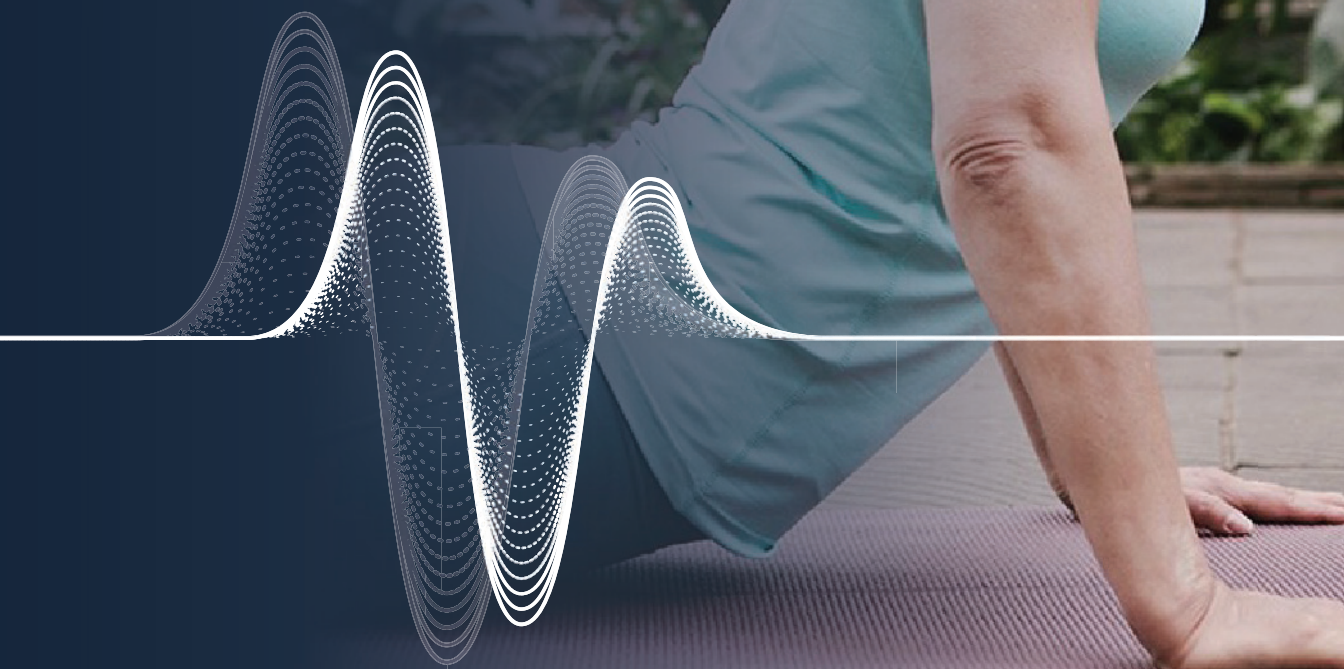
saluda MEDICAL

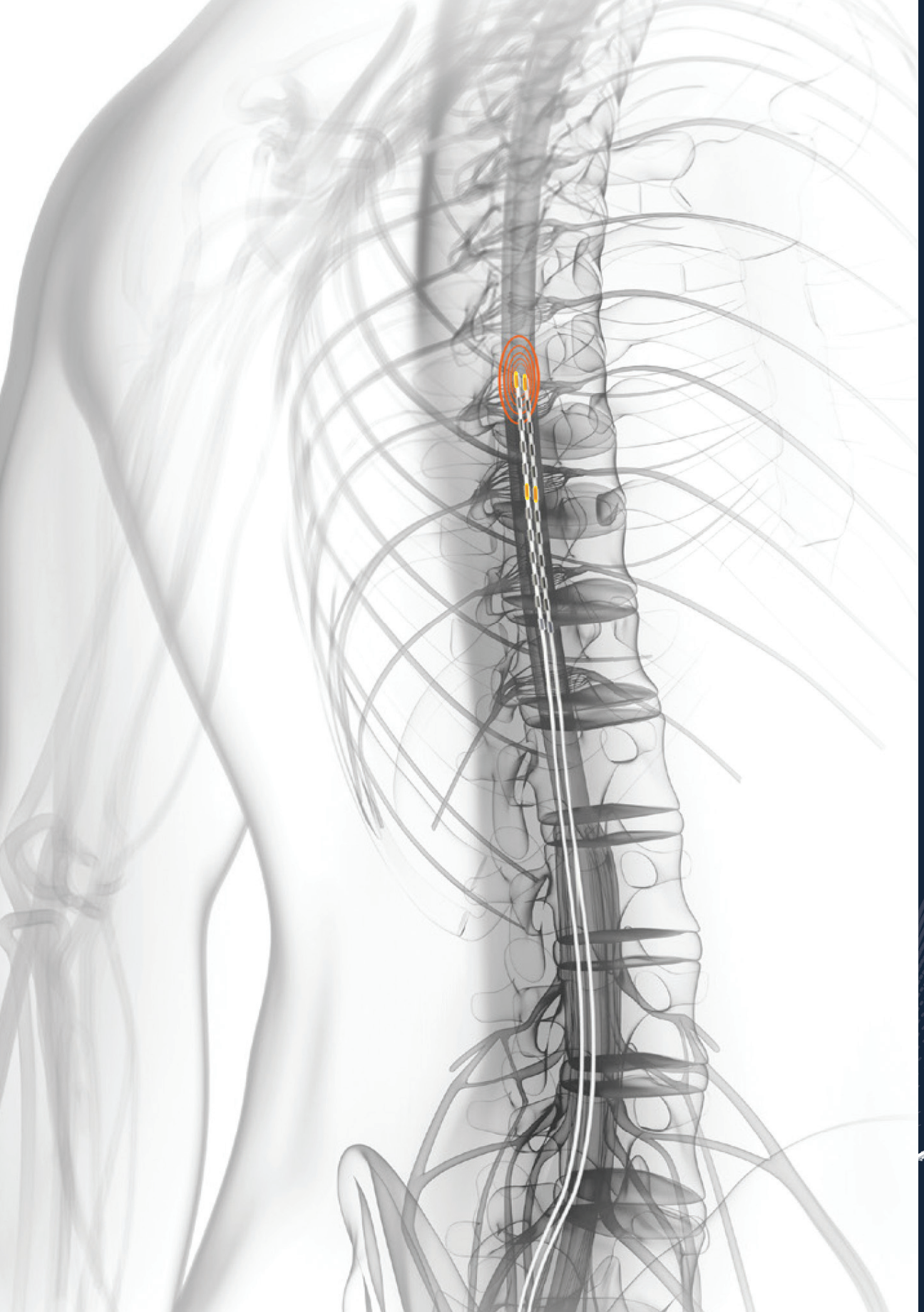
Everything Changes...

THIS CHANGES EVERYTHING.

EVOKE®

powered by SmartLoop™ Technology





EVOKE®

The world's **FIRST & ONLY PRECISION