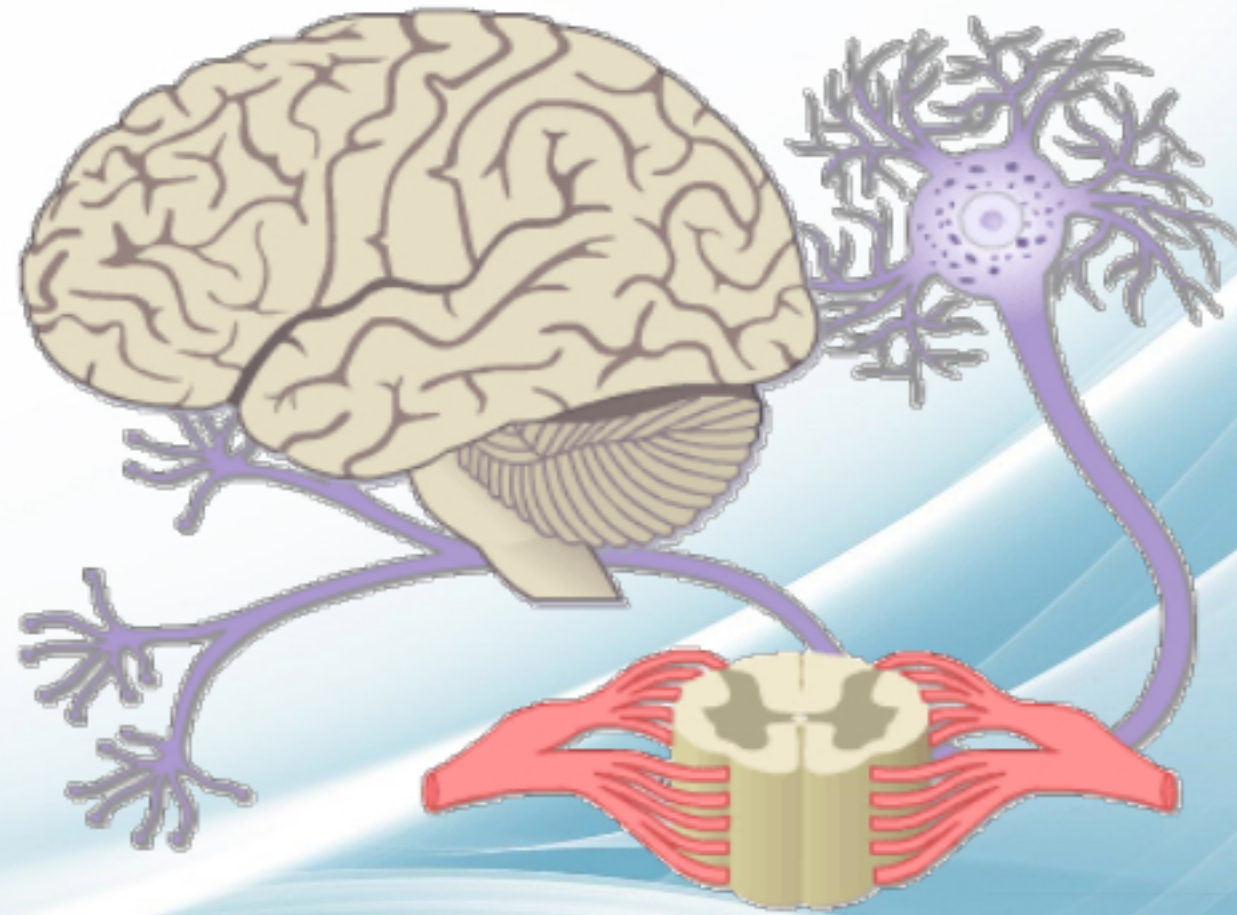


Advances in Interventional Pain Management



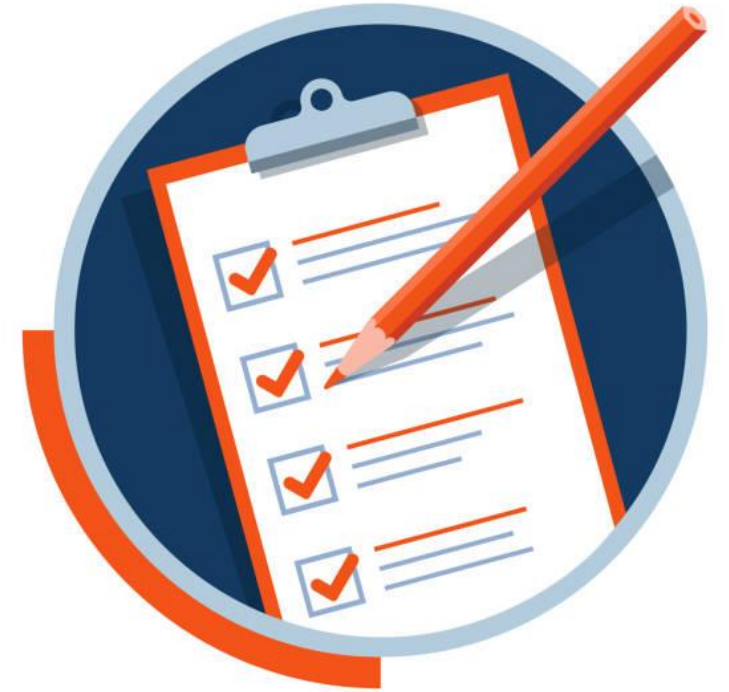
Efrain I. Cubillo IV M.D.
SaddleBrooke Health Night Out
11/10/2025



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of Southern Arizona

Objectives

- Understand spinal stenosis
- Understand how the MILD procedure can help patients with spinal stenosis
- Understand the basics of neuromodulation
- Understand how Saluda neuromodulation can help patients with chronic pain





Efrain I. Cubillo, M.D.

Interventional Pain Specialist

The Pain Institute of Southern Arizona

- **Medical School:**
The University of Arizona College of Medicine (Junior AOA)
- **Maricopa Internal Medicine Internship**
- **Anesthesiology Residency: The Mayo Clinic, Phoenix, AZ**
- **Interventional Pain Fellowship:**
Harvard Beth Israel Deaconess Medical Center
- **Recognition**
 - **Mayo Clinic Resident of the Year Award**
 - **Harvard Pain Fellow of the Year Award**



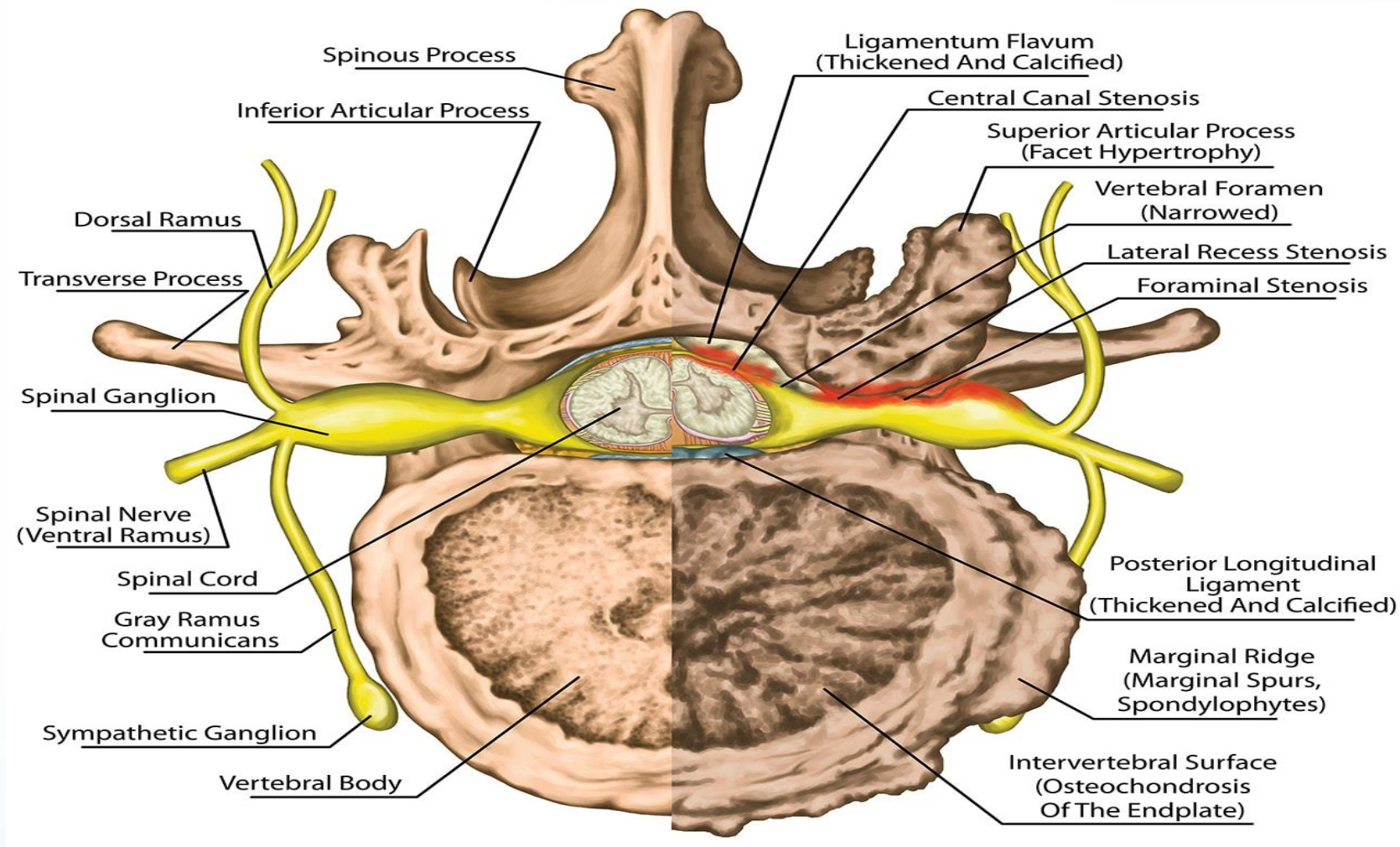
Pain Institute of Southern Arizona Mission Statement

***Through **compassion** and **innovation**,
we will make a **meaningful difference**
in the lives of individuals and in
communities.***



