


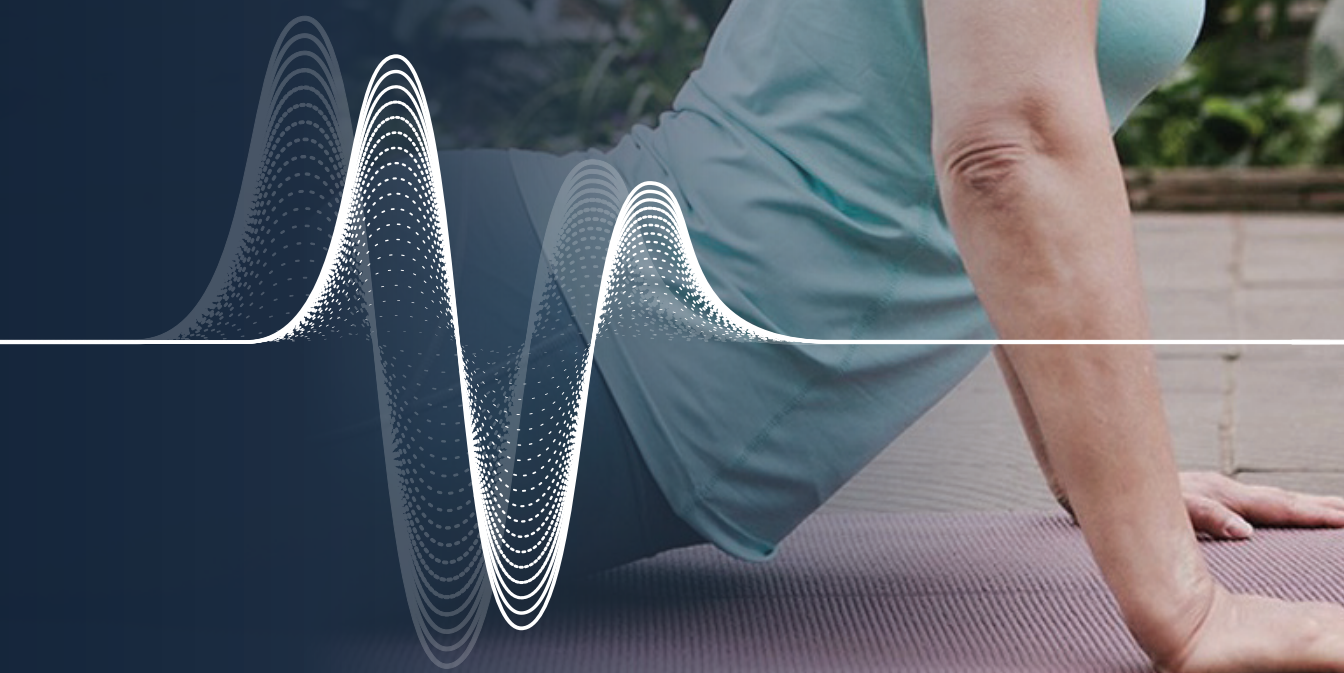


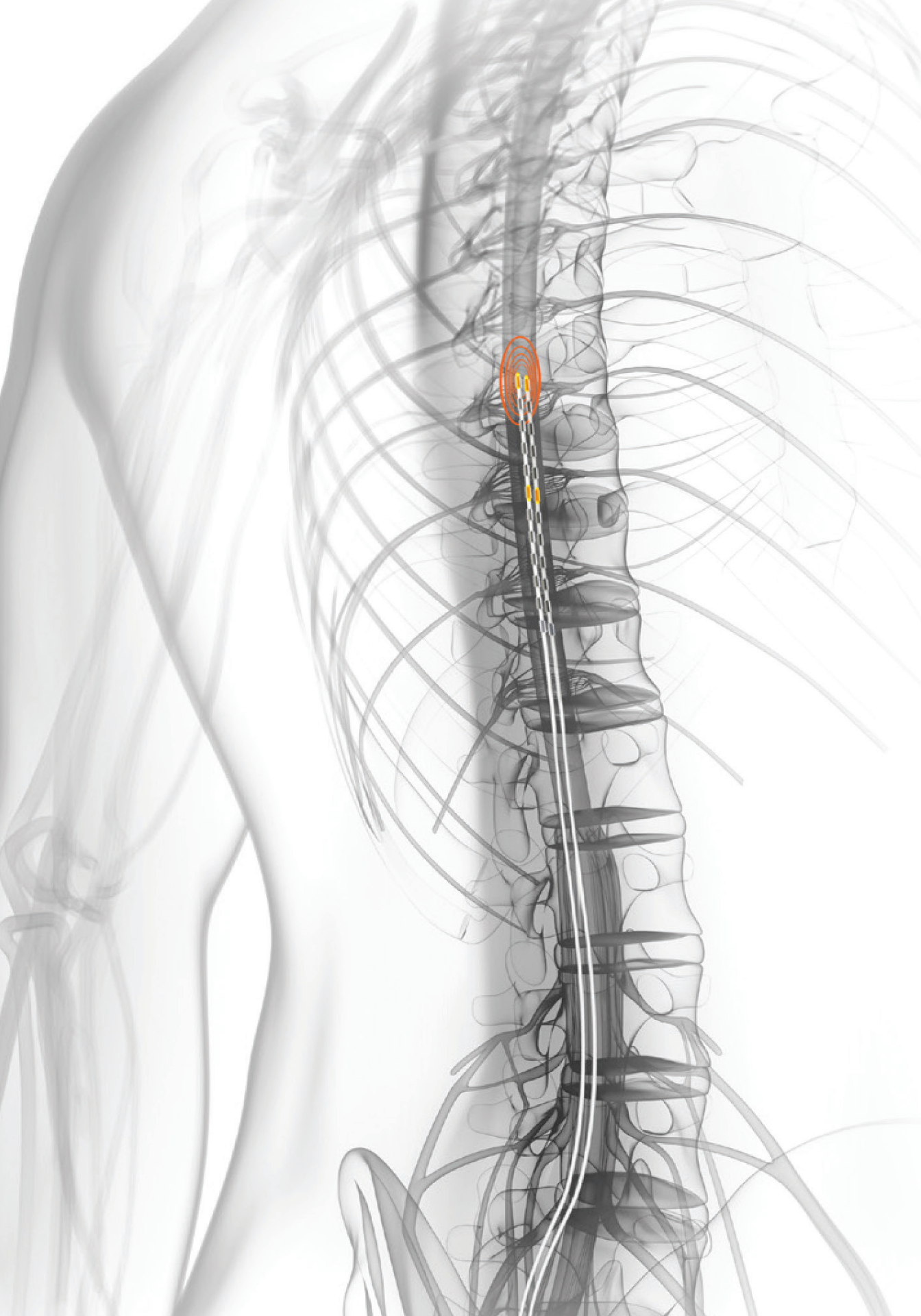
Everything Changes...

**THIS CHANGES
EVERYTHING.**

EVOKE[®]

powered by  SmartLoop[™] technology





EVOKE[®]

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

SMART by Every Measure
The only SCS to directly measure & confirm the spinal cord's response to stimulation.

Relief on **AUTOMATIC**
The only SCS to automatically adjust with the patient in real time 4+ million times a day.[†]