DOSE-CONTROL, CLOSED-LOOP SPINAL CORD STIMULATION** (SCS) system for the treatment of chronic pain.

SMART by Every Measure

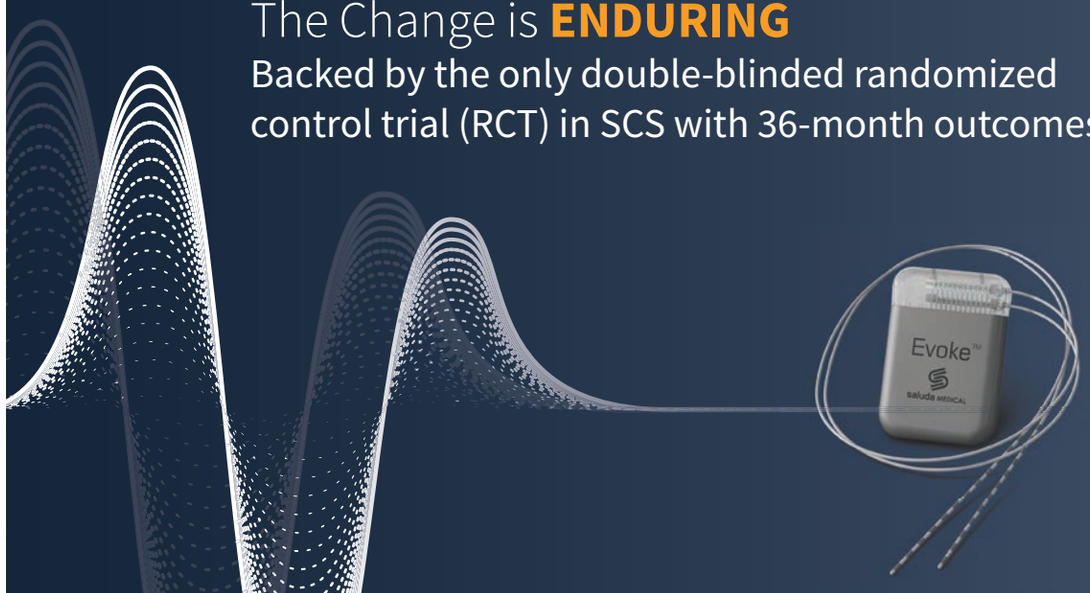
First SCS to directly measure and confirm the spinal cord's response to stimulation.