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SPINAL ANATOMY



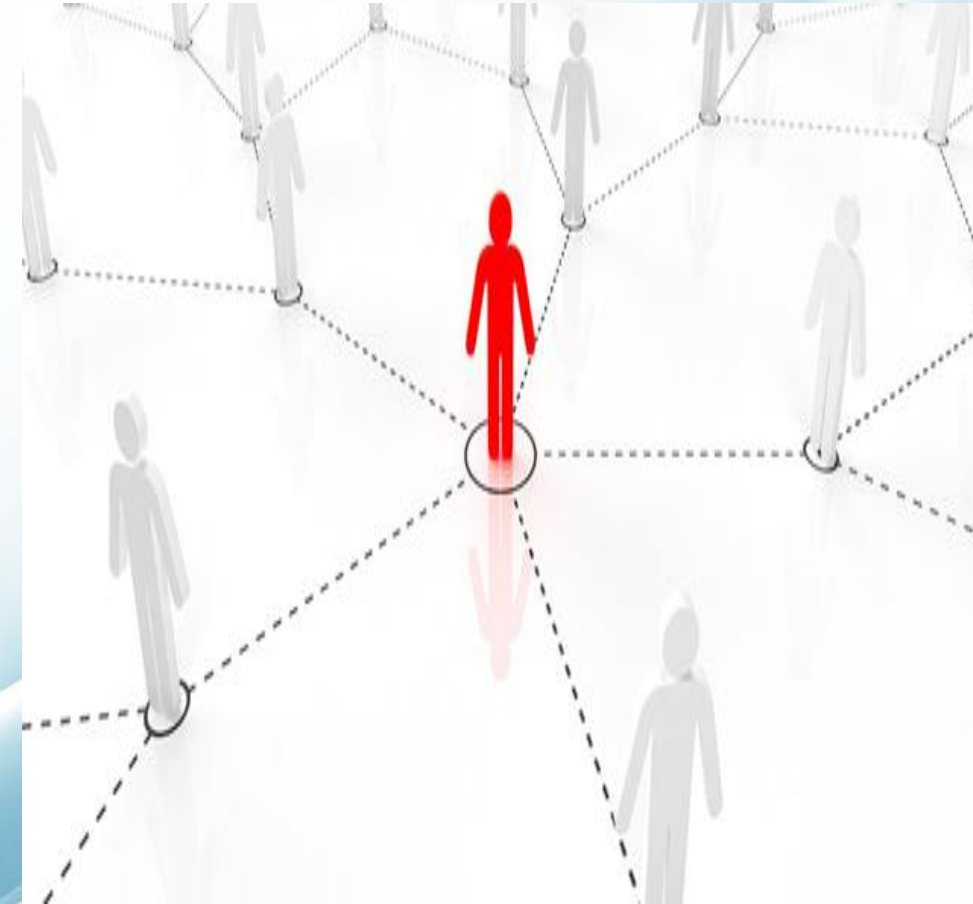
History of Spinal Stenosis

- In 1954, the Dutch neurosurgeon Henk Verbiest provided the first clinical definition of lumbar spinal stenosis (LSS).
- Since that time, LSS has been well studied, and is recognized as a progressive clinical entity causing chronic lower extremity pain and/or weakness.
-



EPIDEMIOLOGY

- A recently published systematic review concluded that the pooled prevalence estimates of LSS were 11% in the general population and ranged from 25% to 39% in clinical settings.
- Studies have found that more than 80% do not experience symptoms.
- Surgical treatments were performed in 135.5 to 137.5 patients per 100,000 Medicare beneficiaries between 2002 and 2007, with estimated hospital costs of \$1.65 billion. When considering lost or reduced productivity from surgery, costs greater than \$100 billion per year



WHAT IS LUMBAR SPINAL STENOSIS (LSS)?

A gradual narrowing of the space in the spine where nerves pass through. The narrowing can cause a “pinching” on the lower back nerves resulting in tingling, numbness, weakness and/or pain in one or both legs and/or lower back. **Relief can be experienced when bending forward slightly or sitting.**



HEALTHY



STENOSIS



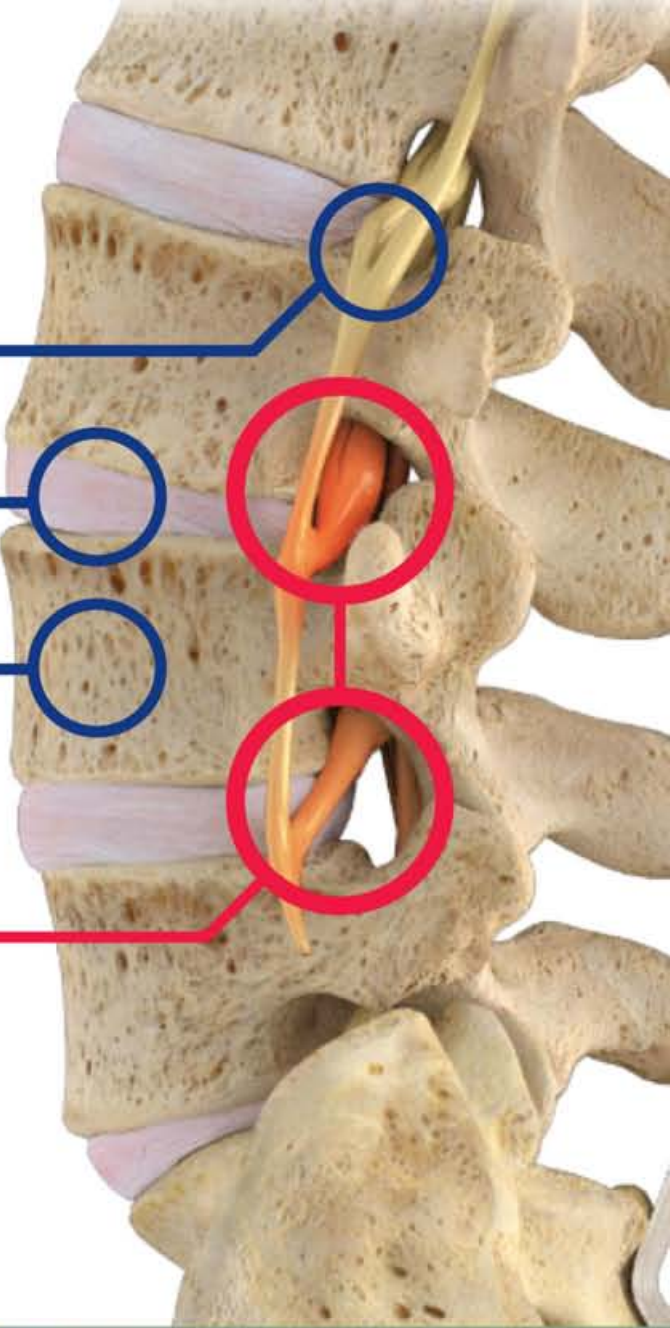
HEALTHY
NERVE

DISC

VERTEBRAE

PINCHED
NERVE

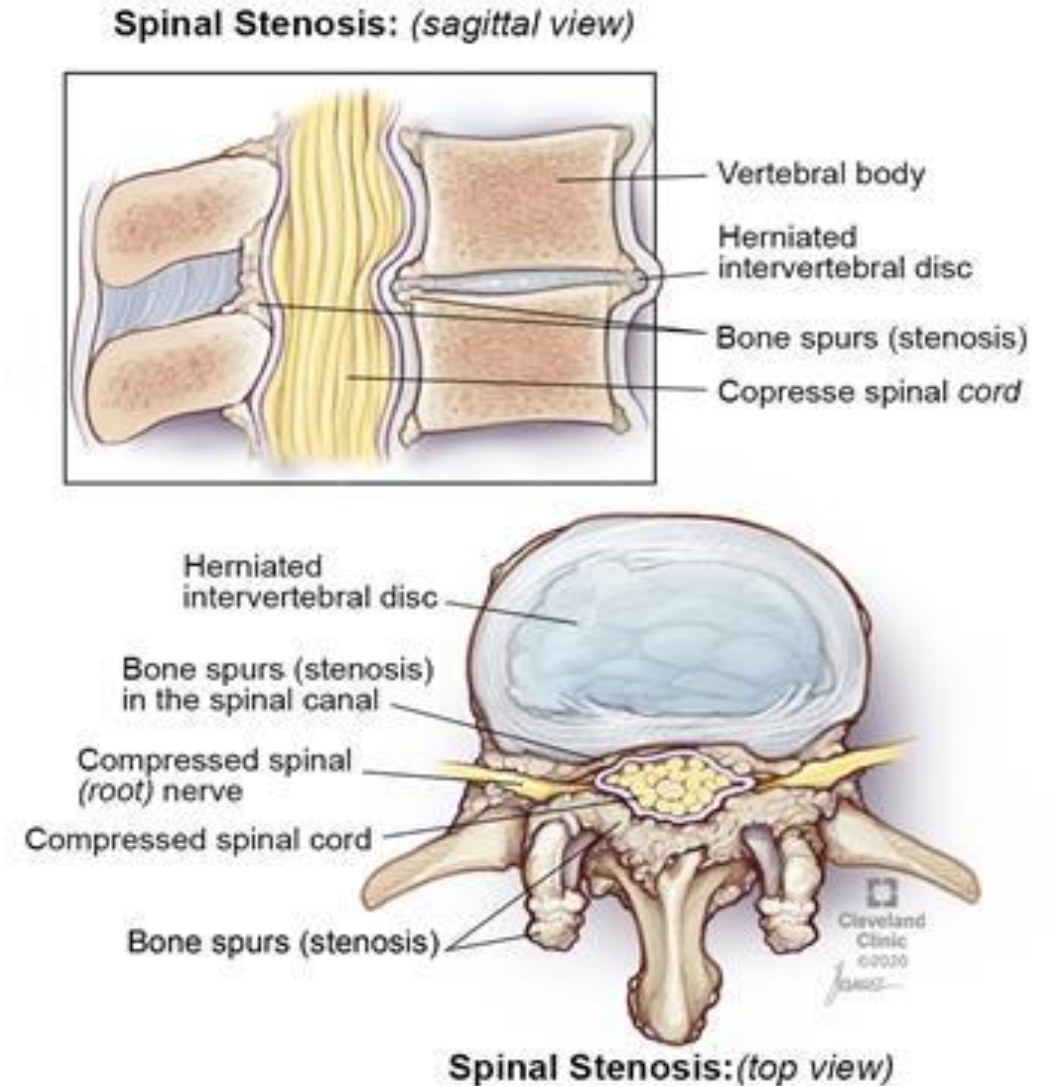
Pain radiates
down lower
back and into
the legs.



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PATHOPHYSIOLOGY

- The **most common type** of LSS is secondary due to **degenerative pathology** and can involve the central canal, lateral recess, neuroforamen or a combination of these locations.
- The **spinal cord** and nerve roots are **protected** by **osseous, ligamentous, and intervertebral disc structures** that all are subject to degeneration and **hypertrophy**, leading to encroachment of the canal that causes compression of neurovascular tissue.
- This compression can lead to **mechanical** and/or **chemical irritation**.
- **Multistructural narrowing** involving the central, lateral recess, and neuroforamen is the **most frequently encountered LSS in those >60 years old**.



