EVOKE®

SmartSCS™ System

As Unique As You.

Finally, a smarter way to treat chronic pain.

saluda MEDICAL

If You've Been Suffering From Chronic Pain, There Is Hope

What is Spinal Cord Stimulation?

Spinal Cord Stimulation (or SCS therapy) is a safe and effective treatment that has been in use for over 55 years.[1] SCS therapy uses a small implantable device to deliver tiny electrical pulses to your spinal cord. These pulses interrupt your body's pain signals to reduce the sensation of pain before they travel up your spinal cord and reach your brain.

- A small device called an **implantable pulse generator (IPG)** is implanted under your skin and connected to thin leads that are placed near your spinal cord to conduct the electrical impulses that block the pain signals being transmitted to your brain.
- The **temporary trial period** is one of the benefits of spinal cord stimulation therapy. This will allow you the ability to assess improvements in your pain and function.
- At the end of your trial, leads will be removed and you and your provider will discuss your improvement and whether to move forward with the minimally invasive procedure for a permanent implant.

The Evoke® System Difference

As unique as you.

Everyone experiences pain differently. The Evoke® System is the first and only smart spinal cord stimulation (SCS) system that allows therapy to be precisely tailored to meet your unique needs.

Just like your home's smart thermostat, the **Evoke® System** is constantly listening to your body as you move and automatically adjusting **4+ million times a day** to maintain pain relief.*

The Centers for Medicare and Medicaid Services (CMS) has deemed the **Evoke® System "a substantial clinical improvement"** over current SCS devices and created a new category for reimbursement.

** 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.*

A Proven Treatment

The most durable patient outcomes from a randomized controlled trial in SCS history.[2]

The Evoke® System was approved by the FDA based on the most rigorous clinical study in the history of spinal cord stimulation of 134 patients. Saluda Medical's Evoke® SCS System delivered pain relief and clinically superior therapy.[3] The EVOKE Study reported industry-leading quality of life outcomes, with 3-year data, and has the longest follow-up evidence from a randomized clinical study in spinal cord stimulation.[2]

93% Patient **satisfaction**

83% experienced long-term pain relief

55% voluntarily reduced or eliminated their opioid use

85% improved ability to perform daily activities

More than **two-thirds** showed clinically significant mood improvements

68% showed clinically significant improvements in sleep time and quality

Evoke® patients gained on average an additional 1.2 hours of sleep per night

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

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

Evoke® System Components

As you consider spinal cord stimulation (SCS), it may be helpful to understand the various components of the Evoke® System.

Evoke® Closed-Loop Stimulator (CLS)

The Evoke® CLS is an implantable pulse generator (IPG) that connects to thin wires, called leads, and is implanted under the skin. The CLS is the heart of the system and generates the electrical signals that interrupt your pain signals.

Evoke® Patient Controller (EPC)

The Evoke® Patient Controller (EPC) is a hand-held remote control that you can use to adjust the level of stimulation at home. The Evoke® System is designed to automatically optimize your therapy, but the EPC gives you the ability to manually adjust stimulation or turn off the stimulator if necessary.

Evoke® Percutaneous Leads

The Evoke® Percutaneous Leads are thin leads that are placed in the epidural space. One or two leads can be temporarily connected to an external trial system or permanently implanted and connected to a CLS for long-term therapy.