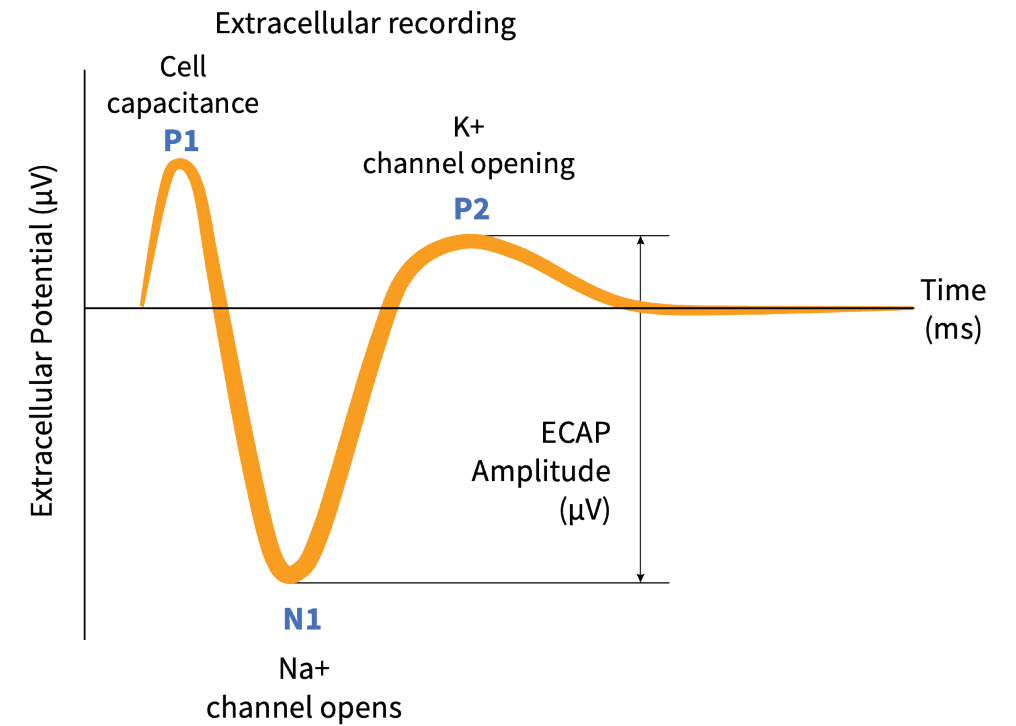
The Change is **ENDURING**
Backed by the only double-blinded RCT in SCS with 36-month outcomes.