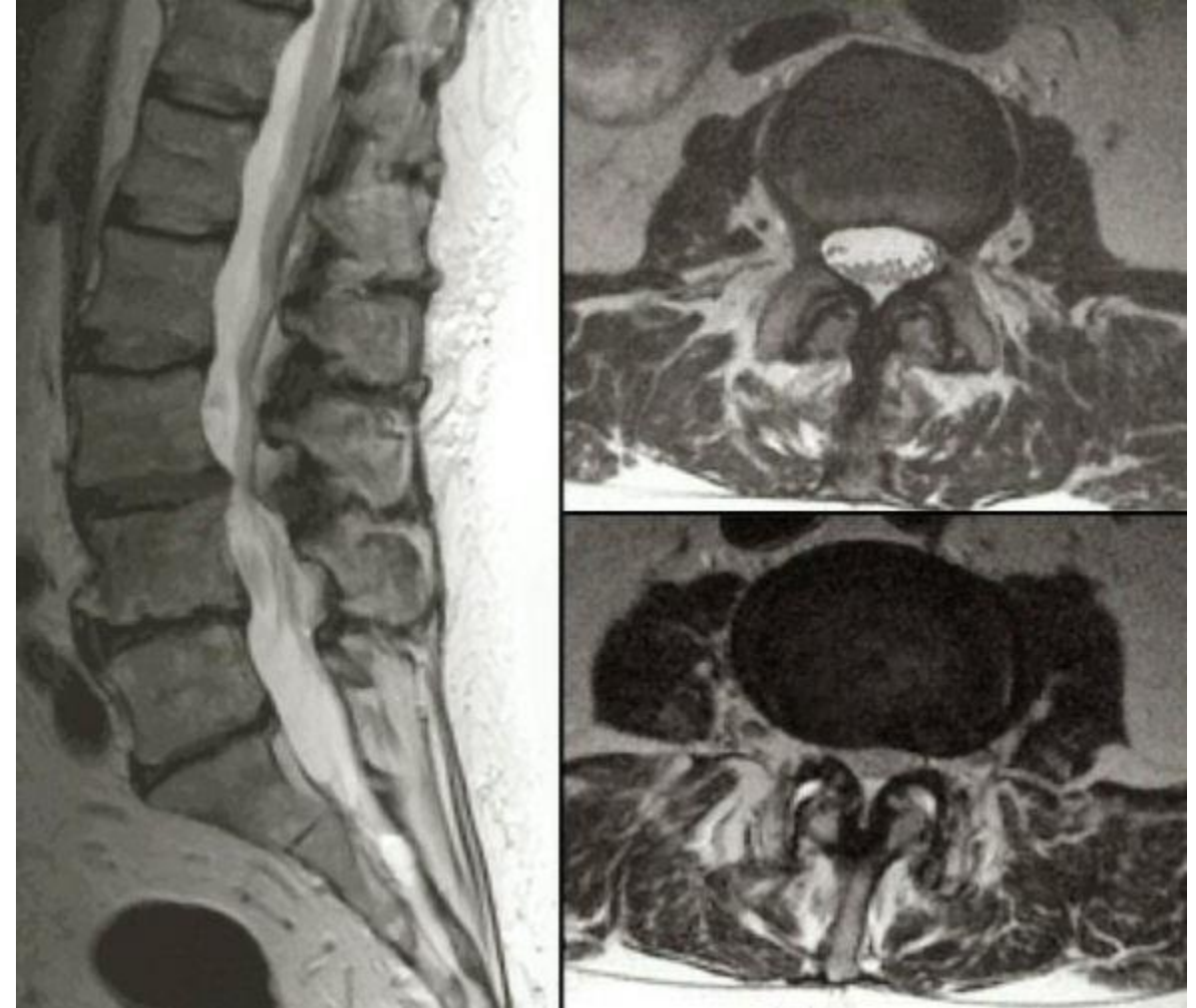
NEUROGENIC CLAUDICATION

- Neurogenic Claudication (NC) is a pain syndrome whose **etiology is LSS**.
- **Intermittent pain in the lower extremities** that is exacerbated by activity and relieved with rest.
- In addition to pain, patients with NC may complain of **leg heaviness, numbness, tingling, and weakness**. The pain from NC is classically **worsened by lumbar extension and alleviated with lumbar flexion**.
- The improvement in pain and facilitating of ambulation with forward flexion is sometimes called the positive **shopping cart sign**.
- The diagnosis of NC is made from the history and involves **pain in the low back, buttocks, thighs, and/or legs that develops with prolonged standing and walking and is relieved when the patient sits down**. The symptoms of NC are generally bilateral.



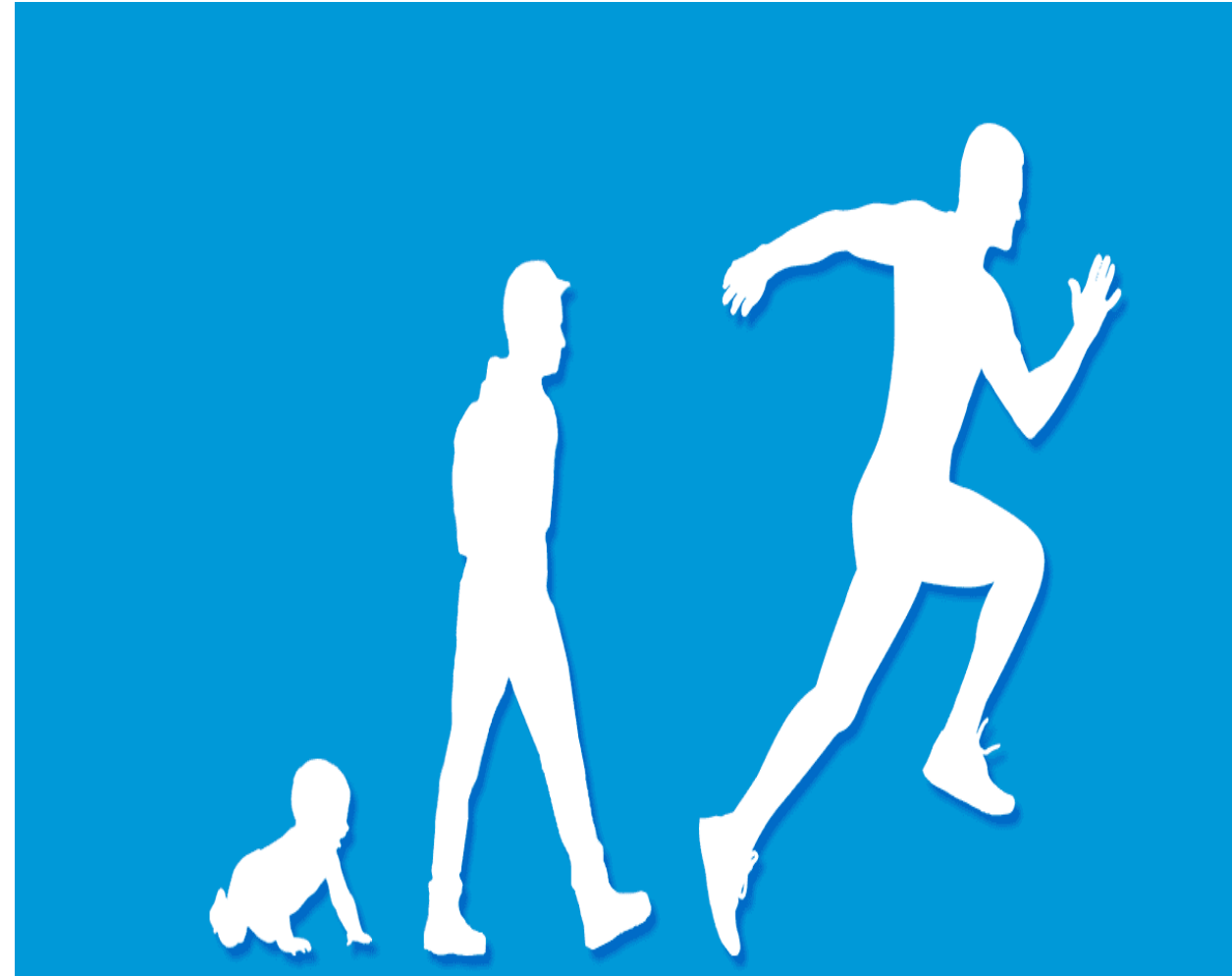
WORK UP

- **Focused Physical Examination Findings can be normal or nonspecific:** On examination, patients often ambulate with a flexed posture
- **IMAGING:** The superiority of MRI to CT as stand-alone modalities has been suggested.
 - The concomitant application of **standing flexion-extension films** in **combination with MRI** evaluation is a predictor of instability
- Electromyogram (EMG) and nerve conduction velocity (NCV) often are normal or may demonstrate multisegmental abnormalities in the bilateral lower extremities: **NOT SPECIFIC**



TREATMENT

- Nonsteroidal anti-inflammatory drugs (NSAIDS)
- Acetaminophen
- Neuropathic agents (gabapentin and pregabalin)
- Physical therapy
- Acupuncture
- Chiropractic manipulation and traction
- After failure of conservative treatment modalities, interventional techniques, including ESIs and **MILD**
- **Spinal Cord Stimulation**
- In refractory cases, where patients fail conservative interventional techniques, surgical decompression and spinal fusion may be needed.



MINIMALLY INVASIVE LUMBAR DECOMPRESSION (MILD)

- Efficient, low risk, minimally invasive lumbar decompression for patients who have hypertrophied ligamentum flavum of 2.5 mm or greater within the lumbar spinal canal, contributing to 50-85% central canal narrowing.^{1, 2}
- Indicated for lumbar spinal levels from L1-S1.^{3, 4}
- Technique
 - 5.1 mm port specifically designed for minimally invasive instruments to debulk lamina and small portions of the ligament.
 - In the contralateral oblique fluoroscopic view, a bone run rongeur is used to perform selective laminotomies of the superior and inferior lamina to gain access to the interlaminar space.⁵
 - This is followed by a tissue sculptor via the same trocar to debulk sections of the ligament of flavum.
- Risk profile is identical to that of an epidural injection

Procedure Steps



5.1mm

Outpatient decompression achieved through a tiny incision, smaller than the size of a baby aspirin



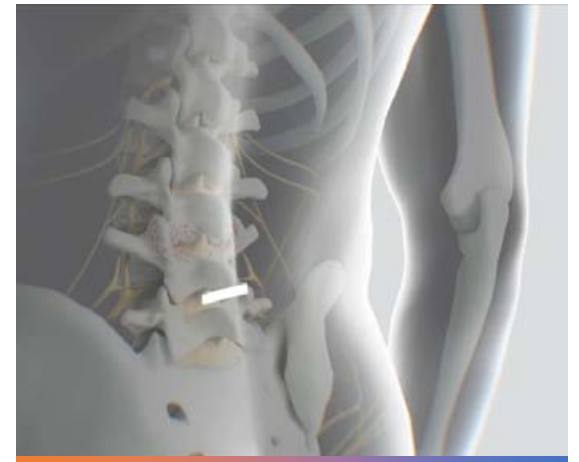
**INSERT PORTAL
(5.1MM)**



**REMOVE BONE TO
ACHIEVE ACCESS**



**DEBULK HYPERTROPHIC
LIGAMENT**



**REMOVE INSTRUMENTS &
CLOSE W/ STERI-STRIP™**



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mild Addresses a Major Root Cause of LSS to Improve Back & Leg Pain

BEFORE

AFTER

“Remove the kink in the drinking straw”



5.1 mm

Incision smaller than the size of a baby aspirin.
No implants left behind, *only a Band-Aid.*



Short outpatient procedure



Safety profile equivalent to an ESI²



Can be performed using local anesthetic and light sedation



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An Option for a Broad Spectrum of Patients



Early to Late Disease State

Degenerative condition, prevalent in patients aged 60+



All Lumbar Levels

Including L5-S1



Medical & Spinal Comorbidities Not Contradicted

Often compatible for those who are unable to tolerate surgery (e.g., high BMI, anesthesia intolerance)



Often Not Candidates for Other Therapies

Usually an option for patients with:

- Hardware at adjacent level
- Grade ≤ 2 spondylolisthesis
- Bone integrity/Osteoporosis

Broad Foundation of Scientific Evidence



Level 1 Data

Two multicenter Level 1
RCT studies



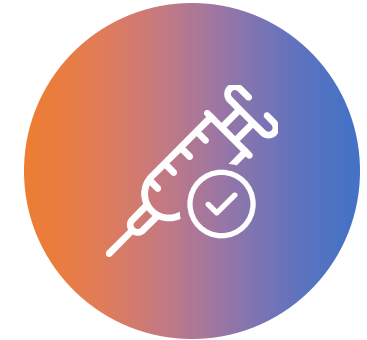
Significant Functional Improvement¹

Clinically meaningful and
statistically significant mobility
and pain improvement