Charger & Coil

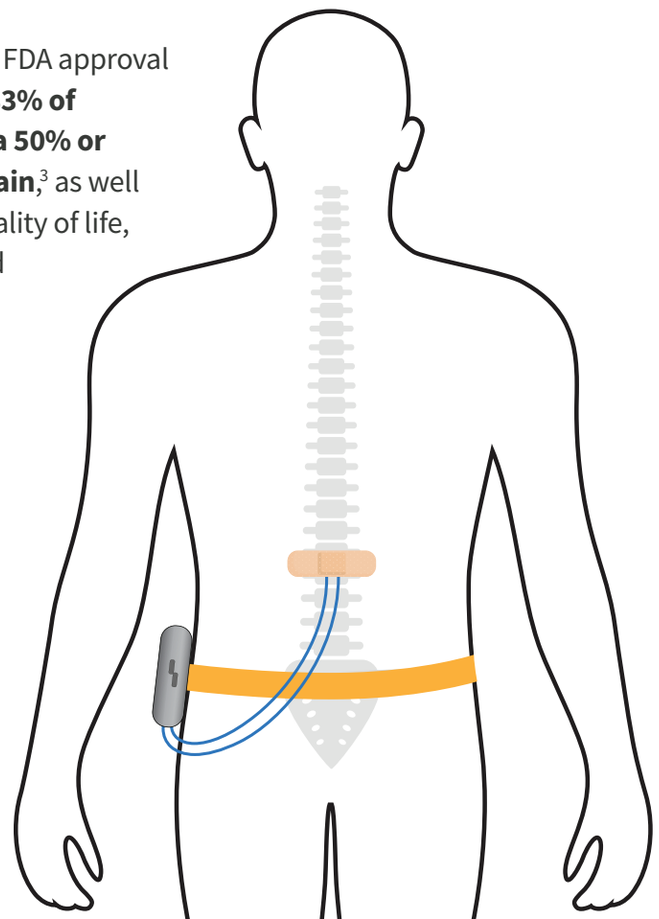
The CLS needs to be recharged to continue delivering therapy. The Evoke® Charger consists of a portable controller and charge coil. The charge coil is placed over the stimulator (on top of your clothes) and held in position until your battery is fully recharged.

If you have any questions about the Evoke® System, contact your clinical team.

The Evoke® System Trial

You are able to trial the Evoke® System before deciding to get a permanent implant.

- One of the advantages of SCS therapy is that **you try it before deciding on a permanent implant.**
- The goal of the trial is to **reduce your pain by at least 50%** and improve your ability to do the things you find challenging due to your pain.
- In the Clinical Study for FDA approval of the Evoke® System, **83% of patients experienced a 50% or greater reduction in pain**,[3] as well as improvements in quality of life, functional status, mood and sleep.



What to expect with the trial.

- Leads are placed inside your body near your spinal cord in the epidural space and an external pulse generator is taped to your skin.
- Your health care team establishes your baseline stimulation level.
- You receive instructions about how to use the wireless remote control and how to track your comfort during the trial, as well as any restrictions or limitations during the trial.
- It may take time for your body to adjust to the Evoke® System, but some patients report feeling pain relief right away!

At home

- You will document how you're feeling.
- You will receive calls from your care team throughout your trial to help optimize your experience.
- You will track your pain relief and functional improvement throughout the trial.