Relief is **AUTOMATIC**

Dose-control SCS therapy auto-adjusts with the patient in real time, 4+ million times a day.†

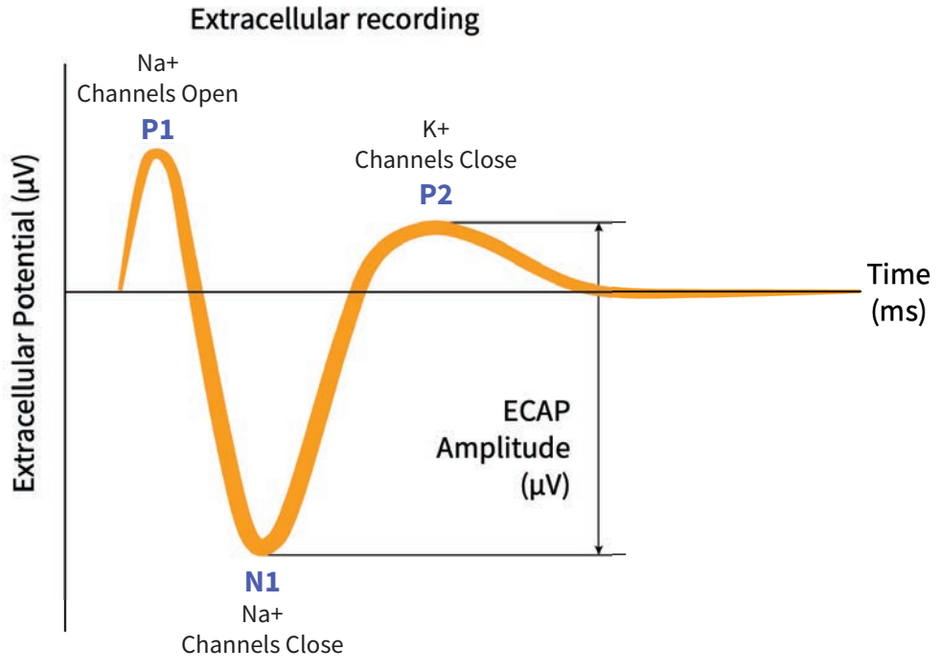
The Change is **ENDURING**

Backed by the only double-blinded randomized control trial (RCT) in SCS with 36-month outcomes.