5-Year Durability²

88% of *mild* patients avoided
back surgery for at least 5 years
while experiencing significant
symptom relief



Safety Profile Equivalent to an ESI³

Clinically proven safety
equivalence to ESIs

16 clinical studies & >30 published articles



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Significant Functional Improvement

Cleveland Clinic Study, 1-Year Study¹



Mean **Standing Time**

600%
Improvement



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Significant Functional Improvement

Cleveland Clinic Study, 1-Year Study¹



Mean **Walking** Distance

Over
1,500%
Improvement



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High Patient Satisfaction & Easy Recovery

Level 1 RCT: MiDAS ENCORE • 2-Year Follow-up

85%

Patient
Satisfaction¹



Patients typically resume
normal activity within

24 hours

with no restrictions²



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Case 1

- 78 YOF presented to me with severe lbp and le pain 4/8/2025
- Patient with Ultra severe canal stenosis at L2-3 and moderate canal stenosis at L3-4 we did proceed with lumbar epidural steroid injection with short-term benefit we then proceeded to plan for the mild procedure
- Mild procedure L2-3 and L3-4 completed 6/10/2025 with 80% relief
- Follow-up visit on 11/5/2025 with no leg pain and residual back pain from arthritis her stenosis was not symptomatic



Case 2

- 90 YOM presented to me with severe lbp 10/31/2024 and we did proceed with lumbar ablation therapy did not help
- Then we moved forward with a Lumbar Epidural Steroid Injection on 3/25/2025 addressing his moderate canal stenosis at L5-S1 (short term relief)
- MILD procedure done on 6/9/2025
- F/U visit on 8/5/2025 100% relief

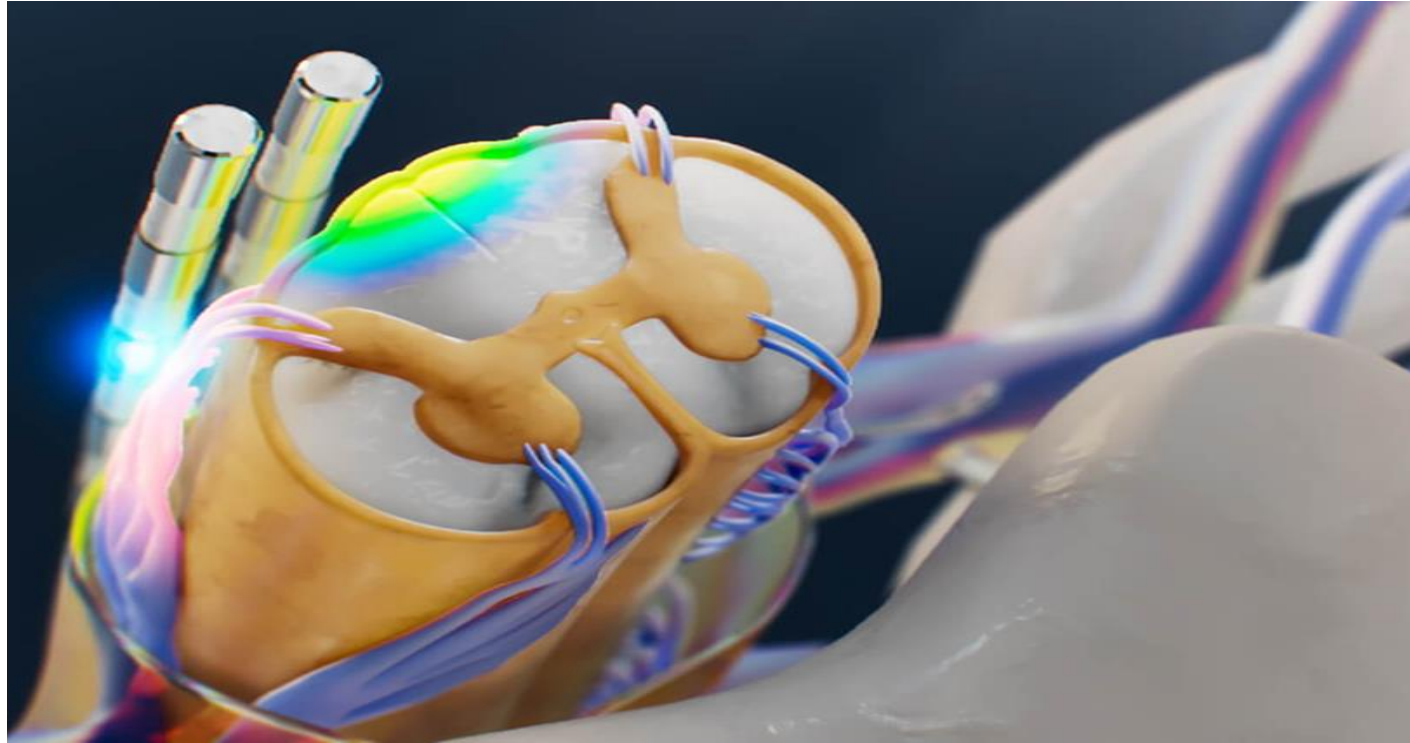


Case 3

- 76 YOM avid hiker presented to me 2/14/2023 with with severe lbp and cramping
- Treatments included lumbar ablation which did not alleviate his pain and short term relief from epidural steroid injection at l3-4 (moderate canal stenosis)
- MILD procedure done on 3/12/2024
- F/U visit on 4/18/2024 100% relief is able to hike without pain



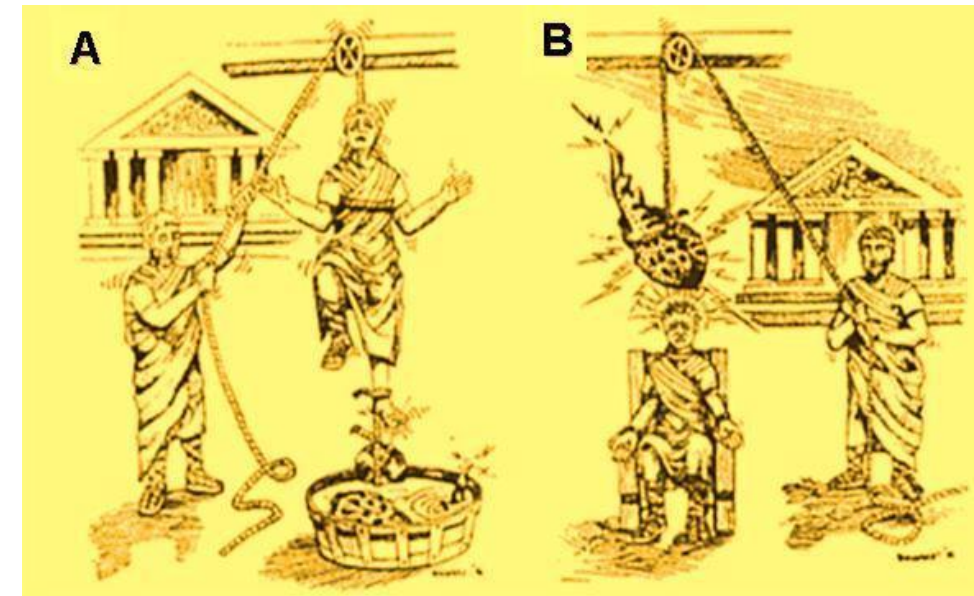
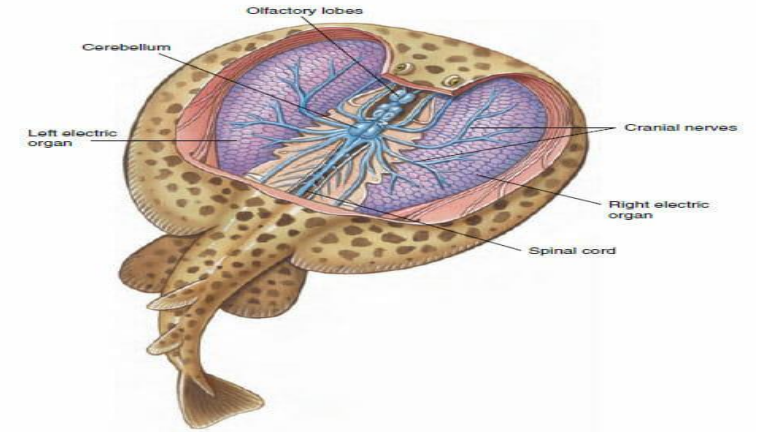
Neuromodulation



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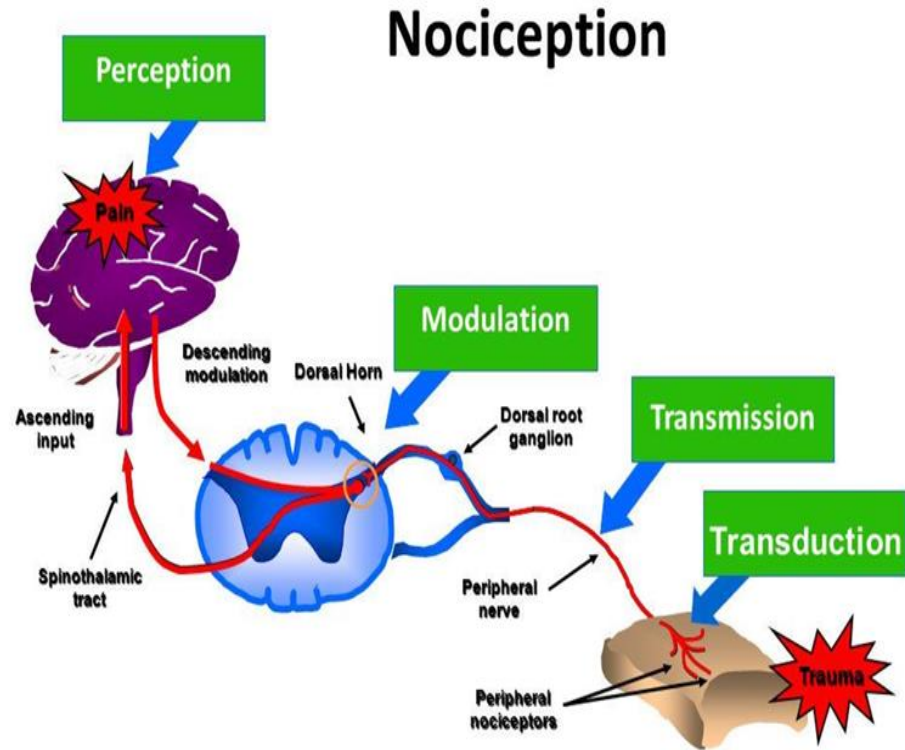
What is Neuromodulation?