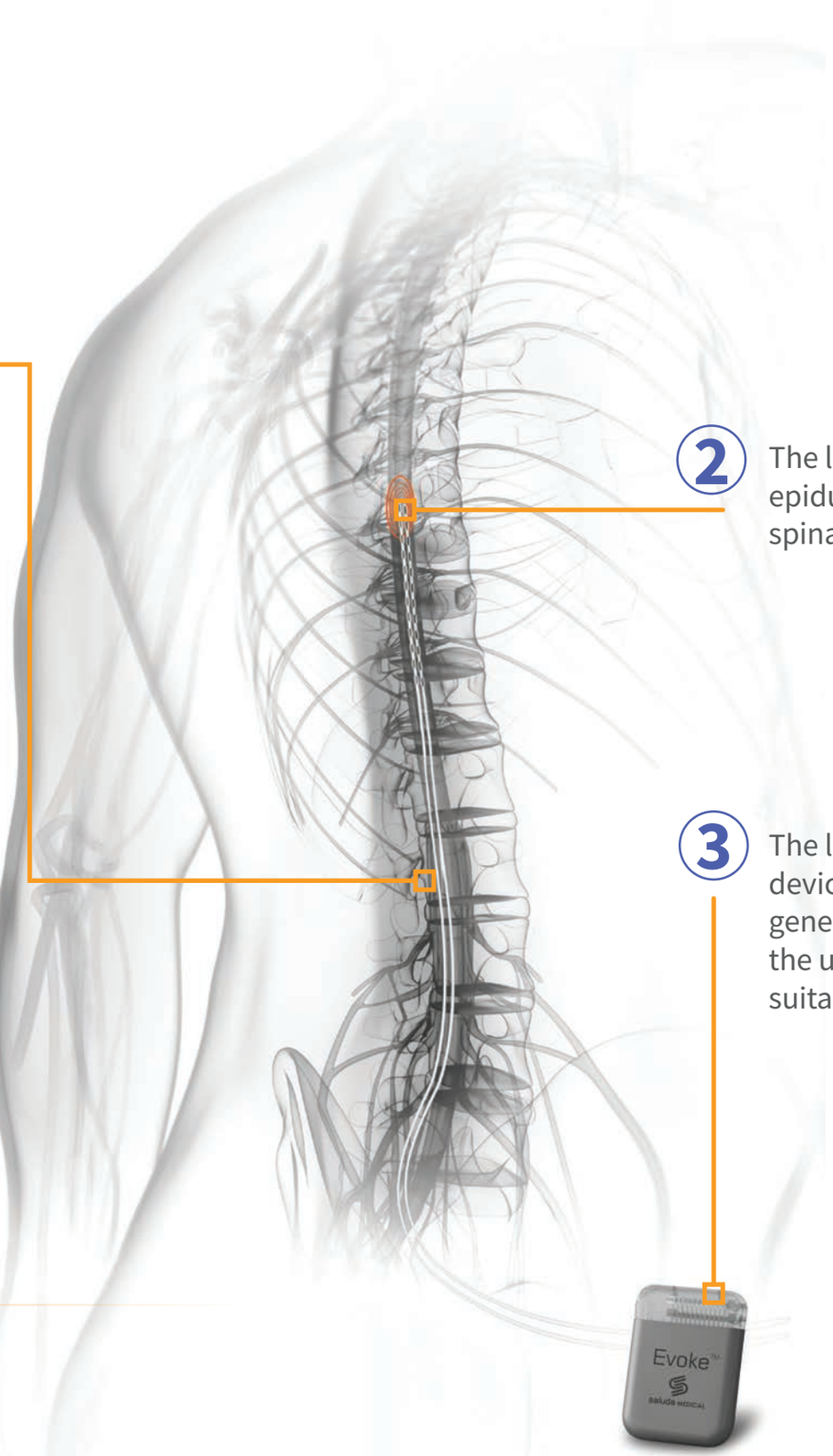
Implanting the Evoke® System

1 A small incision is made and leads are inserted using a special type of needle in an area where epidural injections are typically given.

The procedure is **minimally invasive.**

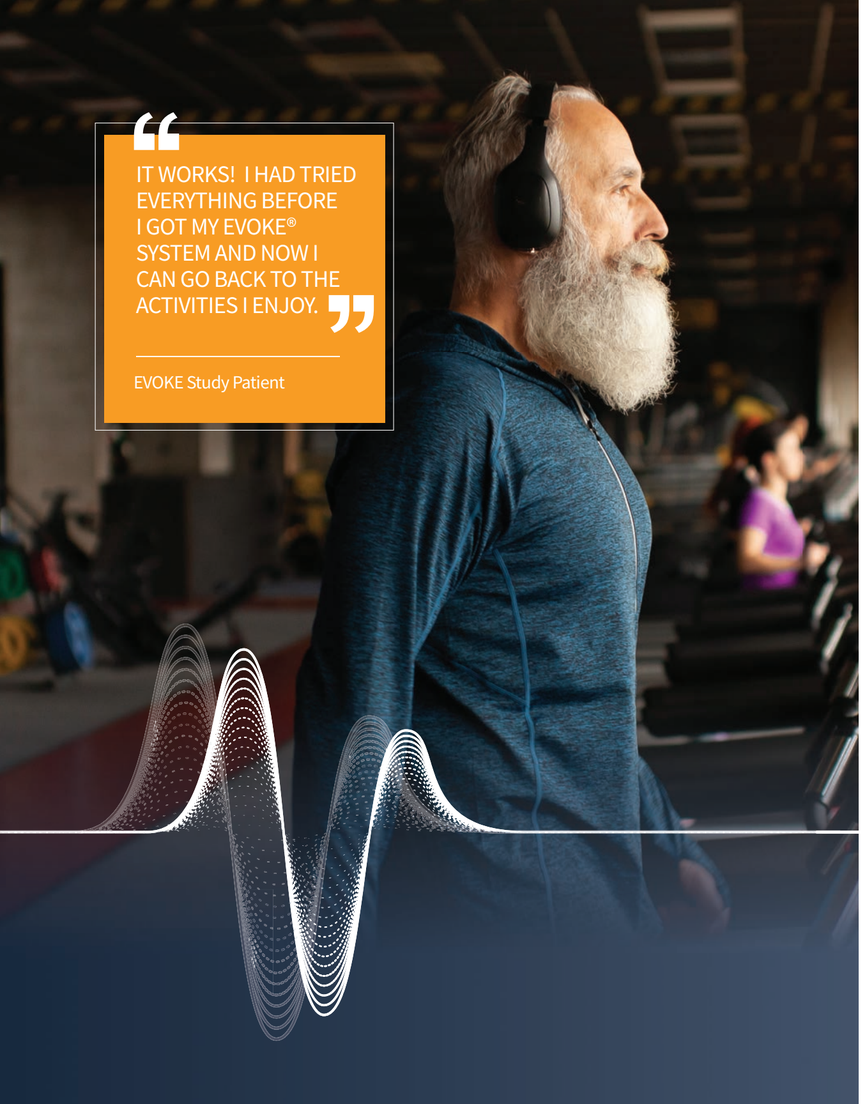
Typically, you will be **discharged the same day.**

