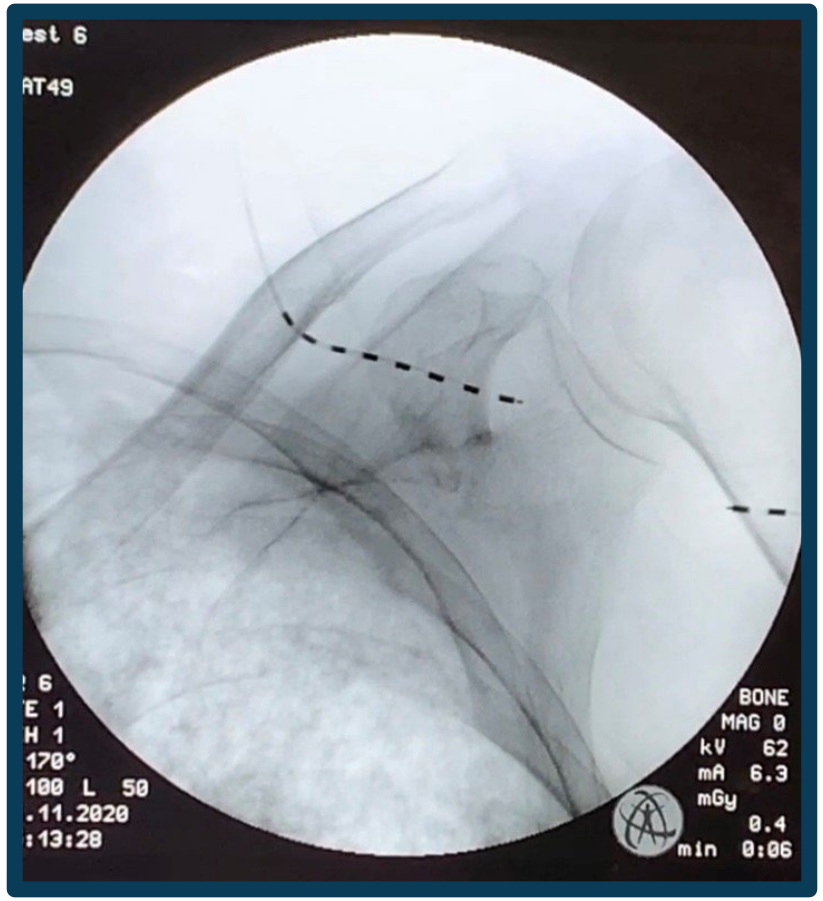
- Ilioinguinal
- Iliohypogastric
- LFCN

Upper Extremity

- Ulnar
- Radial
- Medial
- Axillary
- Suprascapular

