SPINAL CORD STIMULATION

saluda MEDICAL

THE EVOKE® SYSTEM

Disrupting pain by removing guesswork.

EVOKE®

SALUDA MEDICAL CORE VALUE

“We know that you cannot improve what you cannot measure.”

EVOKE®

Meet The Evoke® System — objective by design.

We listened to the spinal cord — and changed SCS forever.

In a world where chronic pain affects millions of people, Saluda Medical is disrupting pain. How? By doing what others said couldn’t be done: listening to the spinal cord itself.

The Evoke® System removes guesswork — by measuring. With over a decade of research, development, and clinical experience, we’ve designed the first system that directly records the spinal cord’s response to stimulation using Evoked Compound Action Potentials (ECAPs).

We know that every spinal cord is different. That’s why The Evoke® System targets the right dose for confidence on day one and auto-adjusts with every pulse, maintaining consistent, personalized pain relief.

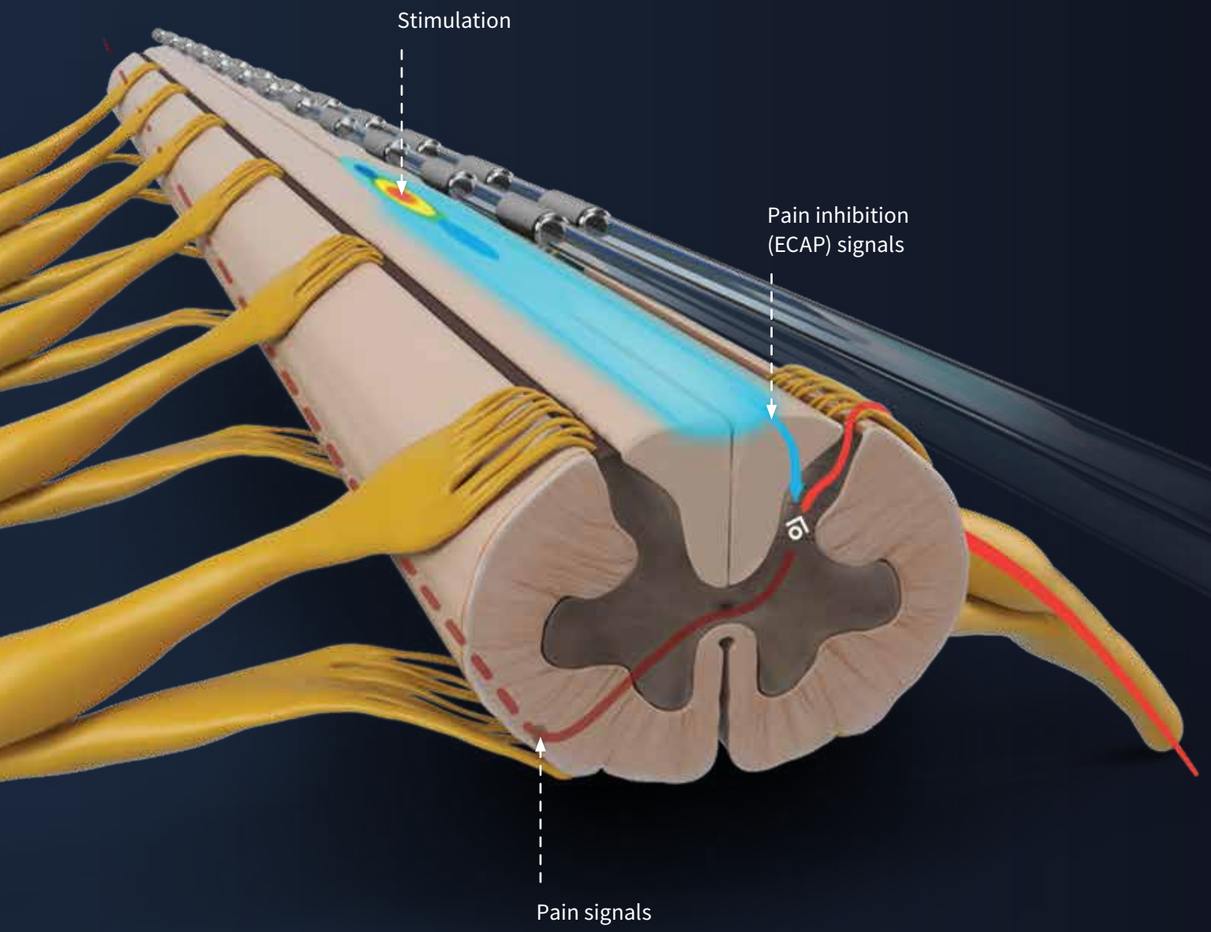
Saluda Medical — disrupting pain by removing guesswork.