- Neuromodulation is the alteration of neural activity in the **central, peripheral, or autonomic nervous systems.**
- The earliest use of neuromodulation dates to the **first century, circa 15 AD**, when a freedman of Emperor Tiberius stepped on a **torpedo fish**.
- The ensuing shock taught him a valuable lesson, but an even greater one to his local physician, **Scribonius Largus**. **Improvement in the man's chronic gout pain** following the shock. **Scribonius** would then go on to **adopt torpedo fish for the treatment of pain.**
- In **1965**, Melzack and Wall theorized that **pain perception is gated based on the balance of firing from small and large neural fibers**

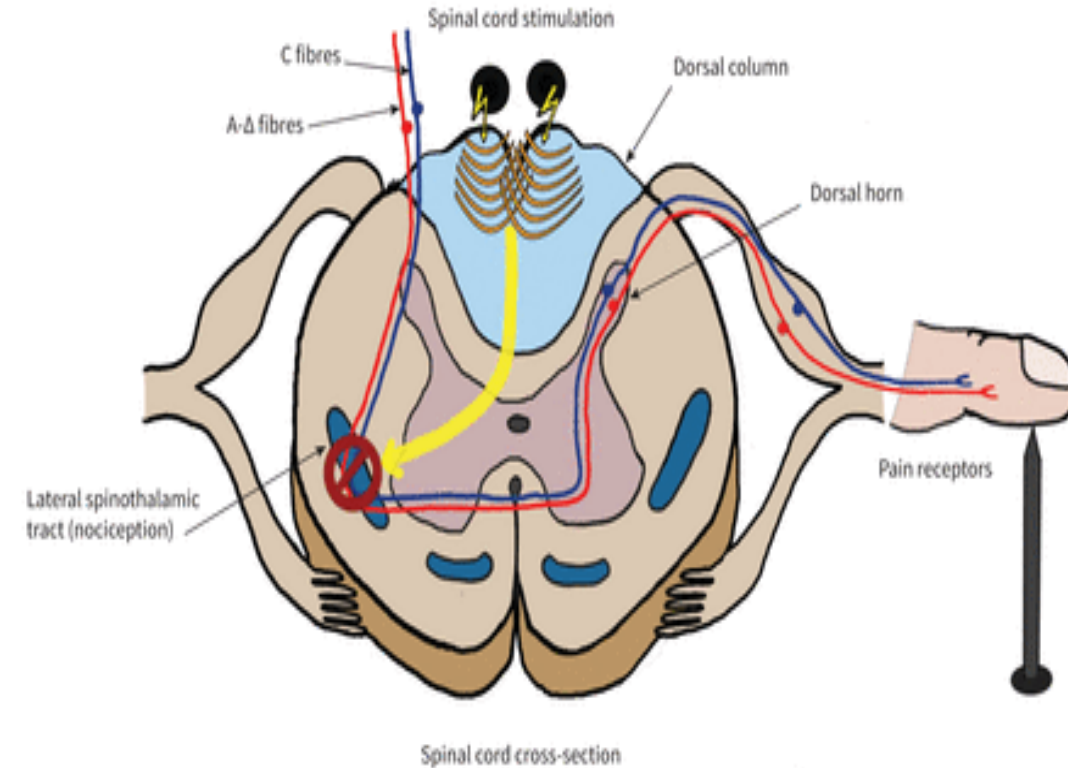


Gate Control Theory

- Proposes that a "gate" in the spinal cord modulates pain signals, with **large-diameter A-beta fibers (carrying non-pain signals like touch)** inhibiting pain signals from small-diameter A-delta and C fibers.



Adapted from Gottschalk A et al. *Am Fam Physician*. 2001;63:1981, and Kehlet H et al. *Anesth Analg*. 1993;77:1049.



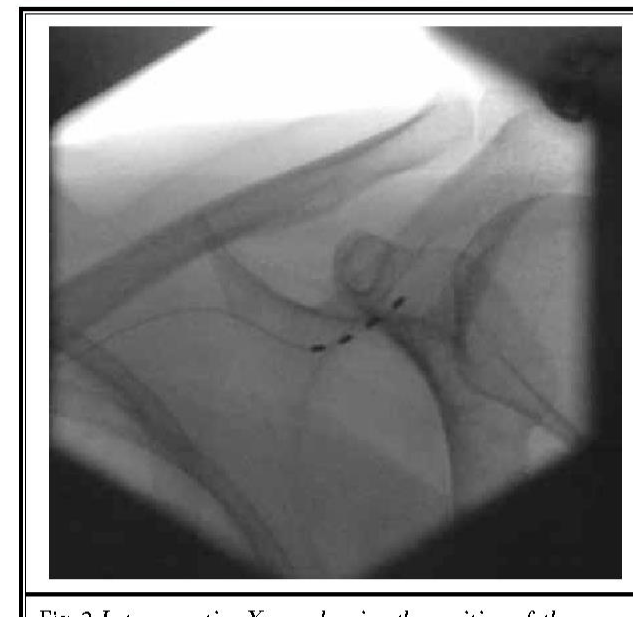
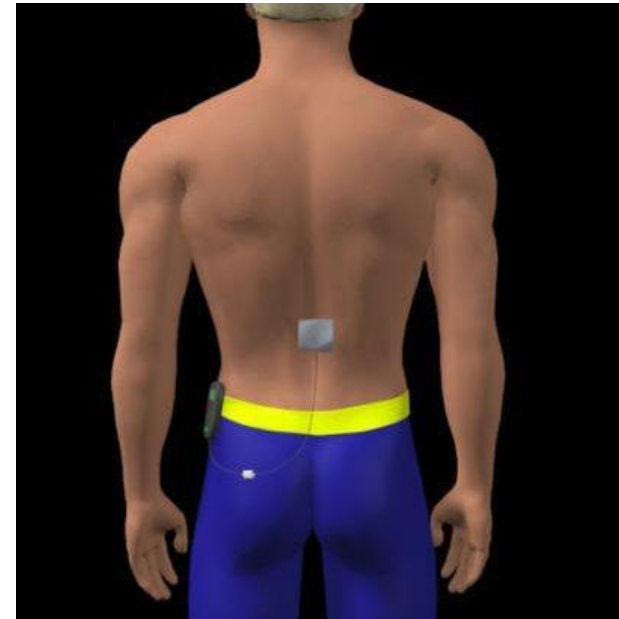
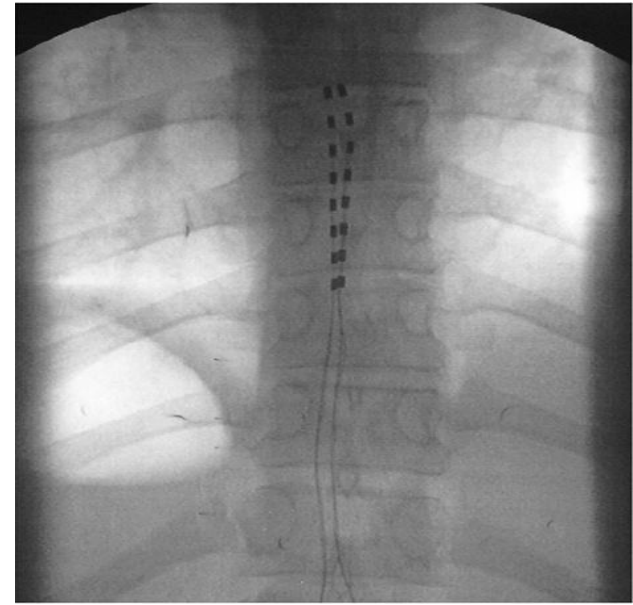
Who is a Candidate for Neuromodulation?

- A patient who has **chronic pain** or other conditions that haven't responded to conventional treatments
 - Failed Back Surgery Syndrome (FBSS)
 - Complex Regional Pain Syndrome (CRPS)
 - Neuropathic Pain:
 - Phantom Limb Pain
 - Chronic Angina
 - Arachnoiditis
 - Movement Disorders
 - Peripheral Vascular Disease
 - Ischemic Disorders:
 - **Most Chronic Pain Syndromes of the Peripheral Nervous System (anything outside of the spine)**
- Patient must **pass a psychological evaluation** prior to moving forward (this is typically an over the phone discussion with licensed mental health professional)



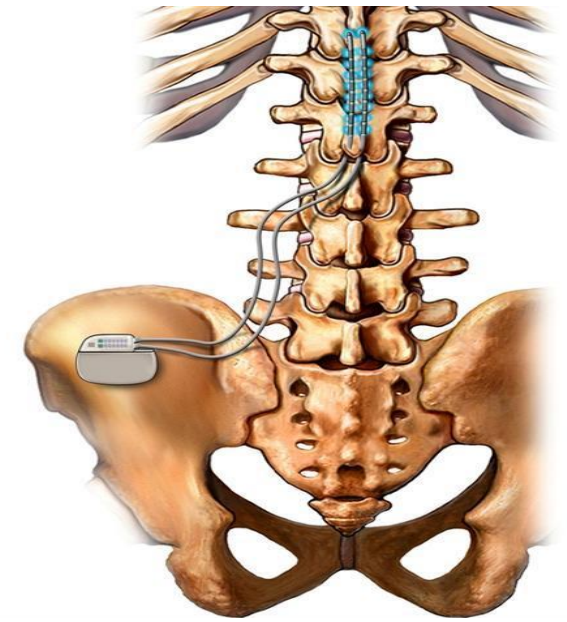
Neuromodulation Process I

- Once the decision is made that neuromodulation is the best clinical course, the patient then undergoes a “ **Trial**” (not a surgical procedure) temporary test run of 7 days.
- During the trial procedure the **leads** are placed at the **appropriate anatomical site**. (ie if **spinal cord stimulation leads** placed in the **epidural space**, if **peripheral nerve stimulation** leads are placed over the **peripheral nerve** driving the pain)
- **At day 7**, the **leads are removed** and if the patient achieves greater than 50% relief, the patient will then undergo the **implant** (minor surgical outpatient procedure)



Neuromodulation Process II

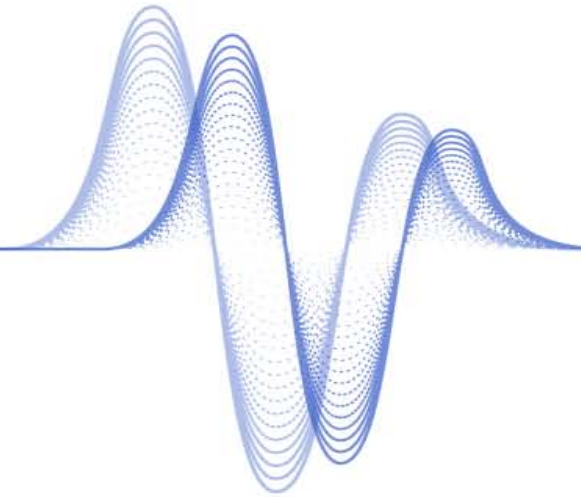
- The Neuromodulation **implant** is very similar to the trial as the leads must be placed in the same exact location as the trial, but this time the **leads and Implantable Pulse Generator are placed underneath the skin.**