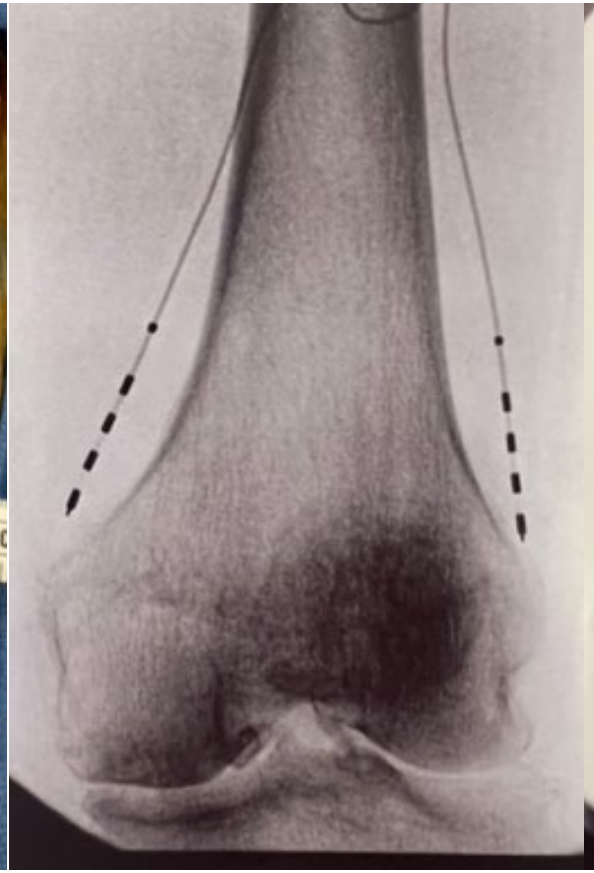
Fluoroscopy Targets

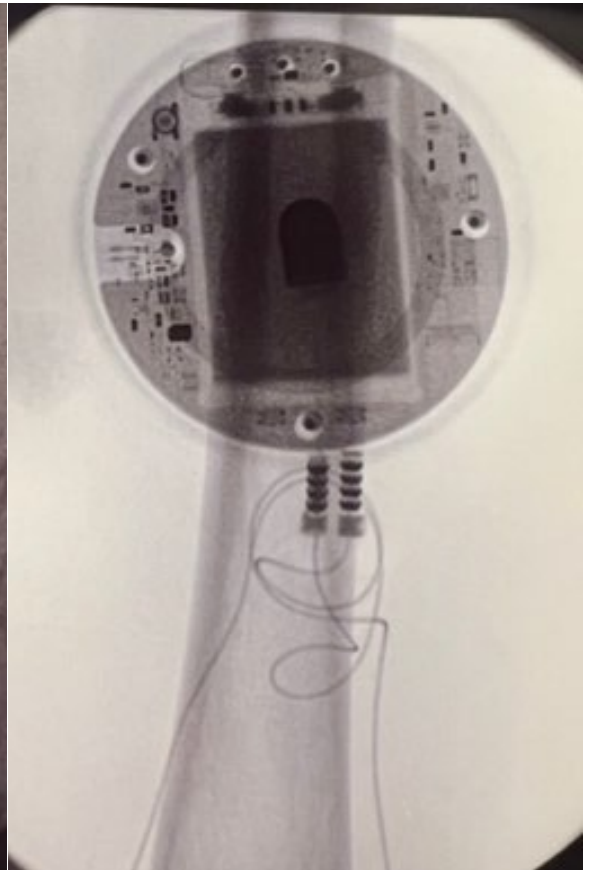
- Suprascapular
- Axillary
- Superior Genicular
- Intercostal
- Cluneal