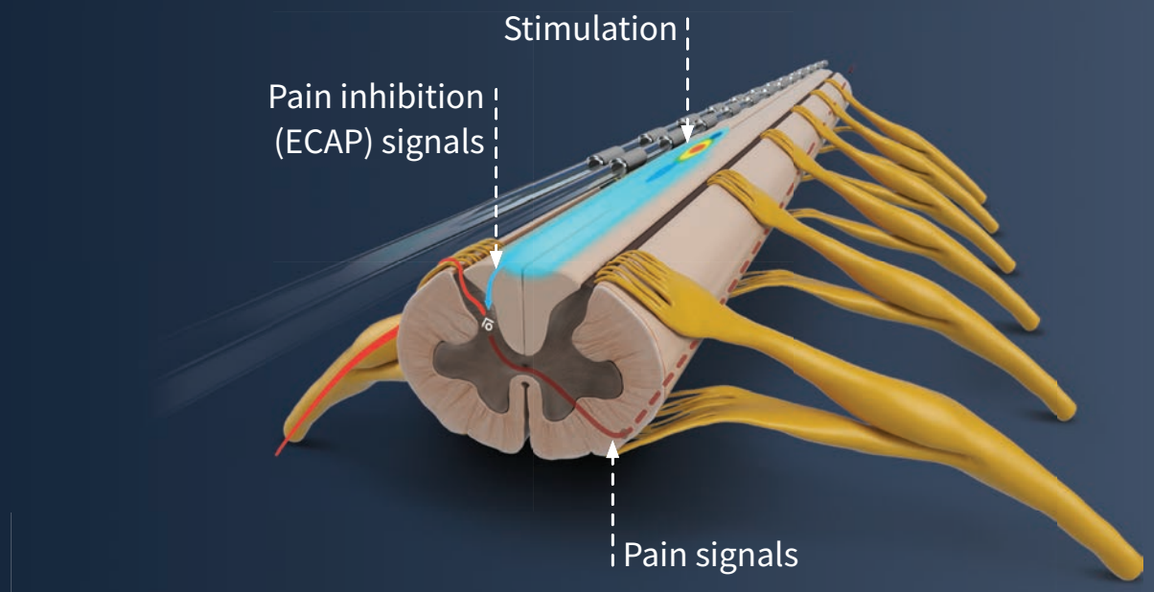


SMART
by Every Measure

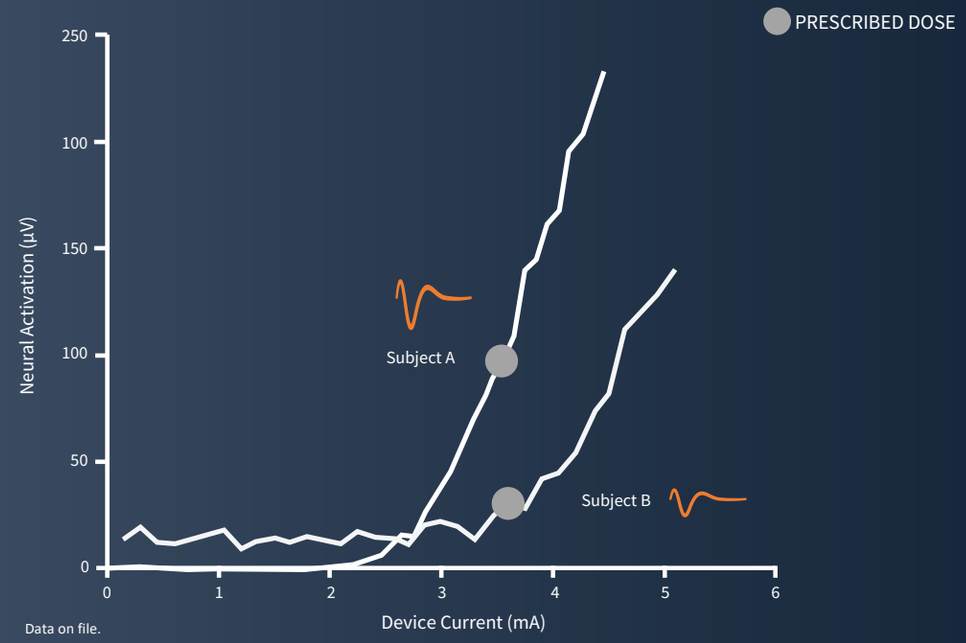
Directly measures the spinal cord's physiologic response to stimulation through **Evoked Compound Action Potentials (ECAPs)**, a unique neural signature for each patient.



Pain relief starts with neural activation.
ECAPs are a measure of Aβ-fiber activation within the dorsal column that drives pain relief in SCS.



Only the Evoke® SmartSCS™ System can translate each patient's unique neural signature from the spinal cord into a **precise stimulation dose** individualized to their unique physiology and sensitivity.