SMART

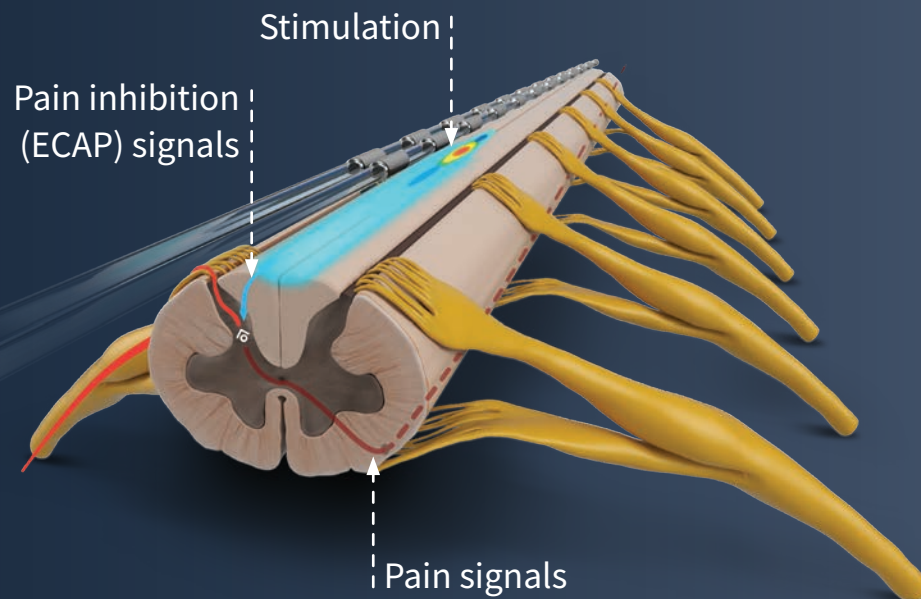
by Every Measure

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

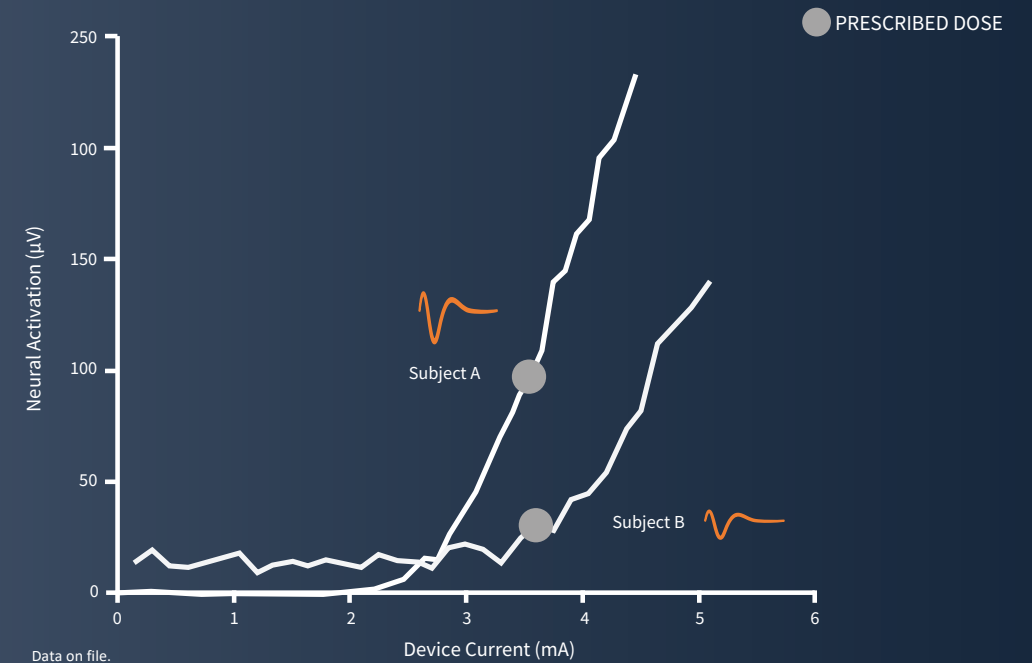


Pain relief starts with neural activation.

ECAPs are a measure of aβ-fiber activation within the dorsal