Next, let's talk about

A NEW “Smart” Treatment
Option for Chronic Pain

EVOKE™



Introducing the Evoke® SmartSCS™ System



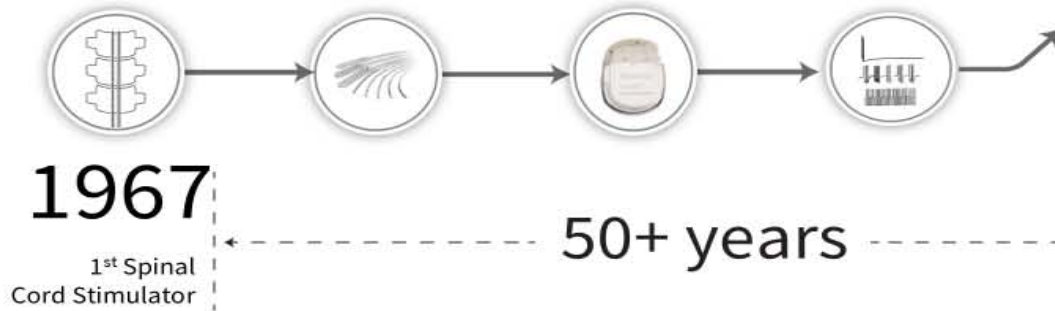
EVOKE®
SmartSCS™



Approved as Safe
and Effective^{1,2}



Recognized by Medicare as
“substantial clinical
improvement”³

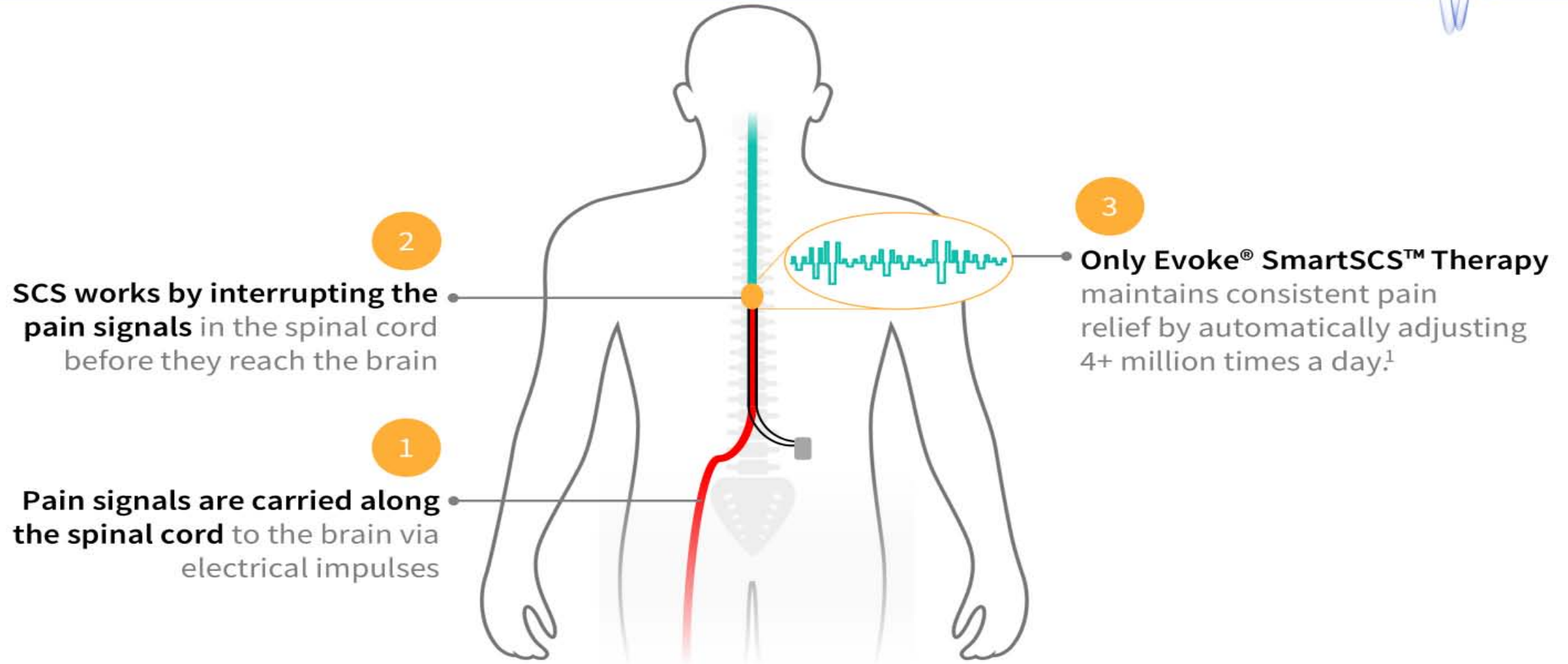


1. P190002 Summary of Safety and Effectiveness Data - page 61, 62, 64

2. P190002 Summary of Safety and Effectiveness Data - page 46, 48

3. Calendar Year 2023 Medicare Outpatient Prospective Payment System, Final Rule [CMS-1772-FC], Federal Register, November 1, 2022

How does Evoke® SmartSCS™ Therapy Work?



1. Stimulation adjustments are made at the same rate as frequency. 4+ million adjustments per day is based on 50Hz.

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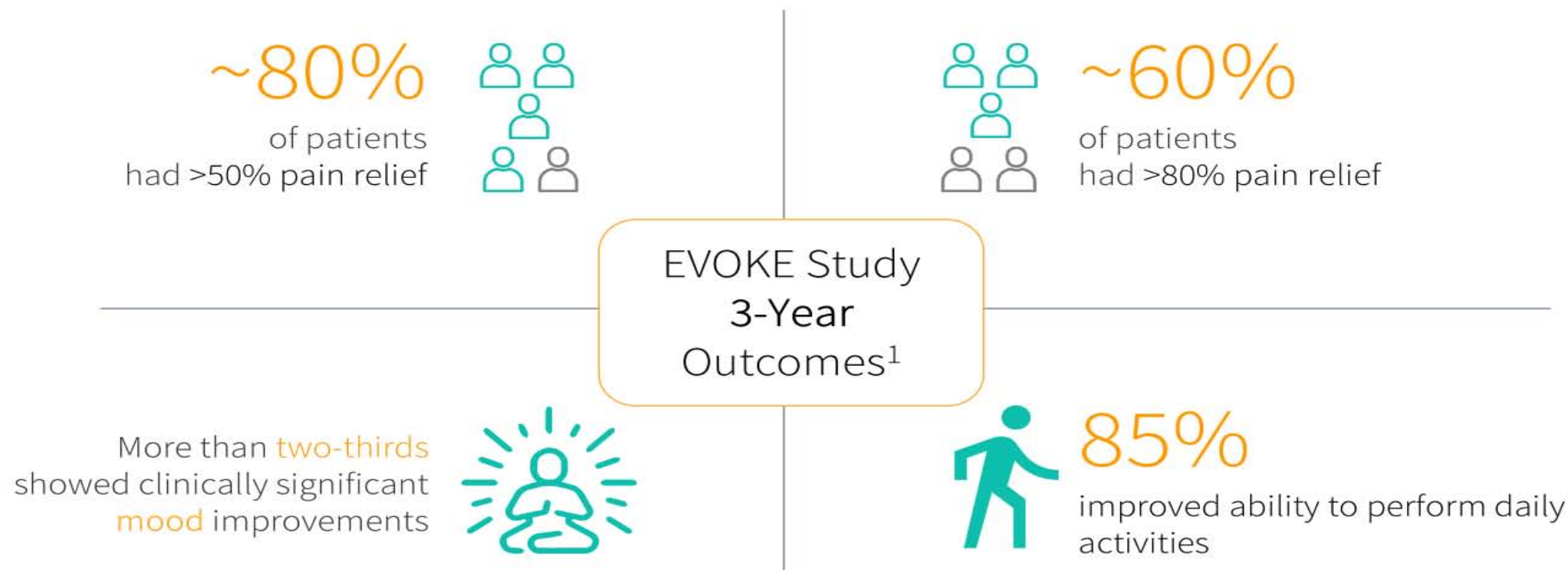
Saluda SCS

SmartLoop™ Dose-Control Technology senses and confirms the nerves' response AND automatically adjusts on every pulse



- 1 Stimulate the target nerves
- 2 Sense and Confirm the nerves' response
- 3 Automatically adjust on every pulse

The Evoke® Smart SCS™ is Backed by The Most Rigorous Clinical Trial in SCS History With 3-year Outcomes



1. EVOKE Study 36-month outcomes late-breaker presentation, Mekhail N, NANS 2023. Mekhail, N; On behalf of EVOKE - Study Investigators. ECAP-Based SCS for the Treatment of Chronic Pain: Crossover and 36-Month EVOKE Study Outcomes. Presented at NANS 2023. Data on file. 134 patients enrolled.

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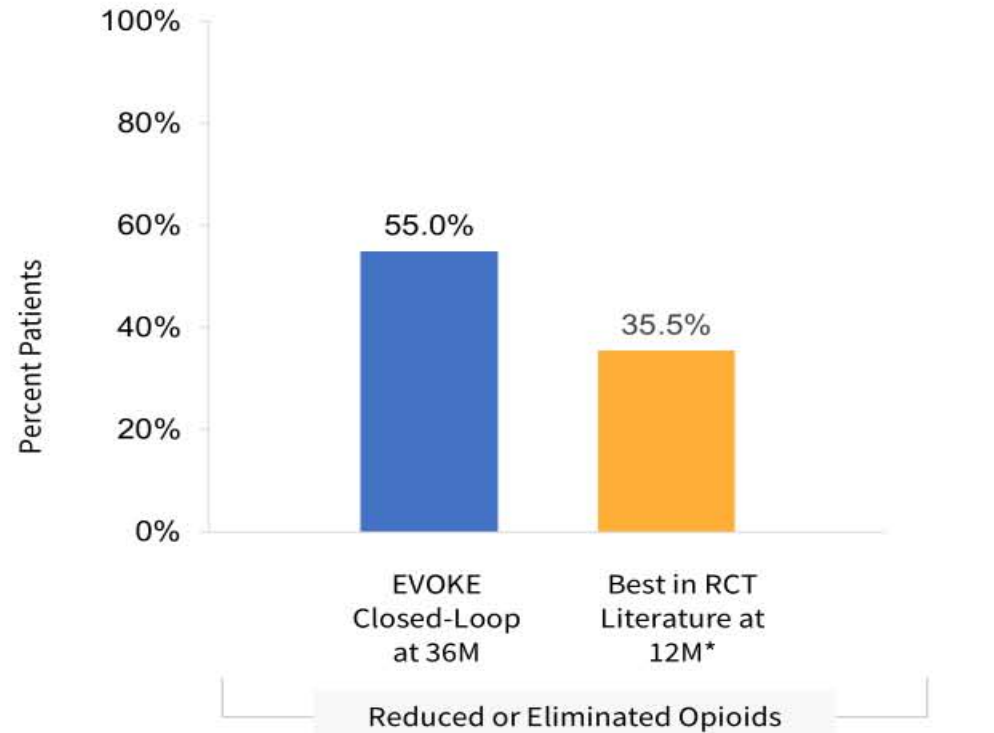


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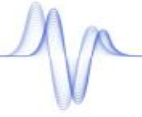
Over Half of Evoke® SmartSCS™ Patients Reduced or Eliminated Opioids at 3-years Post Implant



% Patients who Reduced or Eliminated Opioids



Evoke[®] SmartSCS[™] patients reported significant improvement in sleep quantity and quality



EVOKE Closed-Loop patients gained an additional

 1-2 hours¹

of sleep per night, which is 45-90
extra full nights of sleep*



* Full night = 8 hours of sleep

1. Costandi et. al.; 2022. Impact of Long-Term Evoked Compound Action Potential Controlled Closed-Loop Spinal Cord Stimulation on Sleep Quality in Patients With Chronic Pain: An EVOKE Randomized Controlled Trial Study Subanalysis. Neuromodulation 2022; -: 1-9.