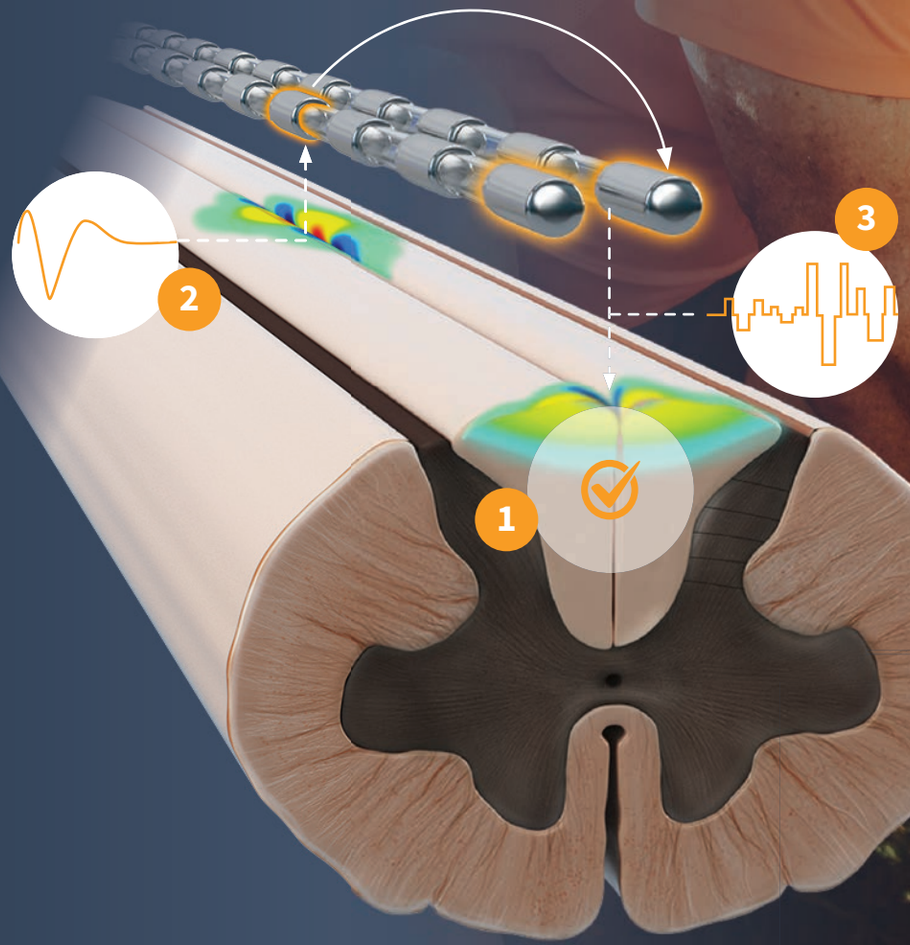


Data on file.

Relief is **AUTOMATIC**

The Evoke® System with SmartLoop™ Technology, **automatically adjusts** with the patient in real time to maintain precise and consistent pain relief **with every heartbeat, breath, and movement.**

1. Stimulate the **target nerves**
2. **Sense the nerves'** response (ECAP signal) in real time to measure and confirm activation
3. **Auto-adjust** stimulation on every pulse 4+ million times a day to maintain activation

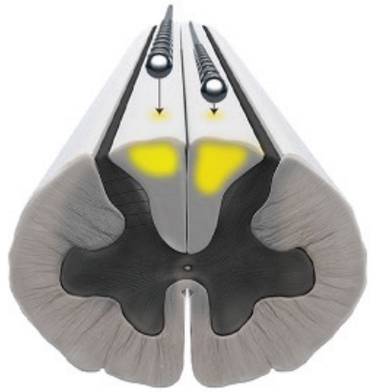


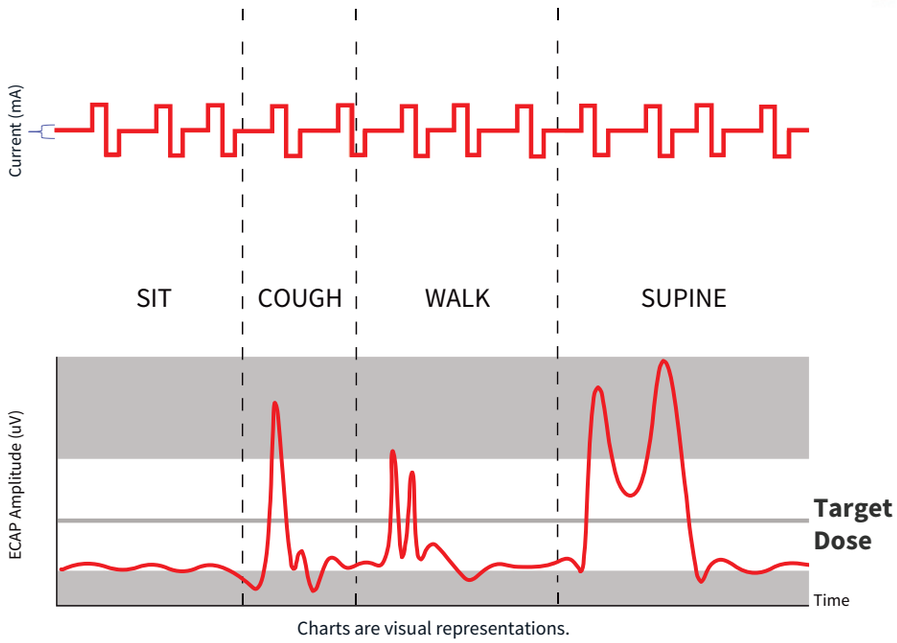
Relief is **AUTOMATIC**

THAT WAS **THEN**

ECAP recordings prove that Fixed-Output Systems deliver inconsistent neural activation which can lead to tolerance and loss of efficacy.