column that drives pain relief in SCS.



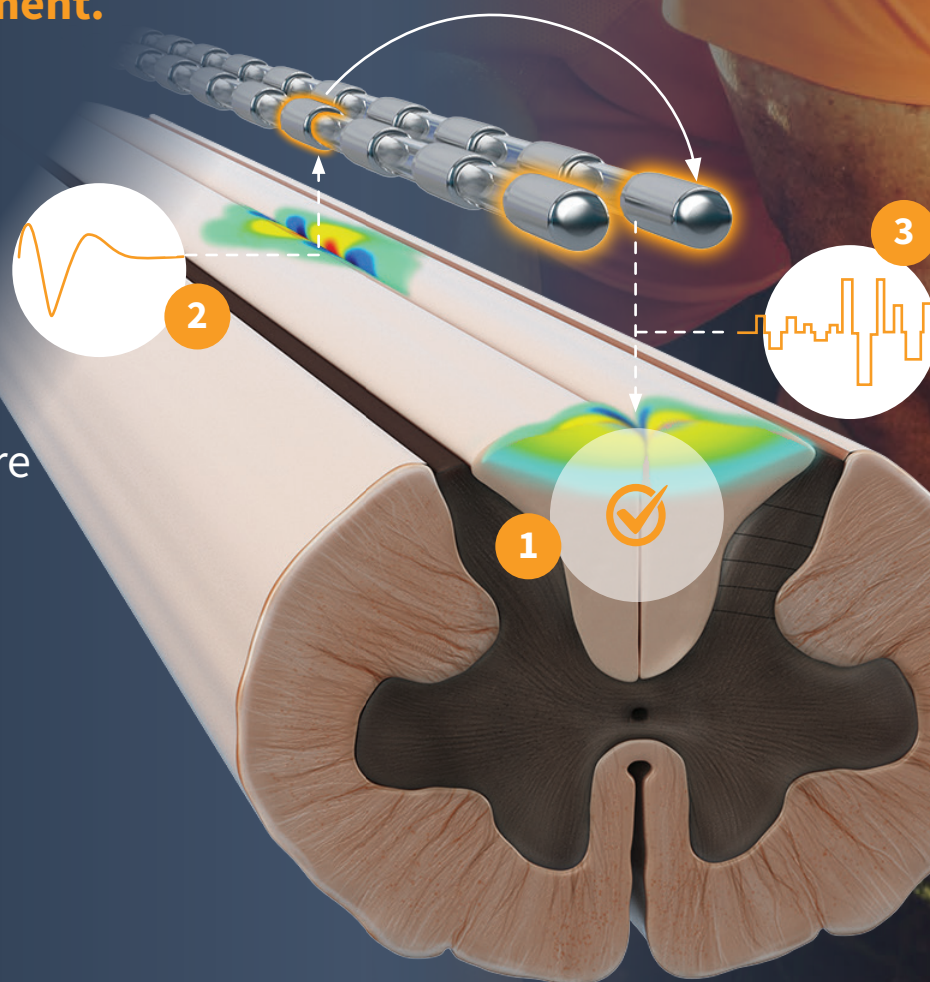
Only the Evoke[®] SmartSCS[™] system can translate each patient's unique neural signature from the spinal cord into a **precise stimulation dose** to maintain consistent pain relief.