Remove clinical guesswork.

Pain relief in SCS is driven by consistent dosing of the spinal cord.

However, traditional SCS systems, regardless of “waveform,” rely on clinical guesswork to program therapy and deliver stimulation without knowing if the spinal cord is being consistently dosed at a therapeutic level.

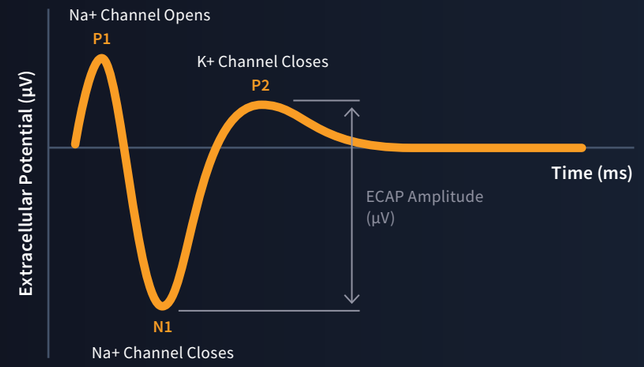
The Evoke® System changes that.



Every pulse — measured.

Evoked Compound Action Potentials, ECAPs, are a measure of Aβ-fiber activation that drives pain relief in SCS and can be used to objectively calibrate therapy.

Extracellular ECAP Recording



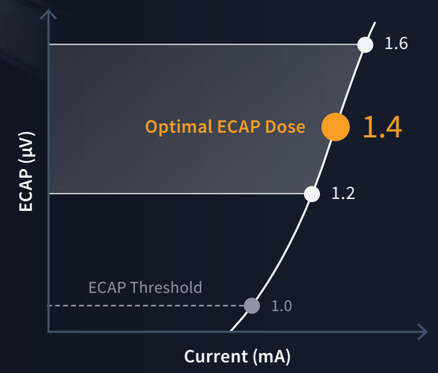
Every dose — personalized.

Every patient’s spinal cord is unique. Only the Evoke® System uses ECAPs to map the physiology of each patient and provide an objective anchor to calibrate therapy.

Dose Ratio

Is the dose optimized?

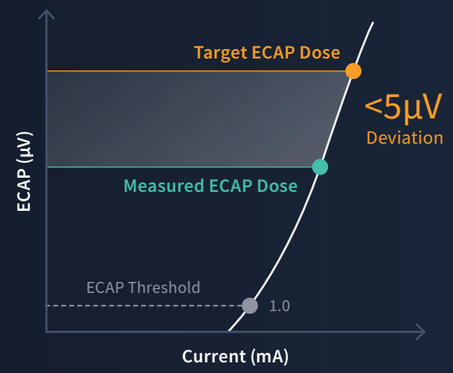
Maximum pain relief has been shown to be 40% above ECAP threshold, which is the moment when an ECAP is first measured.[1,2]



Dose Accuracy

Is the dose accurate over time?

Highly accurate therapy has been shown to maximize pain relief.[1,2]



SAY HELLO TO EVA™

At the touch of a button, EVA™ Sensing Technology objectively scans and analyzes each patient's spinal cord to identify a therapeutic dose at a level beyond human capability.

Trillions

World's largest database of ECAPS recorded and analyzed[3]

