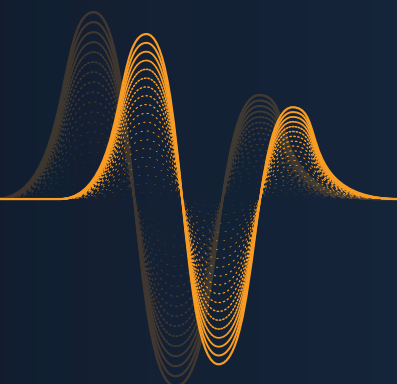




Pain relief that adapts to you.

Smart, proven relief for chronic pain.

LEARN MORE 



EVOKE
SmartSCS™ System



Living with chronic pain?

If you've lived with chronic pain, you know it can touch every part of your life—your sleep, your mood, and even the simplest daily routines. Many people try medications, injections, or physical therapy. But when those don't bring enough relief, there's another proven option—**Spinal Cord Stimulation (SCS)**.

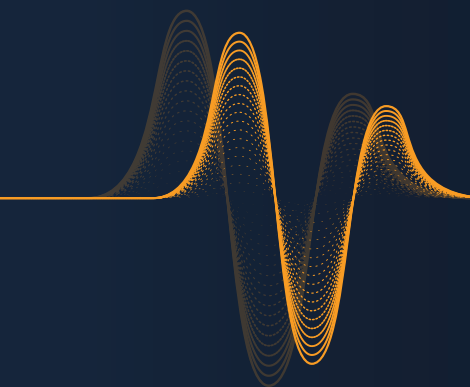
SCS has been used for more than 55 years to help people manage chronic pain.¹ It works by sending gentle electrical pulses to your spinal cord to interrupt pain signals before they reach your brain.

But not all spinal cord stimulators work the same. The Evoke™ SmartSCS™ System is the only spinal cord stimulation therapy that listens to your body and adjusts 4+ million times per day to deliver pain relief starting from day one.²

Who is a good candidate for the Evoke™ SmartSCS™ System?

The Evoke SmartSCS System may be right for you if:

- ✓ Your pain is constant and has lasted more than 6 months.
- ✓ You experience chronic nerve-related pain.
- ✓ You haven't found relief with other treatments such as pain medications, injections, traditional spinal cord stimulators, or back surgeries like fusion or laminectomy.



“This technology works. It has given me my life back.”

Joe G.
Evoke® System Patient
Since 2015

Individual results may vary.



What is the Evoke™ SmartSCS™ System?

Evoke SmartSCS System is a next-generation SCS therapy for chronic pain designed to work in sync with your body.

Unlike traditional SCS, the Evoke SmartSCS System uses real-time feedback from your nervous system to deliver therapy that's smart, personalized, and proven to last.

Think of it like a smart thermostat for your pain: always sensing, always adjusting, always working to keep you feeling better.

How is the Evoke SmartSCS System different?

Every spinal cord is different, yet traditional spinal cord stimulation therapies don't adapt to the needs of your unique nerves. The Evoke SmartSCS System changes that.



Listens

Listens to your spinal cord and has a two-way conversation with your nerves every second to help keep your pain under control.



Adapts

Adapts over 4 million times throughout your day to maximize pain relief.²



Personalizes

Personalizes therapy to your unique needs, so you're less likely to manage your therapy or need constant reprogramming.³



Proven

Proven to be clinically superior to traditional, open-loop systems, as recognized by the FDA.⁴



After getting the Evoke System, I could finally do activities I hadn't been able to because of my pain. ”



Paul P.
Evoke® System Patient
Since 2024

Individual results may vary.

Real results.

In long-term studies, the Evoke™ SmartSCS™ System delivered life-changing improvements.⁵



9 out of 10 patients were satisfied with their results⁶



8 out of 10 patients experienced meaningful, long-term pain relief⁶

And **most patients** reported better sleep, improved mood, and the ability to do more of what they love.



6/10 showed clinically significant sleep time & quality improvements



Evoke patients gained an average of **1.2 hours** of sleep per night



More than **2/3** showed clinically significant mood improvements



8/10 improved the ability to perform daily activities



5/10 voluntarily eliminated or reduced opioid use



You can **drive with this device** in accordance with the patient manual*

*Refer to the patient manual on www.saludamedical.com.



“Now that my pain is under control, I am able to get back to my normal activities, work and just be a happier me.”

Pam M.
Evoke® System Patient
Since 2017

Individual results may vary.