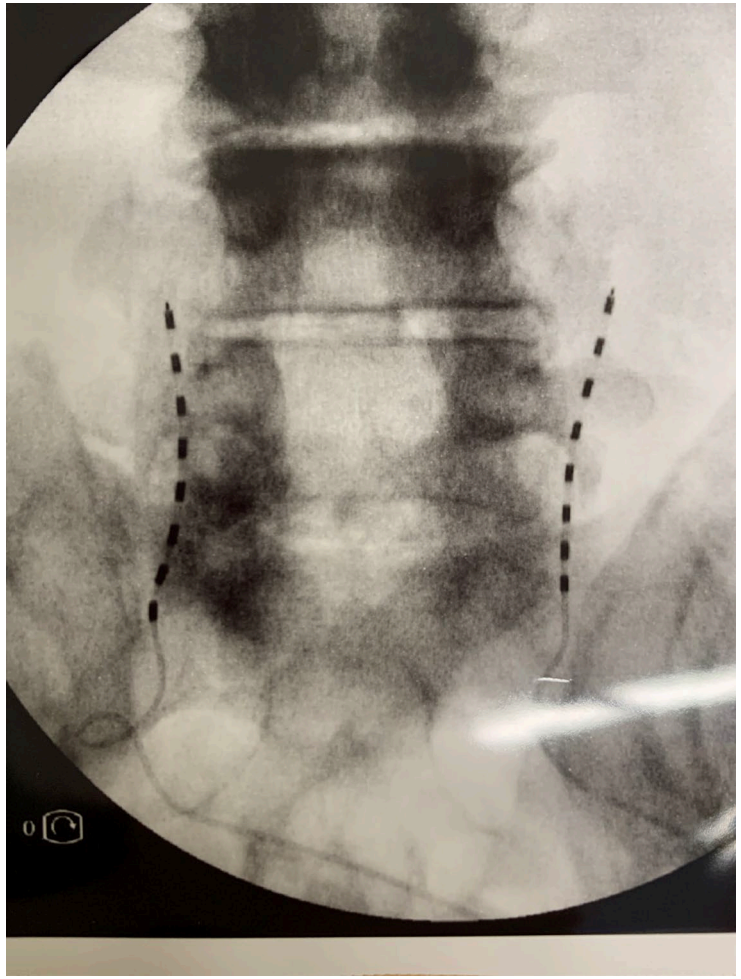
84F, Chronic knee pain

PNS: left superior medial & lateral genicular nerves



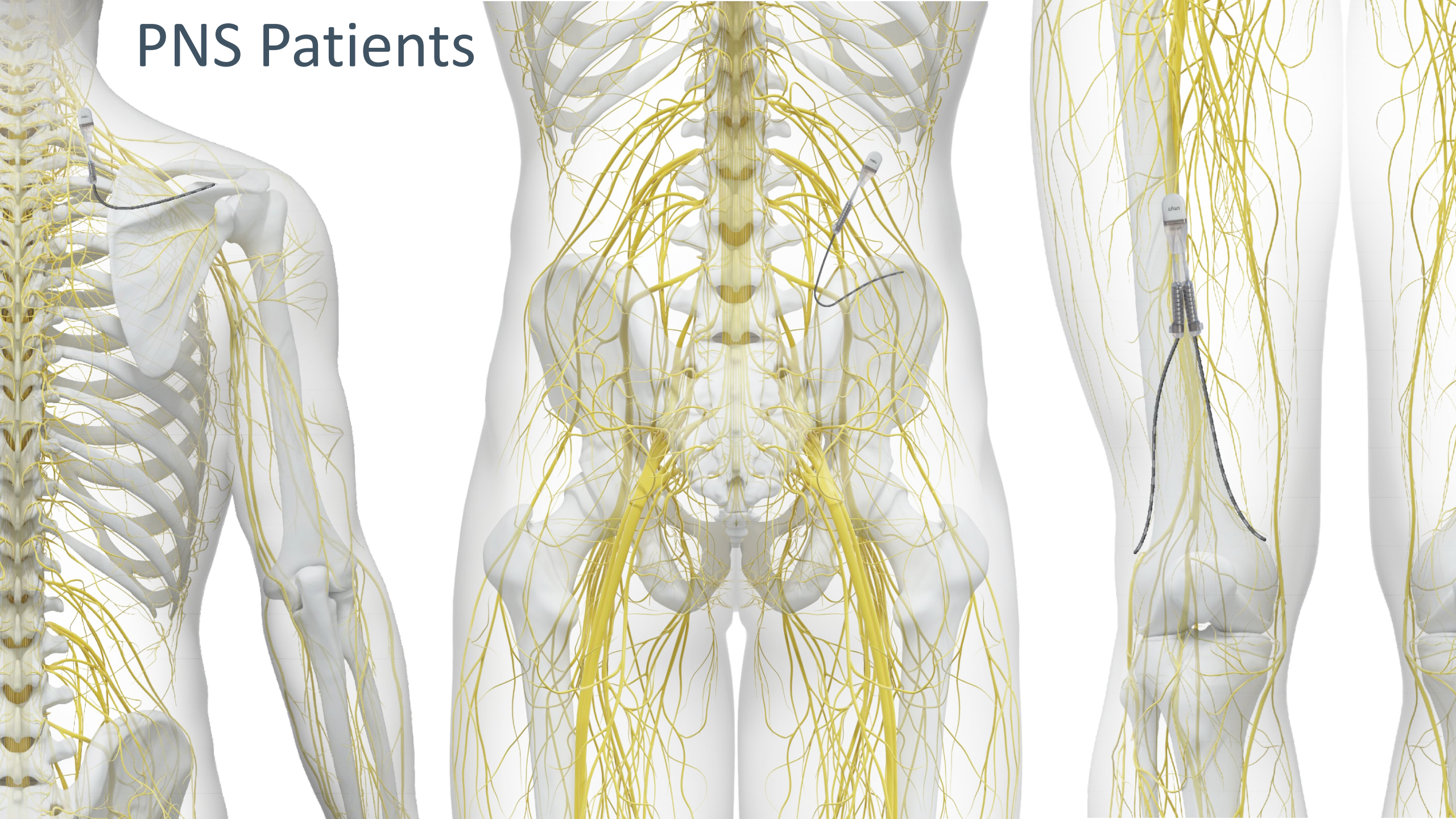


PNS for Failed Back Surgery Syndrome

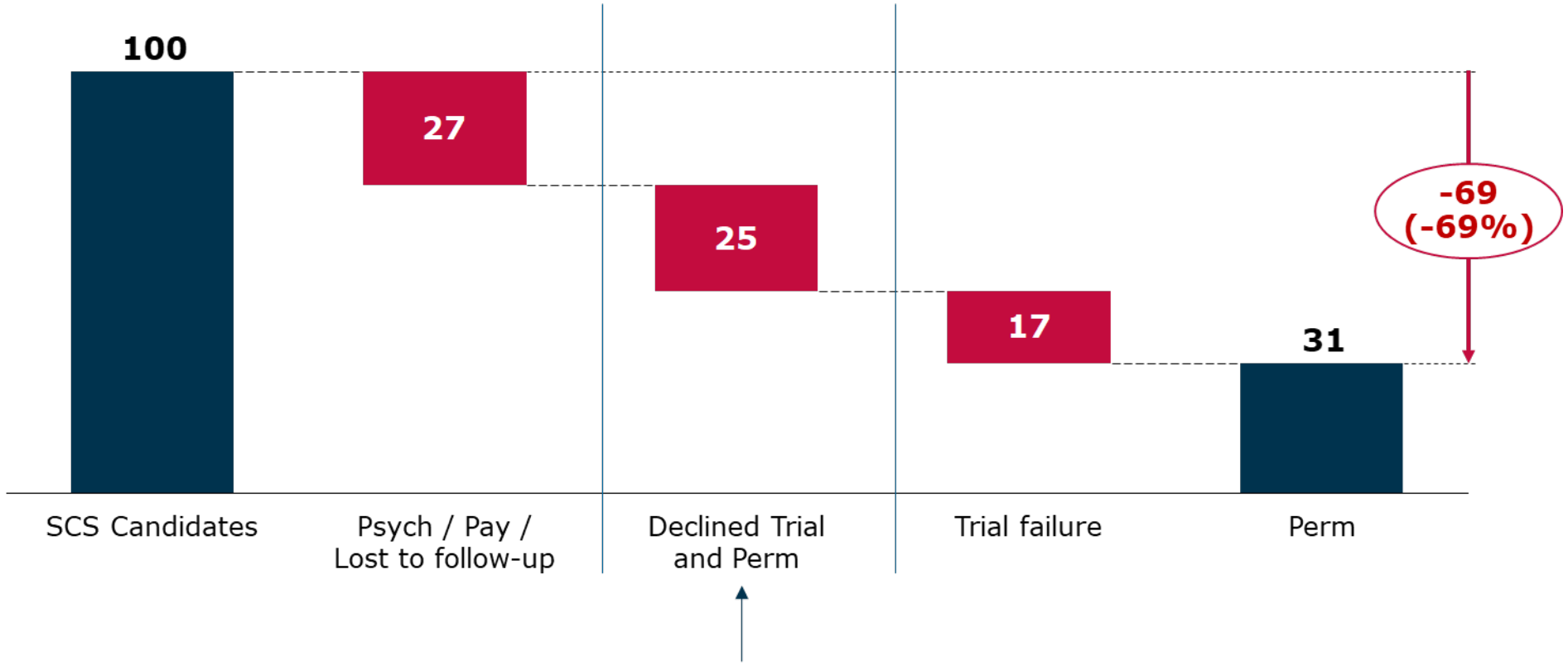


- 68-year-old male, “Joseph”
- Chronic low back pain
- Prior laminectomy
- Dx: failed back surgery syndrome
- Failed traditional SCS trial
- 80% pain relief with 60-day PNS
- Indirect micro-IPG PNS implantation (#2 in U.S.)