- Unknown and inconsistent activation
- Cannot auto-adjust for movement and neurophysiological changes throughout the day





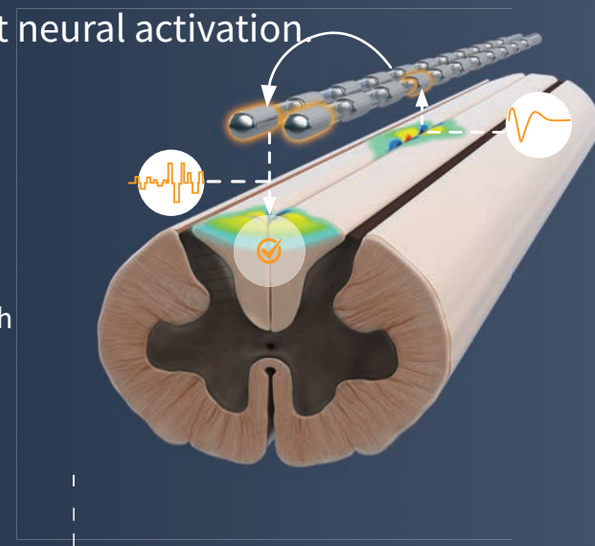
Charts are visual representations.

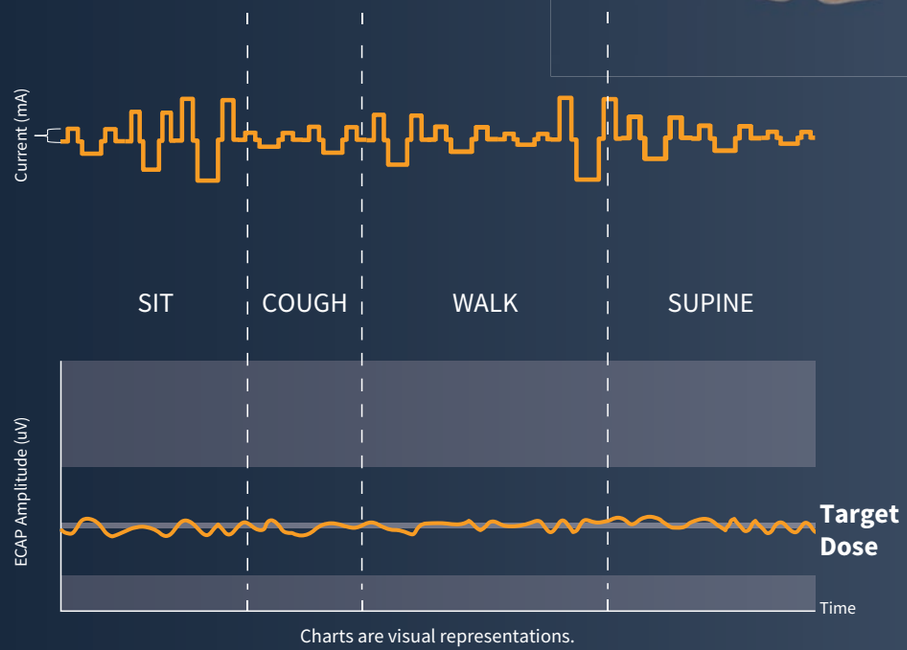
In the landmark EVOKE Study, Saluda SmartLoop™ patients received **3x more neural activation**, delivered **8x more accurately** compared to Open-Loop[1].

THIS IS **NOW**

With SmartLoop™ Technology, each stimulation pulse is automatically titrated in real time to deliver precise and consistent neural activation.

- Known and consistent activation
- Maintains precise and consistent pain relief with every heartbeat, breath and movement





Charts are visual representations.

The Change is **ENDURING**

Backed by the landmark EVOKE Study – the first and only double-blinded, pivotal RCT in SCS with **36-month outcomes**[2].