96%

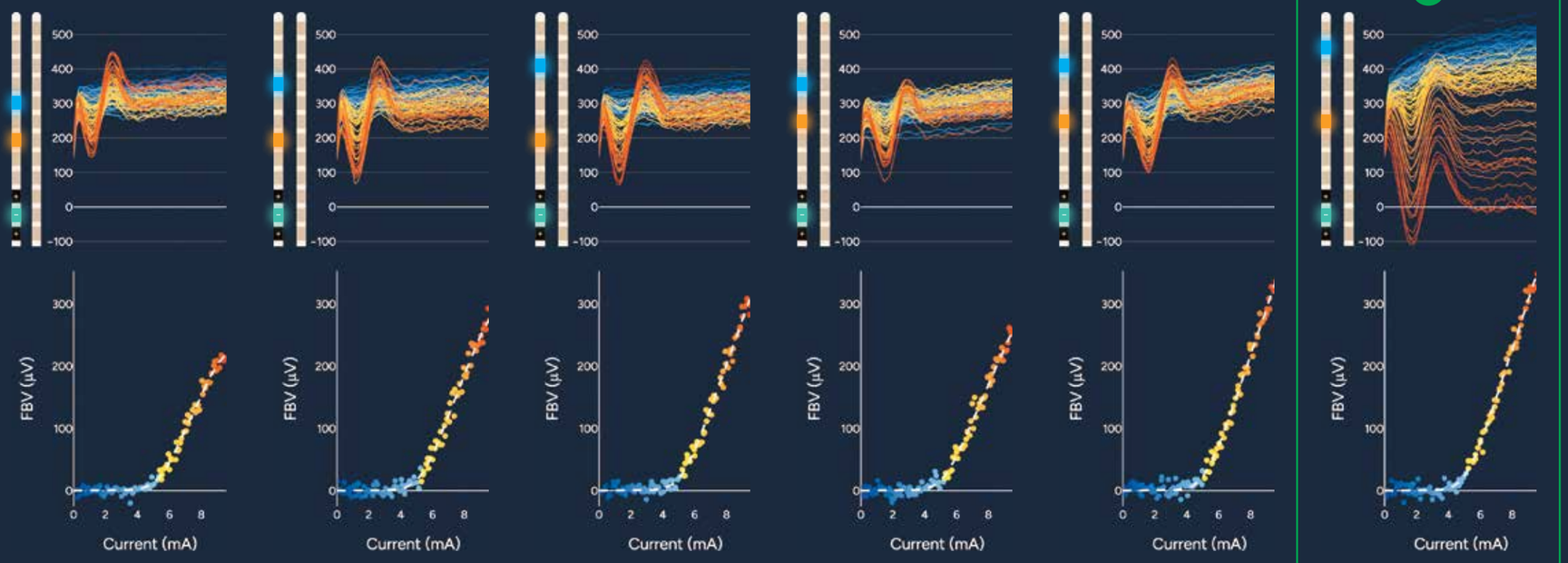
of patients very satisfied or satisfied with their experience[4]

97%

of patients felt in control of their therapy at implant programming[4]

10.5

minutes average programming time[5]

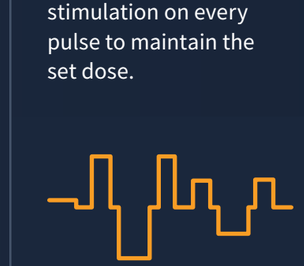


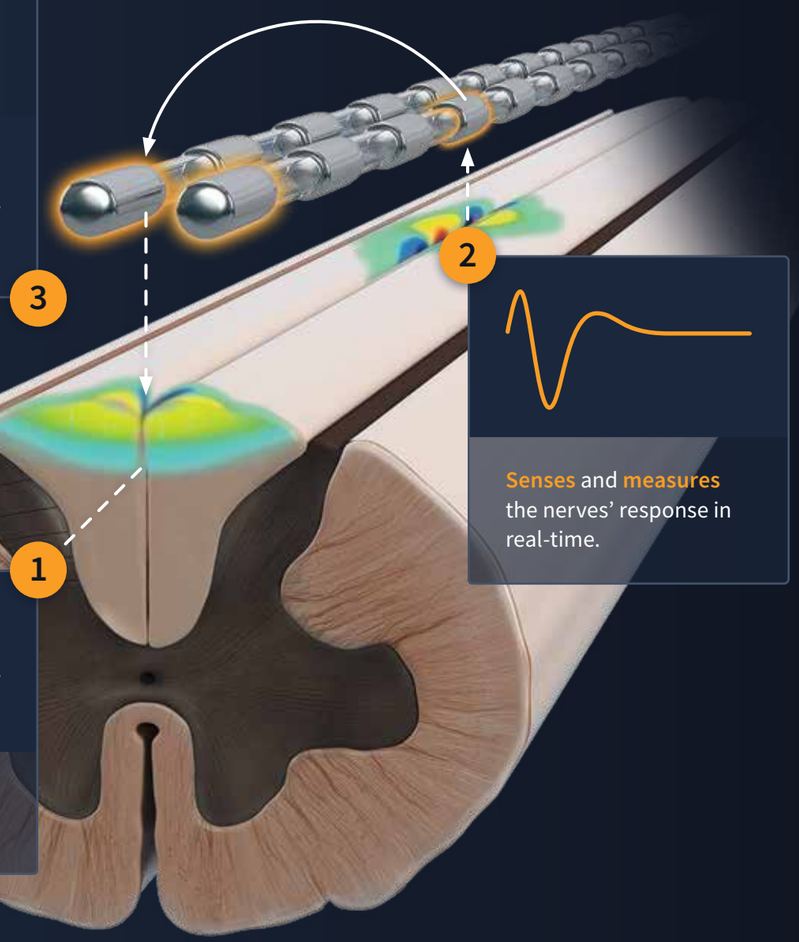
SmartLoop™ Technology that adapts with every pulse.