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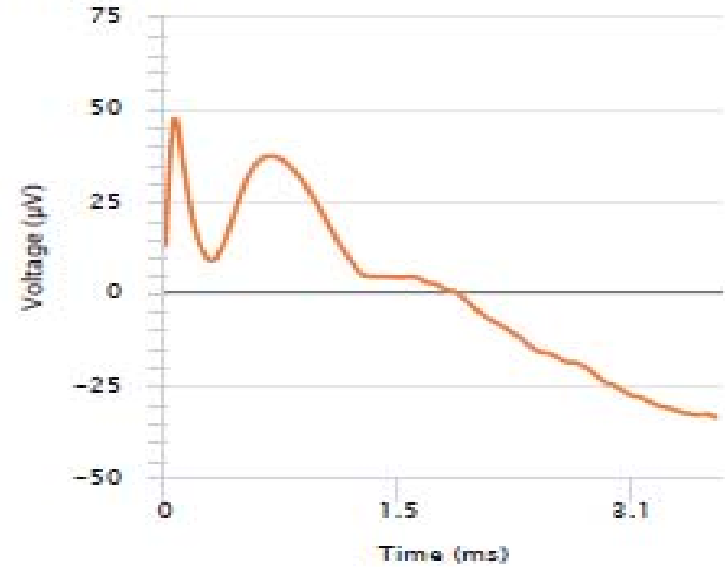


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DETAILED NEURAL METRICS

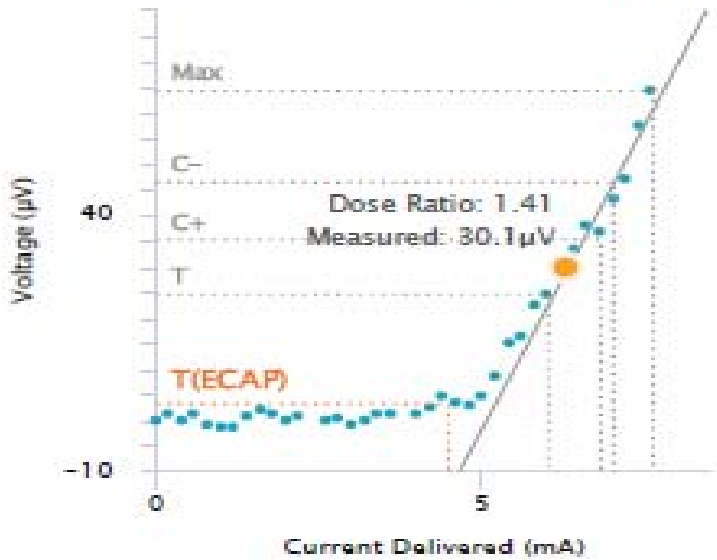
Evoked Compound Action Potential (ECAP)

Perception Level: C+



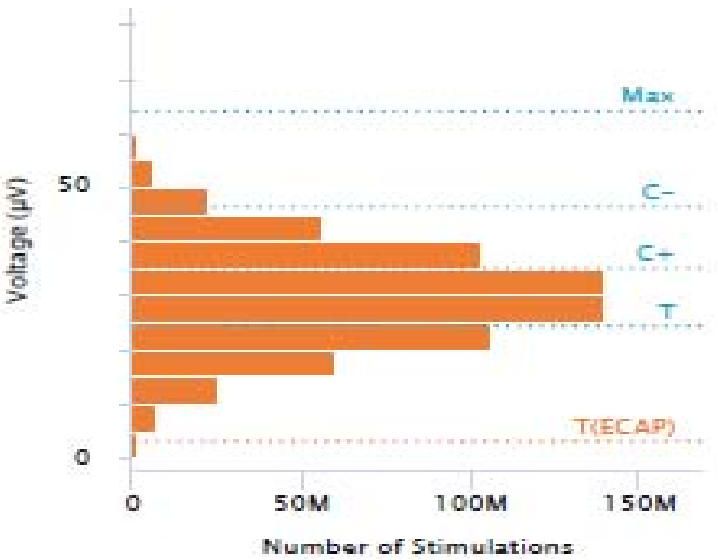
Activation Plot

Sensitivity: 23.81 µV/mA



Device Utilization: 91%

Dose-Control Adherence



Trial relief: 80%

Implant date: 3/4/2024 (18 months)

Implant relief: 90%

Patient pain pattern: right low back and leg pain

Notes: patient has been able to return to playing pickleball and playing with his grandchildren with minimal pain

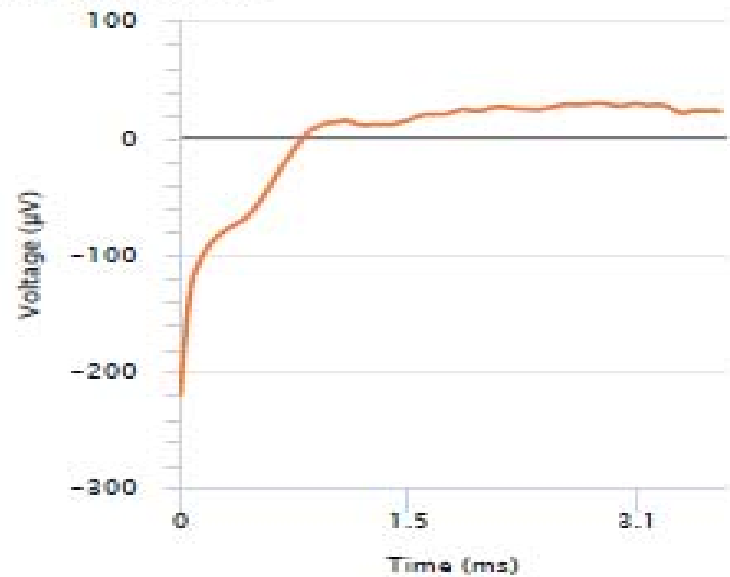


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DETAILED NEURAL METRICS

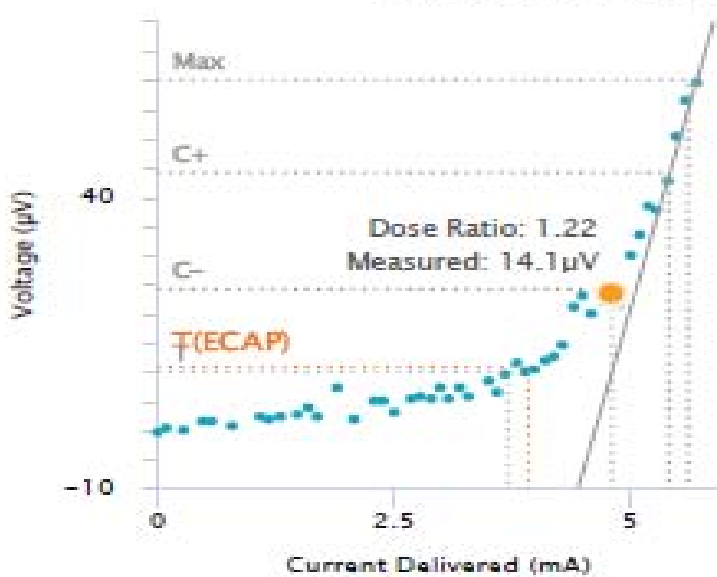
Evoked Compound Action Potential (ECAP)

Perception Level: C+

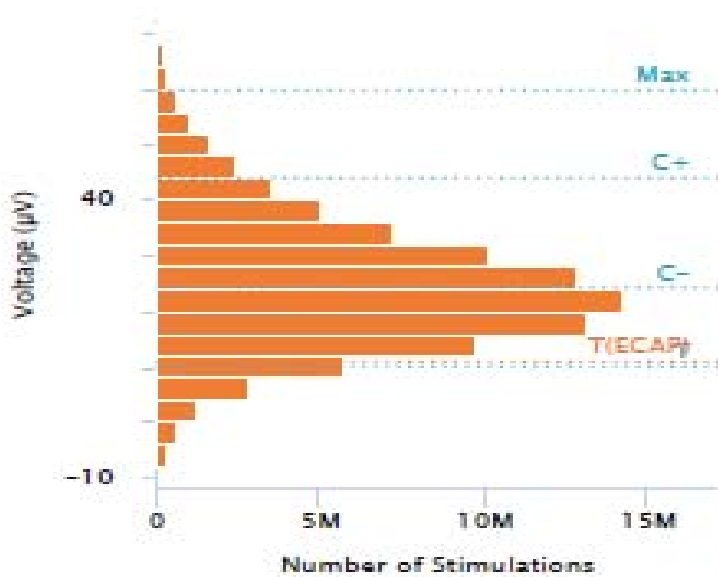


Activation Plot

Sensitivity: 55.89 µV/mA



Dose-Control Adherence



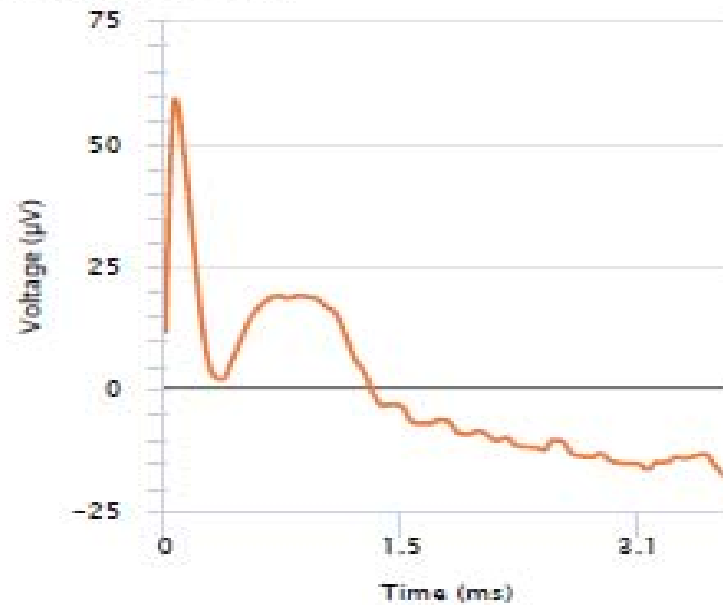
Trial relief: 70%
Implant date: 8/16/2024 (12 months)
Implant relief: 80%
Patient pain pattern: buttock pain into the thighs
Notes: has noted she no longer “waddles” and is able to stand up straight and stand for longer periods of time

DETAILED NEURAL METRICS

Device Utilization: 94%

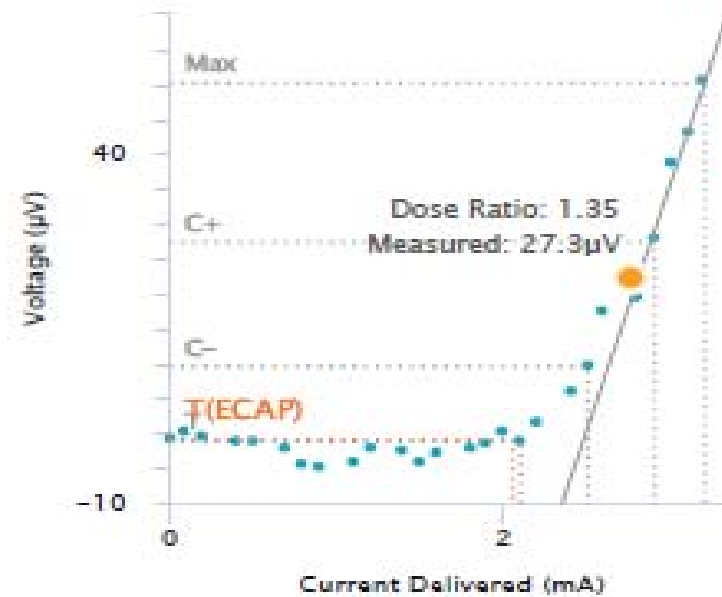
Evoked Compound Action Potential (ECAP)