Relief on **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, step, 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

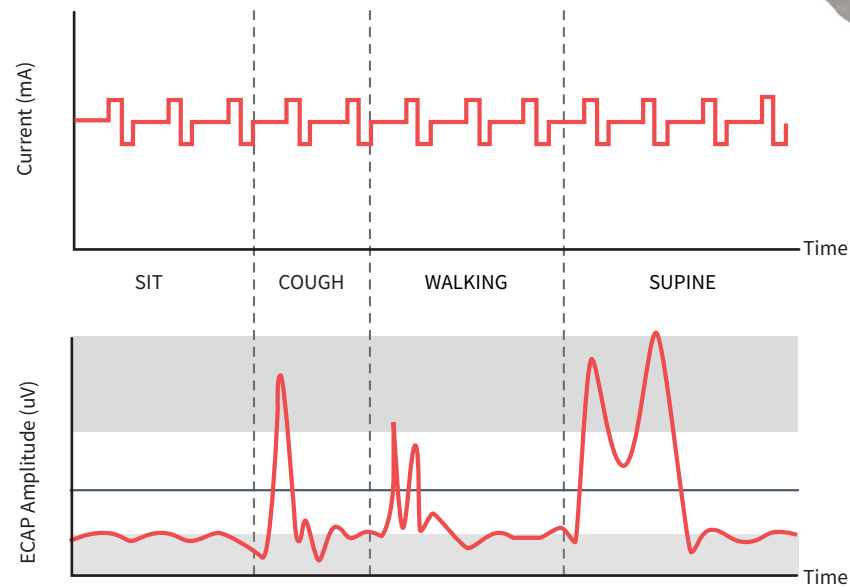


Relief on **AUTOMATIC**

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



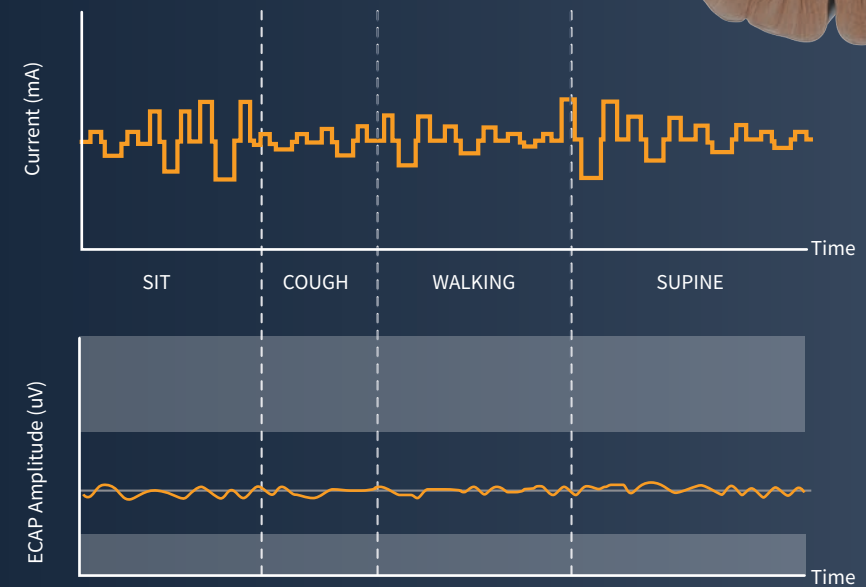
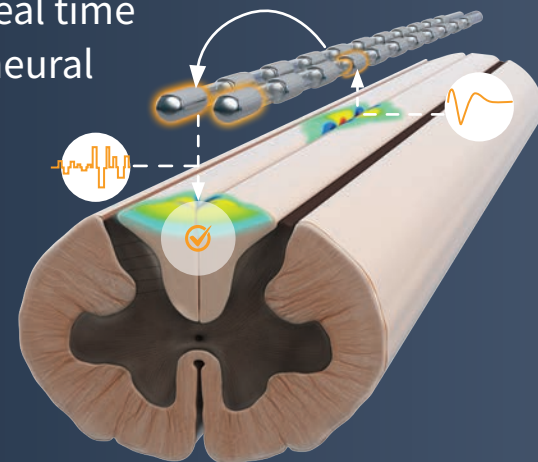
Charts are visual representations

In the landmark EVOKE Study, Saluda SmartLoop™ patients received **3x more neural activation**, delivered **8x more accurately** compared to Open-Loop¹.