Your provider will provide a detailed description of the procedure and instructions on what you can expect after the procedure.



2 The leads are placed in the epidural space above your spinal cord.

3 The leads are connected to a small device called an implantable pulse generator and implanted near the upper buttock, flank or other suitable area.



Get All Your Questions Answered

Here are some of the most frequent questions asked by patients considering the Evoke® System. If you have additional questions, talk to your provider or visit www.saludamedical.com.

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

Providers generally make therapeutic recommendations based on their patient's specific situation and on clinical data. The Evoke® 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.[3]

What is the recovery period for the permanent implant?

After the Evoke® System is implanted, you'll need to take it easy for six to eight weeks as your body heals. It's important to follow your specific recovery instructions and check with your provider before you become too active.

Can I go through an airport security scanner?

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 if you can walk around the scanner. If you are required to go through the scanner, please turn your stimulator off first.

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

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

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

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.

Can I get an MRI scan?

You may be eligible for an MRI Scan with your Evoke® System. Your system is MR Conditional depending on the version of your system, how your system is implanted, and how the MRI scan is performed.

Can I drive?

Yes, if done in accordance with the patient manual.

SCAN ME

For more information, visit www.saludamedical.com.

EVOKE® SmartSCS™ System

Learn More

Tear off and fill out the card below and leave with your provider. For more information, visit www.saludamedical.com.

SCAN ME

saluda MEDICAL

Act now to learn more about the Evoke® System

I have received an information kit from my doctor and I would like to have a member of the Saluda Medical team contact me to answer my questions.

NAME

PHONE

EMAIL

CITY **STATE** **ZIP**

Stay up-to-date! Saluda Medical is committed to transforming peoples' lives with disruptive neuromodulation solutions. Opt in to stay up-to-date with the latest information.

I WOULD LIKE TO RECEIVE FUTURE UPDATES ABOUT THE EVOKE® SYSTEM THERAPY.

YOUR DOCTOR

SIGNATURE/DATE

By submitting this form, you are giving permission to allow Saluda Medical to contact you. You can opt out of receiving information from Saluda Medical at any time by following the instructions in the correspondence that you receive. To ensure your privacy, Saluda Medical will not sell or share your personal information with any third parties or outside mailing lists except as required by law or as stated in our Privacy Policy. See also our Terms of Use at www.saludamedical.com.

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

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

† 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.

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

References:
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. 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. Late-Breaking Abstract Poster, Presented at NANS 2023. Data on file.
3. Mekhail N, Levy RM, Deer TR, et al. Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial. *Lancet Neurol*. 2020;19(2):123-34. PMID: 31870766.