36-Month Highlights of the EVOKE Study

Responder Rate

83%

of patients had ≥50% VAS reduction

High Responder Rate

59%

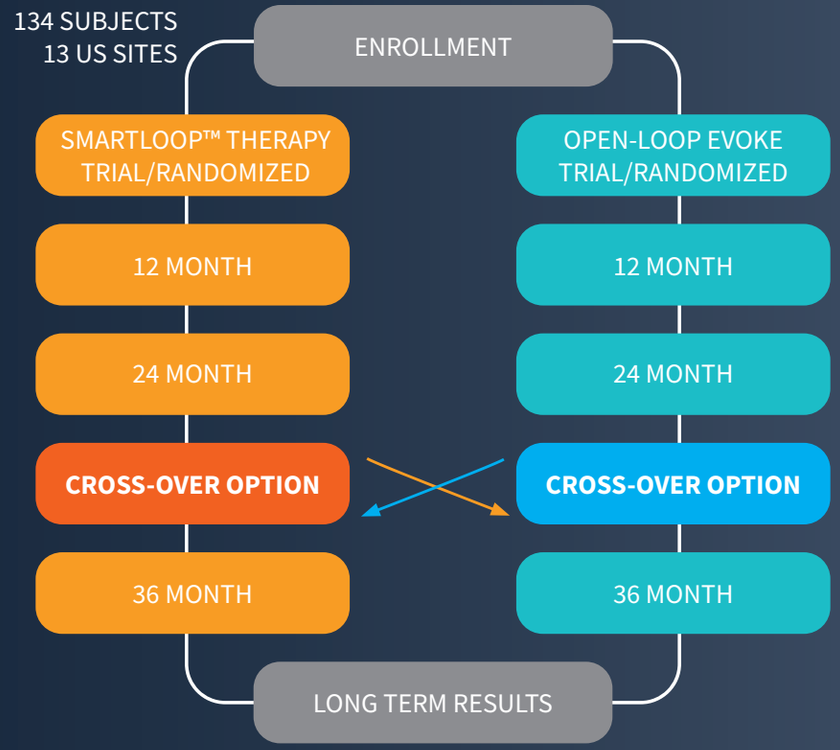
of patients had ≥80% VAS reduction

Therapy Durability

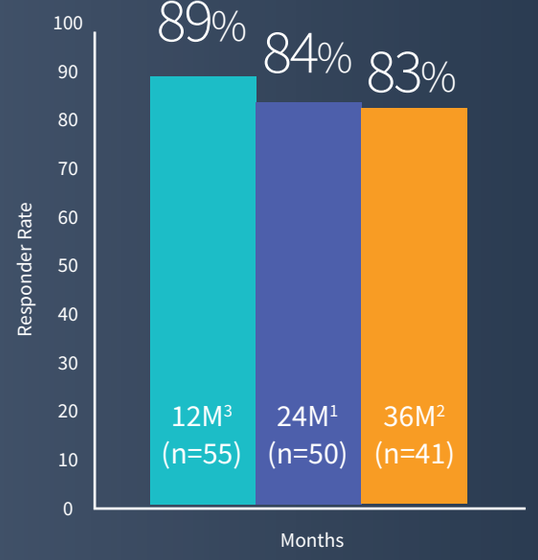
ZERO

Explants due to loss of efficacy

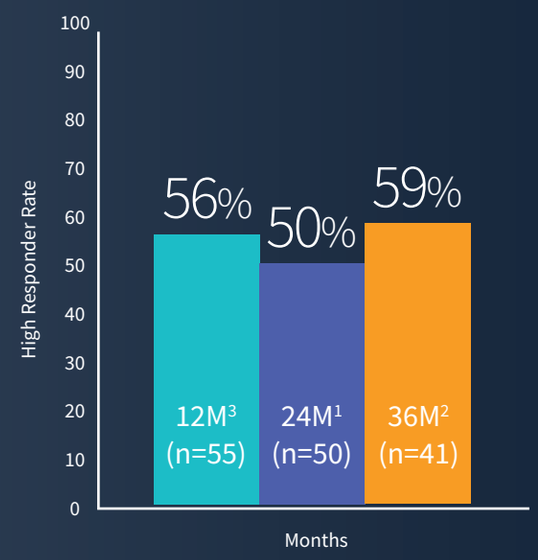
Setting a New Standard with the Landmark EVOKE Study
Double-Blinded, Self-Selected Patient Cross-Over at 24-months



Responder
(≥50% VAS reduction)



High Responder
(≥80% VAS reduction)



To learn more about the EVOKE Study visit www.saludamedical.com.