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, step and movement



Charts are visual representations

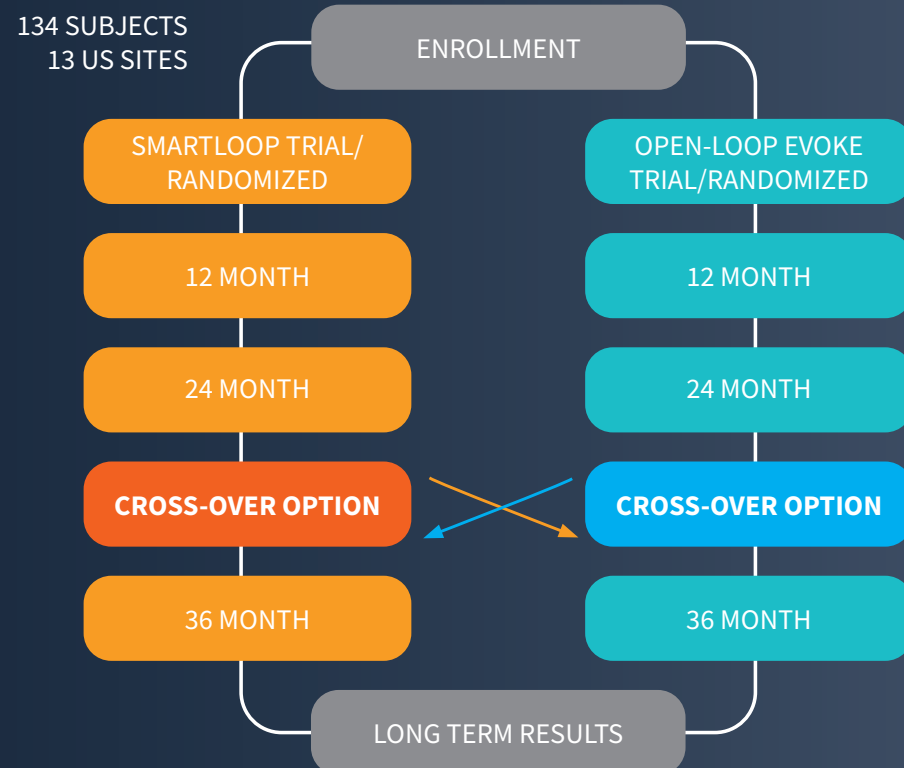
The Change is **ENDURING**

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

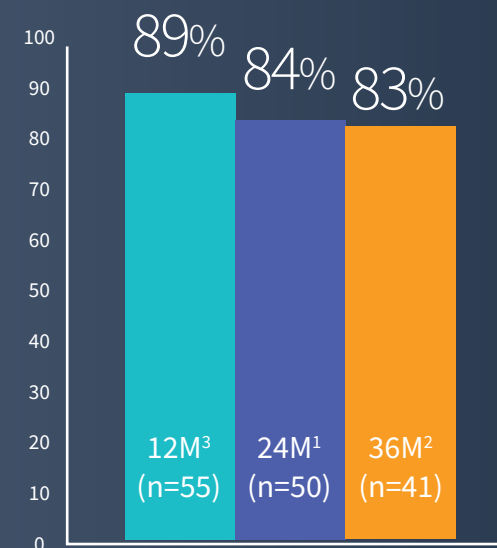
36-Month Highlights of the EVOKE Study

Responder Rate	High Responder Rate	Therapy Durability
83%	59%	ZERO
of patients had $\geq 50\%$ VAS reduction	of patients had $\geq 80\%$ VAS reduction	Explants due to loss of efficacy

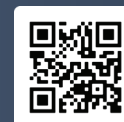
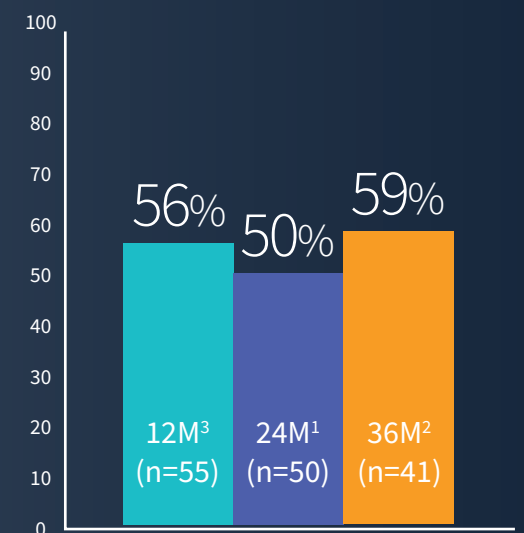
Setting a New Standard with the Landmark EVOKE Study Double-Blinded, Self-Selected Patient Cross-Over at 24-months



Responder ($\geq 50\%$ VAS reduction)



High Responder ($\geq 80\%$ 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 stimulation⁴.