Saluda's proprietary SmartLoop™ Technology automatically adjusts with the patient in real time to maintain precise and consistent pain relief with every heartbeat, breath, and movement.

SmartLoop™

Automatically **adjusts** stimulation on every pulse to maintain the set dose.

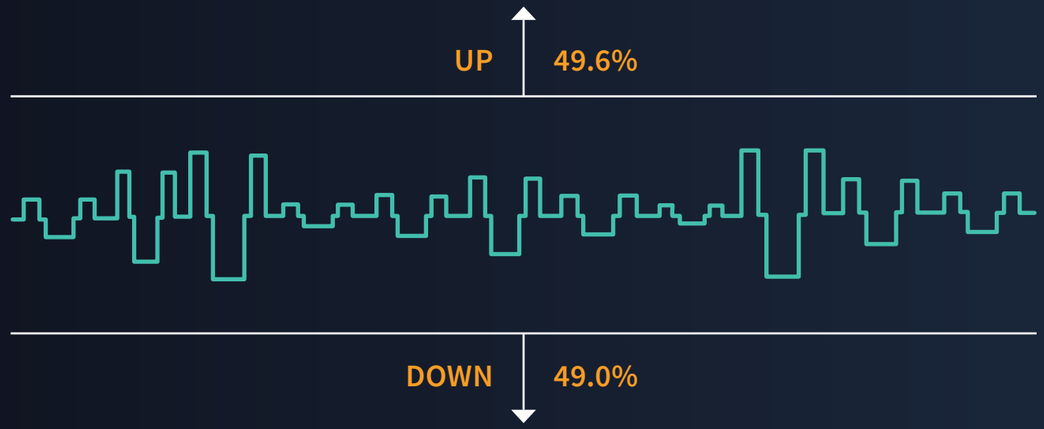


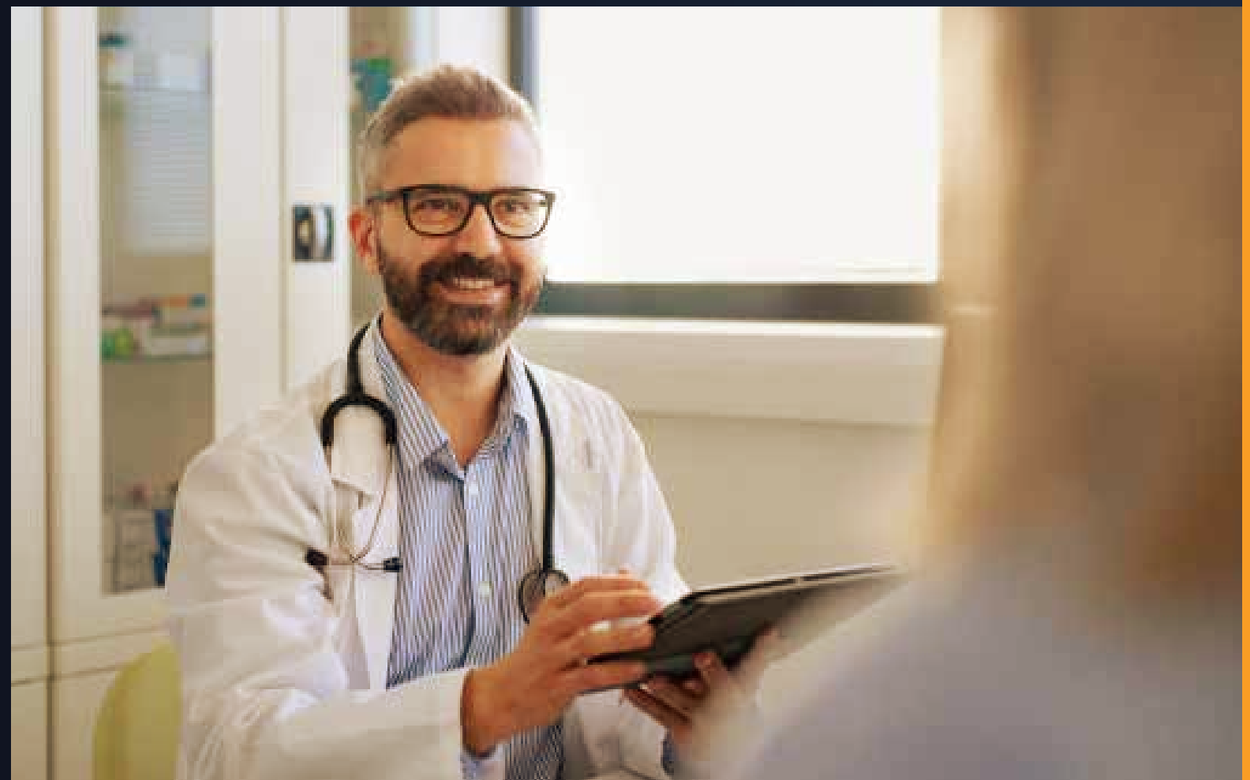