Try the Evoke™ SmartSCS™ System before you decide.

Using a temporary device, the trial gives you a chance to “test drive” the Evoke SmartSCS System and see how it works for you. During the week, you can evaluate your pain relief, notice improvements in your daily quality of life, and decide whether Evoke SmartSCS System helps you meet your personal pain management goals.

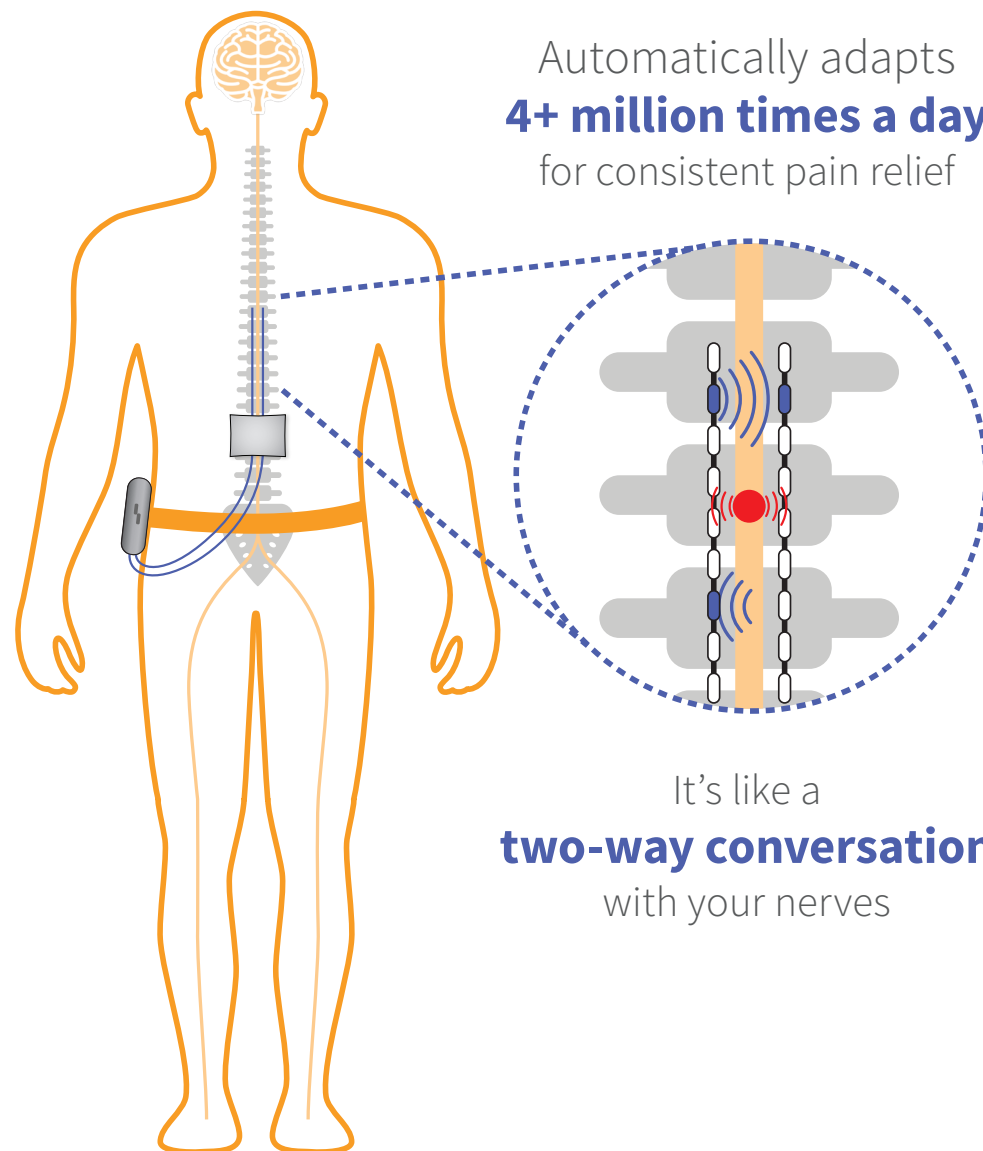
How the trial works:

- ✓ The procedure is a quick, minimally invasive outpatient procedure similar to an epidural injection.
- ✓ A temporary device is taped to your back and easily covered under your clothes.
- ✓ There are minimal restrictions—you’ll be encouraged to maintain your daily routine, aside from avoiding bending, lifting, or twisting.
- ✓ You’ll receive calls from your Saluda Care Team throughout the week to help optimize your therapy.