Double-blinded, Crossover

9 out of 10

Patients chose SmartLoop therapy²

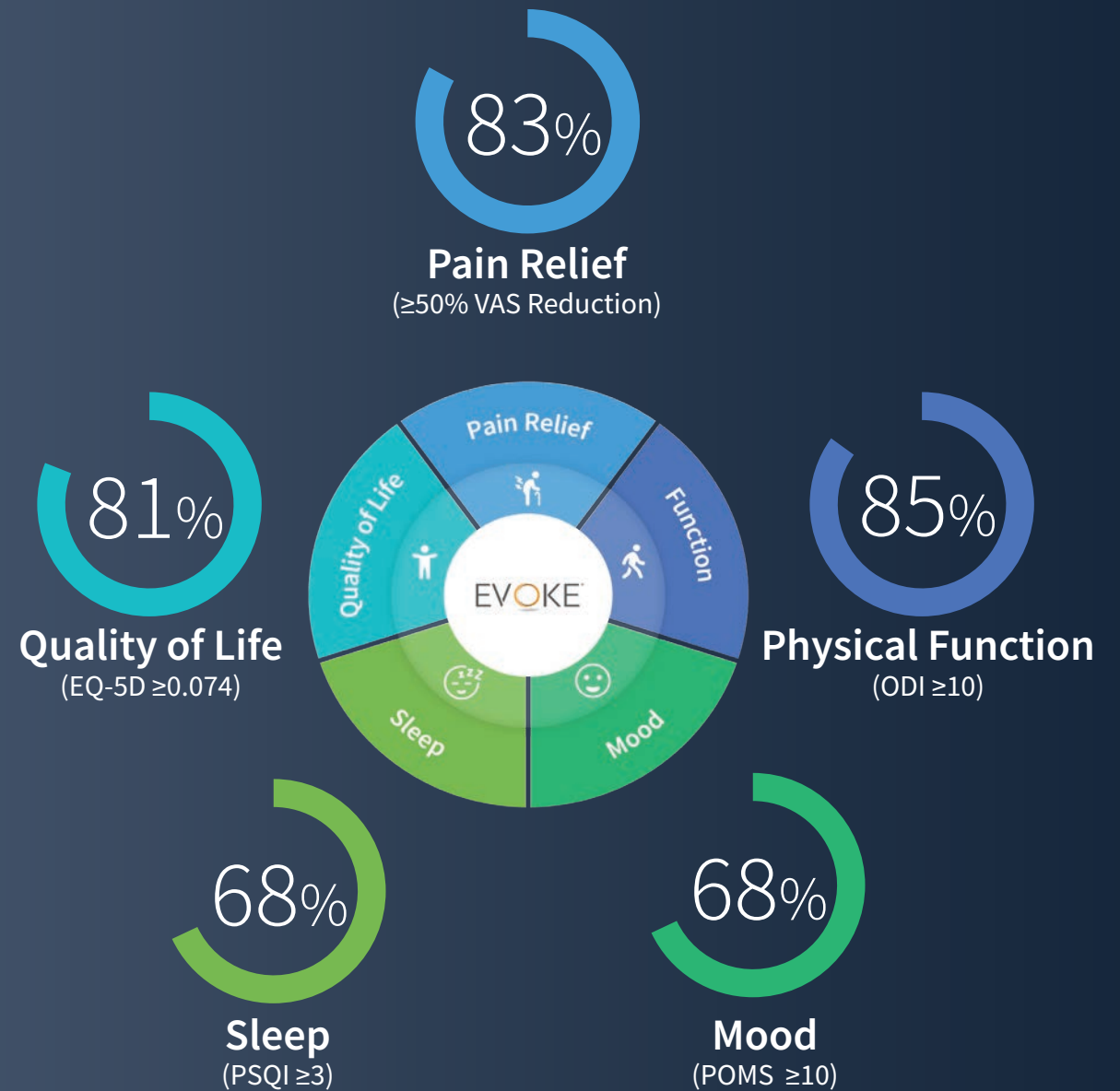


Opioid Reduction

55%

Patients voluntarily reducing/eliminating opioids at 36 months²

Disrupting the chronic pain cycle with significant improvement across Pain, Function, Mood, Sleep, and Quality of Life maintained out to 3 years².



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

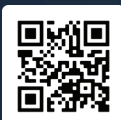
3Y

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

1B+

Over a billion personalized ECAP insights annually per patient.

Lisa S.
Evoke System Patient



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

† 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

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, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain.

Contraindications

The Evoke System must not be used in patients who:

- Do not receive effective pain relief during trial stimulation
- Are unable to operate the system
- Are unsuitable surgical candidates

Safety Information

Although FDA has determined that the probable benefits outweigh the probable risks, there remains some uncertainty on the long term systemic toxicity risks of the leads, lead extensions, and anchors of the device. As a condition of approval, FDA is requiring the manufacturer to provide additional long term systemic toxicity information.

Warnings

Sources of electromagnetic interference (e.g., diathermy, MRI, CT scans, electrosurgery, lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, high-output ultrasound, TENS, psychotherapeutic procedures, laser procedures) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device. Allergic reaction to system components may occur. The Evoke System has not been tested for use in patients who are pregnant or nursing nor in patients under 18 years old.

Precautions

Patients should avoid manipulating the Evoke System through the skin. Therapy should be discontinued immediately in the event of malfunction or failure of any component of the Evoke system.

Potential Risks

Risks may include, but are not limited to epidural abscess, wound infection, lead breakage/fracture, lead migrations, IPG pocket pain, and muscle spasm or cramp.

Rx Only

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