Senses and **measures** the nerves' response in real-time.

Stimulates the target nerves.

SmartLoop™ Technology continuously senses and adjusts, equally up and down, to address both under- and over-dosing.[6]



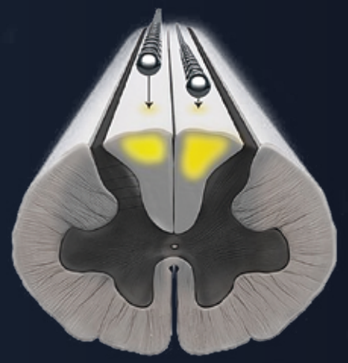


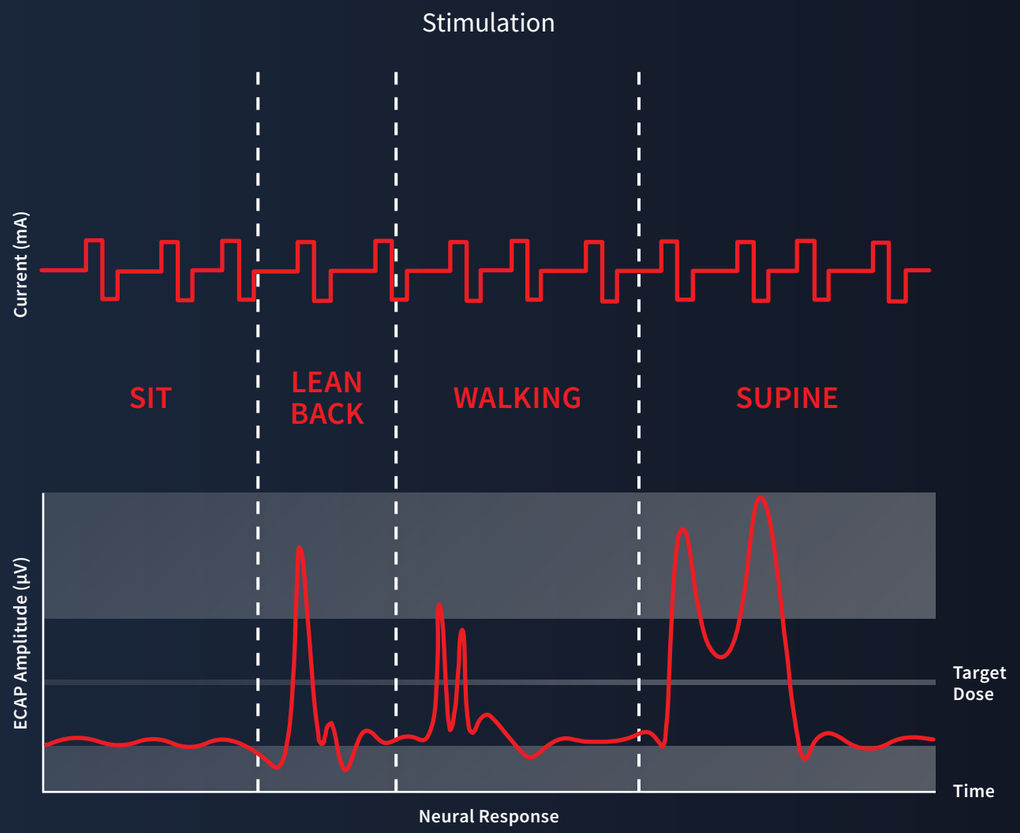
The Evoke® System advantage.