What to expect during the week:

- ✓ The external trial device delivers the same therapy as the implant, giving you the best preview of your potential pain relief.
- ✓ You’ll have the chance to evaluate your pain relief and notice improvements in your daily quality of life.
- ✓ If you experience at least 50% pain relief, you’ll have the option to move forward with a permanent implant.
- ✓ At the end of the trial, you and your provider will decide together if the Evoke SmartSCS System is right for you.

In clinical studies, **9 out of 10 patients** chose to move forward with permanent implantation after experiencing the Evoke® System during their trial—therapy that adapts to you.



Your questions. Answered.

Here are some of the most frequent questions asked by patients considering the Evoke™ SmartSCS™ System. If you have additional questions, talk to your healthcare team or visit saludamedical.com.



Q Why is my provider recommending the Evoke SmartSCS System over other devices?

A Providers generally make therapeutic recommendations based on their patient's specific situation and on clinical data. The Evoke SmartSCS System was part of the most rigorous clinical study in the history of spinal cord stimulation. The study showed the Evoke® System delivers clinically superior therapy to open-loop therapy as well as outcomes that improve quality of life.⁶

Q Is the Evoke SmartSCS System covered by insurance?

A Yes, for covered indications, Evoke SmartSCS System is eligible under all major insurance plans, including Medicare, Medicaid, and government programs.

Q Can I go through an airport security scanner?

A Your stimulation may be affected by security gates, such as those used at public buildings and airports. You should inform the security attendees of your SCS system and ask to walk around the scanner. If you are required to go through the scanner, please turn your stimulator off first.

Q Can I stop all other treatments once my Evoke SmartSCS System is implanted?

A You will continue to work with your pain management provider to ensure you are receiving optimum care with or without other treatments.

Q Will I have any allergic reactions to the materials used in the Evoke® SmartSCS™ System?

A If you are allergic to some metals or plastics, please notify your clinician so that they can check whether the items you are allergic to are used in the stimulation system.

Q Can I get an MRI scan with the Evoke SmartSCS System?

A Yes, with the Evoke SmartSCS System you can safely have a full-body MRI scan.*

*Within conditional parameters. Refer to the Evoke® System MRI Guidelines for detailed information on MRI safety, your Evoke SmartSCS System, and specific conditions. Evoke® MRI Guidelines can be obtained at www.saludamedical.com/manuals

“

Now I'm in control of what I do, not my back problems. I get to focus on living and doing, not the pain.”

”

Jennifer R.
Evoke® System Patient
Since 2022

Individual results may vary.

Support & Next Steps

SmartAccess™ Team

Need help with insurance or coverage questions? Connect with your team by emailing reimbursement@saludamedical.com.

Patient Ambassador Program

Connect with real Evoke SmartSCS System patients who have experienced the therapy firsthand. They're not employees—just people willing to share their honest stories. To learn more, visit www.saludamedical.com/patients-caregivers/patient-ambassador/.



Additional Resources

American Chronic Pain Association:
theacpa.org

U.S. Pain Foundation:
uspainfoundation.org

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.

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. Erkan K, Robin Noordhof RK, van Dongen R, et al. Spinal Cord Stimulation in Failed Back Surgery Syndrome: An Integrative Review of Quantitative and Qualitative Studies. *Neuromodulation*. 2022; 25: 657–670.
2. The Evoke® System takes measurements and automatically adjusts stimulation 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. Calculation based on 50 Hz average frequency.
3. Mekhail N, Levy R, Deer T, Kapural L, Li S, Amirdelfan K, et al. ECAP-controlled Closed-Loop versus Open-Loop SCS for the Treatment of Chronic Pain: 36-month Results of the Evoke Blinded Randomized Clinical Trial. *Reg Anesth Pain Med*. 2024 May;49(5):346–354.
4. P190002 Summary of Safety and Effectiveness Data.
5. Mekhail NA, et al. Neurophysiological outcomes that sustained clinically significant improvements over 3 years of physiologic ECAP-controlled closed-loop spinal cord stimulation for the treatment of chronic pain. *Reg Anesth Pain Med*. 2024 Mar 15;rapm-2024-105370.
6. Mekhail NA et al. ECAP-Controlled closed-loop vs open-loop SCS for the treatment of chronic pain: 36-month results of the EVOKE blinded randomized clinical trial. *Reg Anesthesia Pain Med* 2023;0:1-9.

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