Moving Beyond Pain Relief to Include **HOLISTIC OUTCOMES**

Chronic pain is dynamic and multidimensional.
Published recommendations suggest patient outcomes should be evaluated beyond just pain relief for a more complete assessment of an individual's response to spinal cord stimulation[4].

Double-blinded, Crossover

9 out of 10

Patients chose SmartLoop therapy[2]

Opioid Reduction

55%

Patients voluntarily reducing/eliminating opioids at 36 months[2]

Disrupting the chronic pain cycle
with significant improvement across Pain, Function, Mood, Sleep, and Quality of Life maintained out to 3 years[2].

83%
Pain Relief
(≥50% VAS Reduction)

81%
Quality of Life
(EQ-5D ≥0.074)

85%
Physical Function
(ODI ≥10)

68%
Sleep
(PSQI ≥3)

68%
Mood
(POMS ≥10)

EVOKE®

powered by SmartLoop™ technology

Over 10 years since the first ECAP measurement to unlock the power of

ONE TRILLION+ ECAPs

to change the world of neuromodulation.

10+
Years of experience

20+
Investigator-initiated studies

3Y
The only double-blinded, 36-month RCT in SCS

1B+
Over a billion personalized ECAP insights annually per patient.

To learn more about the Evoke System, visit www.saludamedical.com.

Lisa S.
Evoke System Patient

For MRI safety information refer to the Evoke MRI Guidelines which can be obtained at www.saludamedical.com/manuals

† The Evoke® System takes measurements and adjusts stimulation output at each and every stimulation pulse delivered. On average, the Evoke® System's SmartLoop™ therapy makes 4+ million measurements and adjustments per day depending on each patient's unique needs.

References

1.Mekhail N, Levy RM, Deer TR, et al. Durability of Clinical and Quality-of-Life Outcomes of Closed-Loop Spinal Cord Stimulation for Chronic Back and Leg Pain; A Secondary Analysis of the Evoke Randomized Clinical Trial. JAMA Neurol. 2022;79(3):1-10. Implanted, Completer Analysis at 24 months.

2.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. Implanted, Completer Analysis.

3.Deer T et al., A New Horizon in Neuromodulation; Pain Medicine, 0(0), 2020, 1–2, doi: 10.1093/pm/pnaa197, Advance Access Publication Date: 5 June 2020

4.Katz N. et al., Research design considerations for randomized controlled trials of spinal cord stimulation for pain: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials/Institute of Neuromodulation/International Neuromodulation Society recommendations. Pain. 2021 Jul 1;162(7):1935-1956. doi: 10.1097/j.pain.0000000000002204. PMID: 33470748; PMCID: PMC8208090.

IMPORTANT SAFETY INFORMATION

Patients should consult a physician to understand the potential benefits and risks of treatment associated with Spinal Cord Stimulation (SCS). All patients do not respond the same way to SCS and experiences may vary.

Indications for Use:
The Saluda Medical Evoke SCS System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs.

Contraindications:
The Evoke® System must not be used in patients who:
- Are unable to operate the Evoke System
- Are unsuitable surgical candidates
- Are unsuitable candidates for SCS

Safety Information:
Please see Evoke System manuals for detailed safety information regarding the Evoke System, including the following Warnings / Precautions and Adverse Effects:

Warnings / Precautions:
Diathermy, magnetic resonance imaging (MRI) scans, CT scans, implanted cardiac pacemakers or defibrillators, electromagnetic fields, charging the stimulator, other medical procedures, allergies to system components, cables and small parts, pregnancy, paediatric use, operation of equipment, care after surgery, scuba diving, extreme temperatures, and device damage.

Adverse Effects:
May include: undesirable changes in stimulation sensation and/or location; uncomfortable changes in stimulation (over and/or under stimulation); persistent post-surgical pain at hardware implantation sites; CLS migration, which may result in pain or difficulty in charging; seroma or hematoma at surgery sites; epidural haemorrhage; spinal cord injury and possible paralysis; lead migration resulting in stimulation changes; breakage of the lead or failure of other system components, which may result in loss of stimulation; rejection of or allergic reaction to the implanted components; infection; cerebrospinal fluid (CSF) leakage; inadequate pain relief; erosion of the lead or CLS through the skin; weakness or numbness.

Additional information about the Evoke System, including system manuals, may be found on our website, *www.saludamedical.com*. If you have any further questions, please contact your pain management team. Alternatively, you can email us at *info@www.saludamedical.com*.

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