That was **then**.

Fixed-output SCS:

- ✕ Unknown and inconsistent dosing
- ✕ Cannot auto-adjust for movement and physiological changes throughout the day



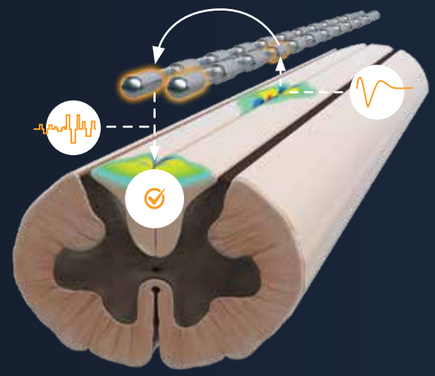


Charts are visual representations.

This is **now**.

The Evoke® System:

- ✓ Known and consistent dosing
- ✓ Automatically adjusts in real-time to maintain consistent dosing across activities



Charts are visual representations.

Proven clinical superiority. Outcomes that last.

Backed by more than 40 publications, including the landmark EVOKE Study with 36-month outcomes. The EVOKE Study is the first and only double-blinded, pivotal randomized clinical trial demonstrating the most enduring patient outcomes from a randomized clinical study in the history of SCS.

It’s one thing to promise better therapy. It’s another to prove it.

Here are 36-month highlights of the EVOKE study:

83% of patients were pain responders (≥50% VAS reduction)[7]

59% of patients were high-pain responders (≥80% VAS reduction)[7]

Over 90% of 3-month responders were still responders at 3 years[7]

Zero explants due to loss of efficacy[7]

From ECAPs to EVA™.

In 2010, Saluda Medical pioneered the ability to measure Evoke Compound Action Potentials (ECAPs), the spinal cord's response to stimulation, paving the way for a new level of innovation in neuromodulation.

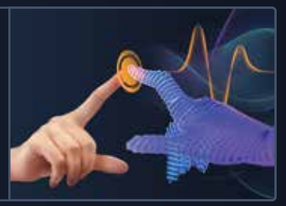
2010
ECAP Sensing
Sense and measure ECAPs.[8]

2014
ECAP-Controlled Closed-Loop
Maintain therapy within prescribed therapy window.[9]

2022
Precise and Consistent Dosing
Precise adherence to prescribed levels of activation.[10]

2024
Biomarker-Based Dosing
1.4 above ECAP threshold drives max pain relief.[1]

2025
Next Generation Sensing Technology
Objectively scan and analyze the spinal cord.[11]



"For 10 years, it has worked amazingly. From experience, I can honestly say to people that are suffering from chronic pain like myself, that there is hope and that this device does work."

Joe G.
EVOKE System Patient
Since 2015

Important Safety Information

U.S. 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, Diabetic peripheral neuropathy of the lower extremities. **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. **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. Surgical complications and adverse events may be more frequent and severe in diabetic patients. The physiologic closed-loop controlled (PCLC) stimulation mode and frequencies greater than 1200 Hz have not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population. **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. The severity of any surgical complication may be greater in diabetic patients, particularly those with inadequate pre-operative glycemic control. **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.

EU/UK 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, pediatric 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 haematoma 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 contact Saluda Medical via email at info@saludamedical.com.

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.

EVA™ refers to the assisted programming module. Programming is performed under the supervision of a trained medical professional.

The Evoke® System with EVA™ is available in select geographies.

1. Levy R et. al., Maximal Analgesic Effect Attained by the Use of Objective Neurophysiological Measurements with ECAP Dose-Controlled Closed-Loop SCS. Neuromodulation. 2024.
2. Muller L, Pope J, Verrills P, et al. First evidence of a biomarker-based dose-response relationship in chronic pain using physiological closed-loop spinal cord stimulation. Reg Anesth Pain Med. Published online March 19, 2024.
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4. Deer T et al., ASPN 2025 Poster. n=98
5. Smith L et al., ASPN 2025 Poster. Overall Median Programming Time. n=143 trial phase, n=180 implant phase
6. Pope et . al,. ASPN 2025.
7. Mekhail NA, et al. Reg Anesth Pain Med 2024;0:1–8. doi:10.1136/rapm-2024-105370.
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10. Mekhail N, et al. N. 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 Neurology. 2022.
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