PNS Patients

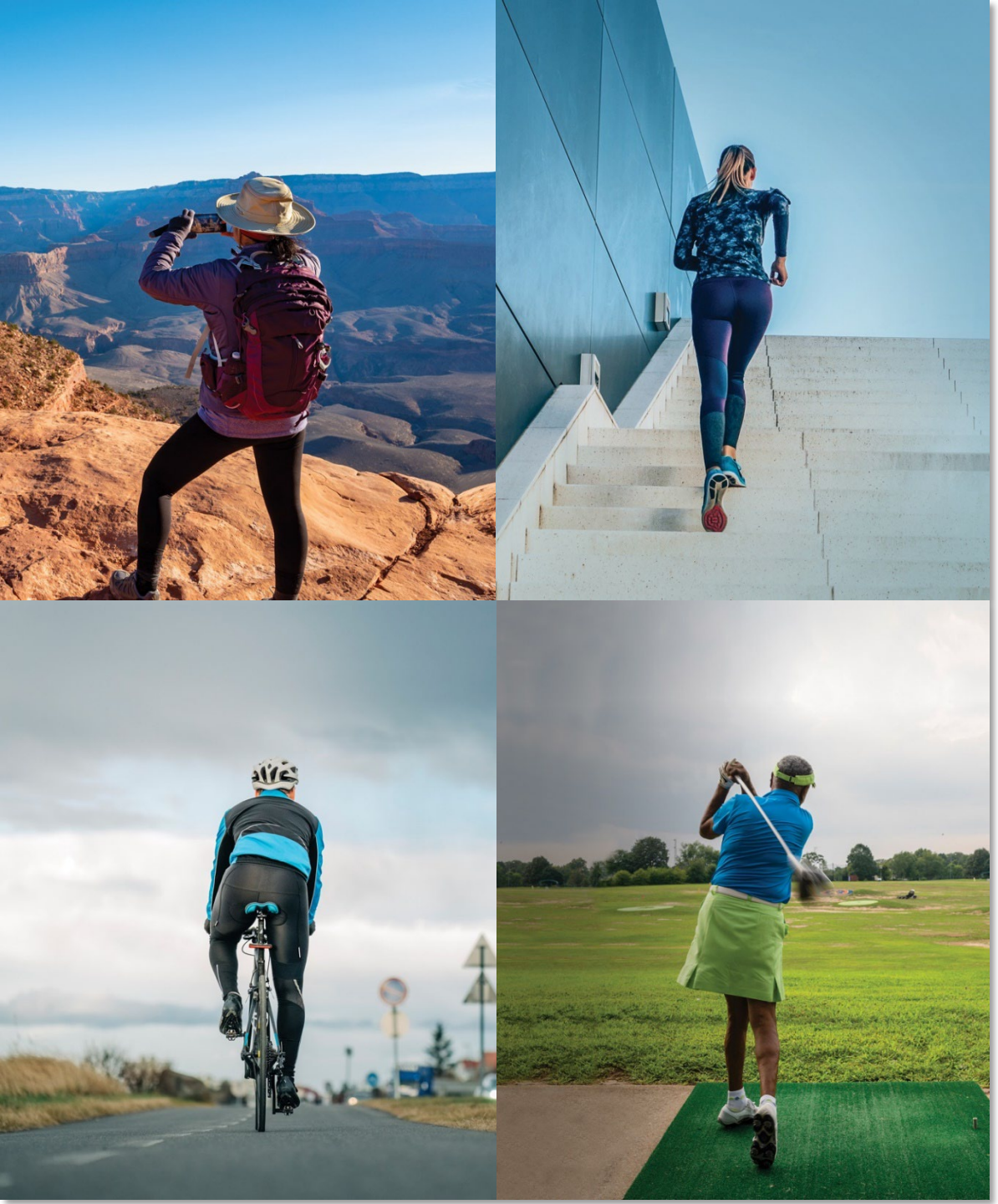


Not All SCS Candidate Undergo Implant



"The most common reasons for rejecting the trial implantation were either **fear of the stimulator** or **unwillingness to undergo another surgery**."

Ruchinskas R & O'Grady T. Neuromodulation. 2000.



- PNS candidates exist today within your practices.
- PNS Today:
  - improved technologies
  - cost effective
  - low risk
  - favorable reimbursement
  - Optimal salvage option (failed 60-day, SCS, DRG, etc.)
- Low barrier of entry - certain PNS targets can be accessed under fluoroscopic guidance