Perception Level: C+

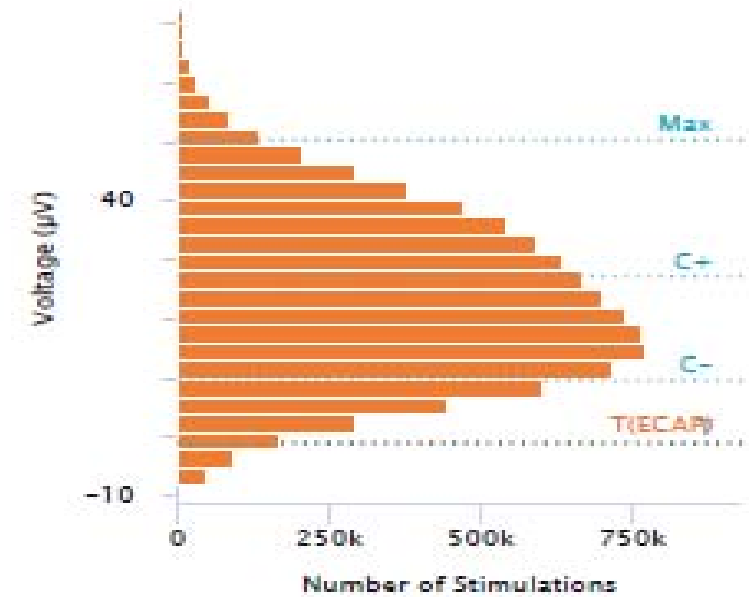


Activation Plot

Sensitivity: 70.36 µV/mA



Dose-Control Adherence



Trial relief: 80%

Implant date: 2/17/2025 (9 months)

Implant relief: 60-70% currently as she comes off of meds

Patient pain pattern: low back pain into the legs

Notes: the device has allowed the patient to come off most of her medications



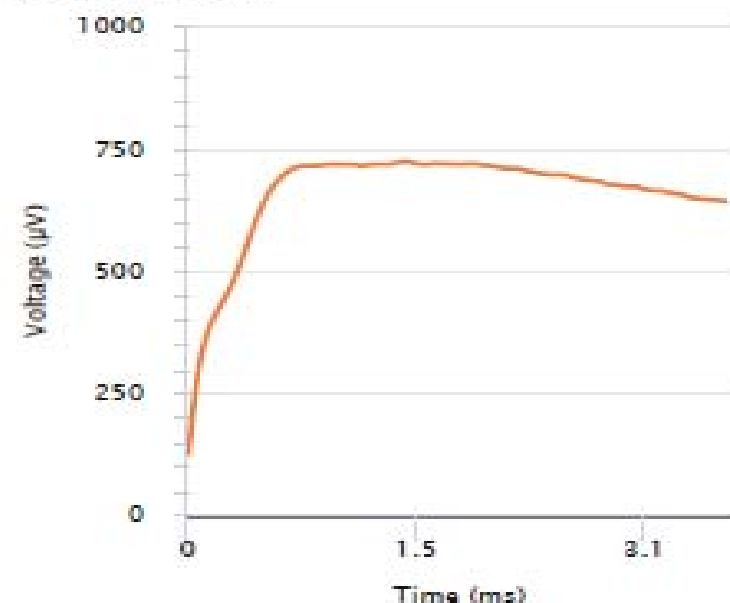
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DETAILED NEURAL METRICS

Device Utilization: 100%

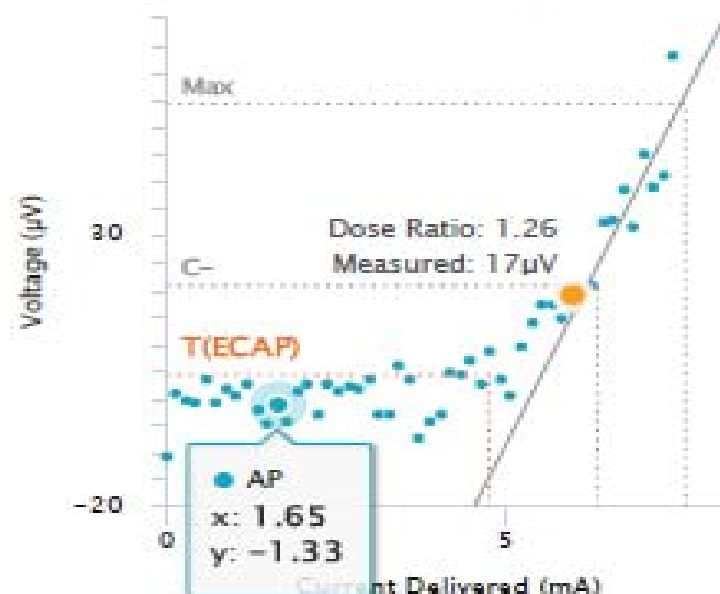
Evoked Compound Action Potential (ECAP)

Perception Level: M

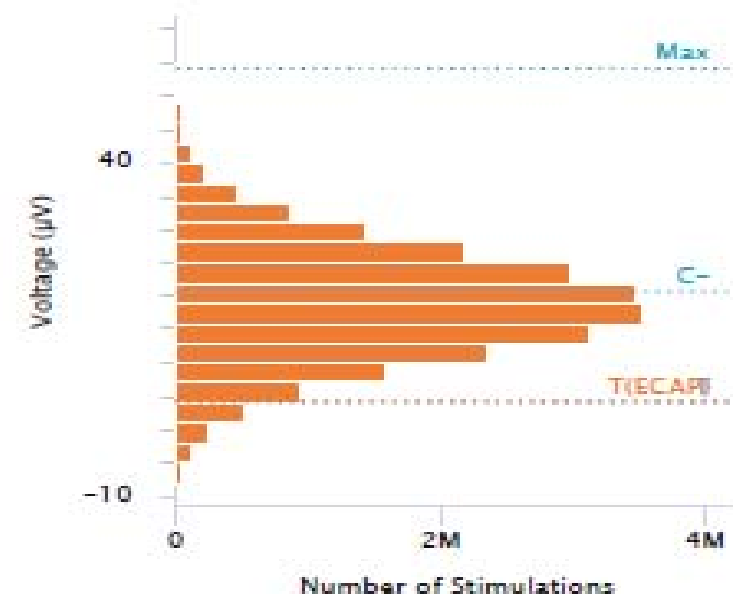


Activation Plot

Sensitivity: 24.42 µV/mA



Dose-Control Adherence



Trial relief: 80%

Implant date: 7/21/2025 (3 months)

Implant relief: 80%

Patient pain pattern: low back pain

Notes: patient is doing very well, sleeping through the night without pain



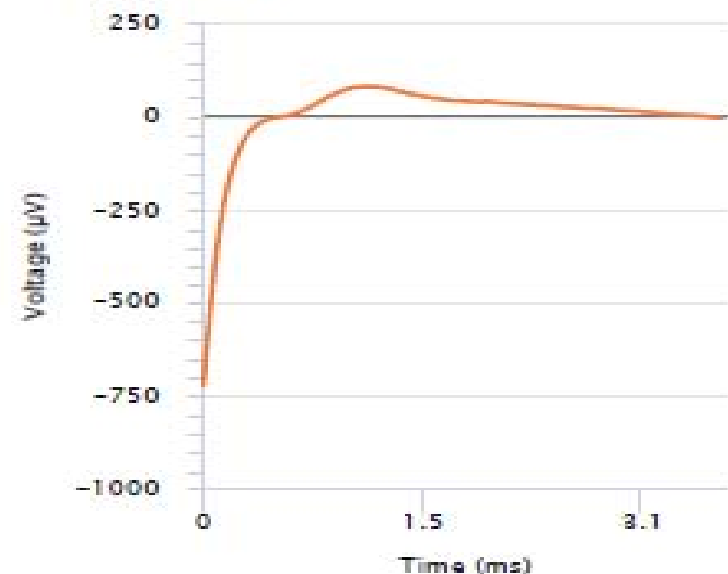
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DETAILED NEURAL METRICS

Device Utilization: 100%

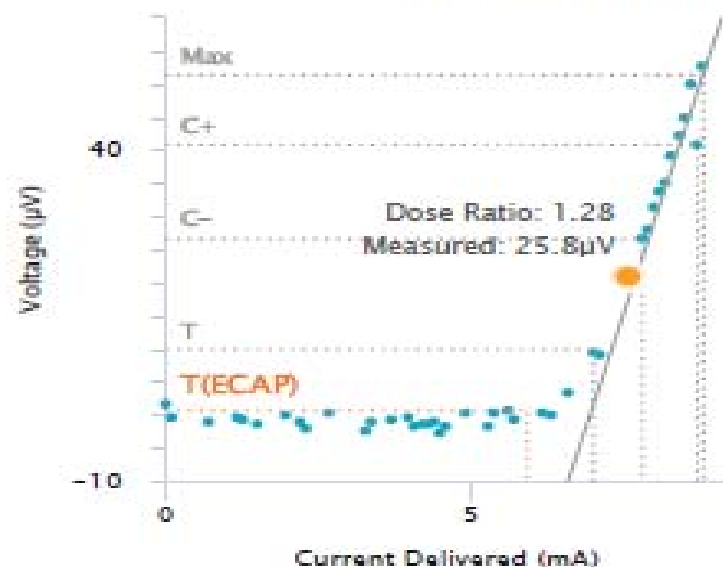
Evoked Compound Action Potential (ECAP)

Perception Level: M

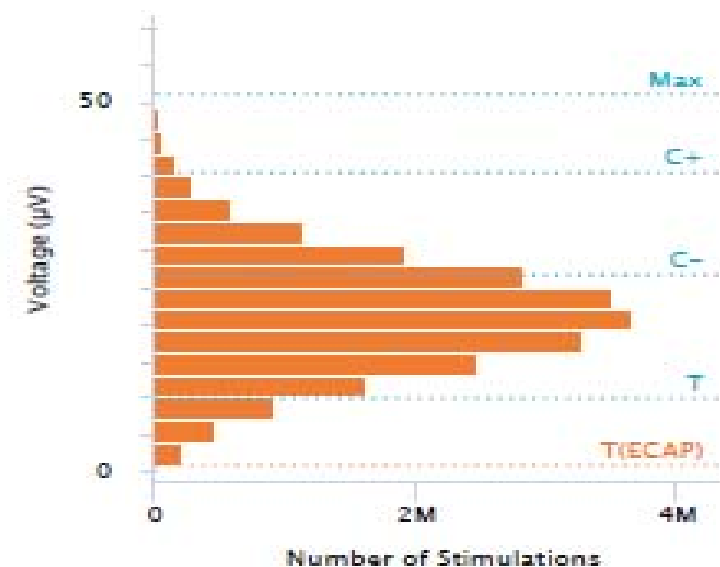


Activation Plot

Sensitivity: 27.70 µV/mA



Dose-Control Adherence



Trial relief: 75%

Implant date: 8/18/2025 (3 months)

Implant relief: 80%

Patient pain pattern: low back into legs

Notes: patient is very satisfied with the device, reporting minimal pain



Pain Institute
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Summary

There have been multiple advancements in interventional pain management including the MILD procedure for spinal stenosis and Neuromodulation with Saluda technologies. With the wealth of data to support these therapies, we now have more minimally invasive options to treat multiple chronic pain conditions with the goal of improving patients' qualities of lives and truly making a meaningful difference.



Thank You



Pain Institute
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