EVOKE® The first SmartSCS™

# 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.

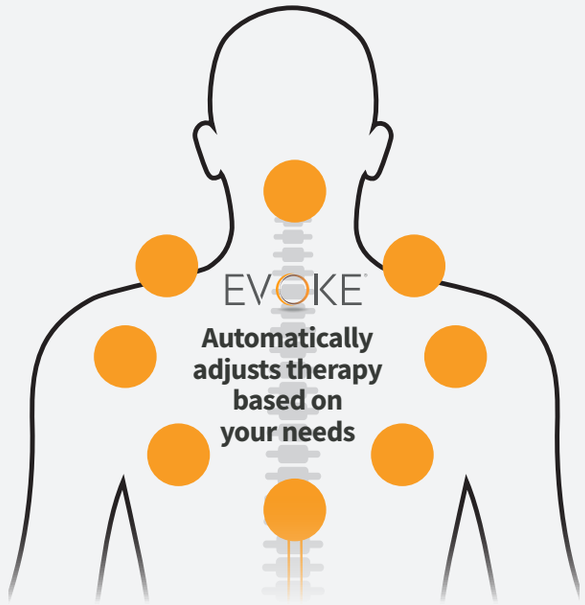
- A small device called an **implantable pulse generator (IPG)** is implanted under your skin and connected to thin leads that are placed near your spinal cord to conduct the electrical impulses that block the pain signals being transmitted to your brain.
- A **trial period** may be considered by your clinical team to assess improvement in your pain.
- At the end of your trial, you and your healthcare team will discuss your improvement and whether you will 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** listens to your body as you move and automatically adjusts **4+ million times a day** to maintain pain relief.*




** The Evoke® System takes measurements and adjusts stimulation output for 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.*

> NOW THAT MY PAIN IS UNDER CONTROL, I AM ABLE TO GET BACK TO MY NORMAL ACTIVITIES AND WORK, AND I CAN BE A HAPPIER ME.
>
> EVOKE Study patient

# A proven treatment

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

The Evoke® System was the subject of 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 when compared to current SCS systems, and with three-year data, has the longest follow-up evidence from a randomised clinical study in spinal cord stimulation.[2]

**93%** Patient **satisfaction**[2]

**83%** experienced long-term pain relief

**55%** voluntarily reduced or eliminated their opioid use

**85%** improved the 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 an average of an additional 1.2 hours of sleep per night***

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

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

> ALMOST STRAIGHT AWAY MY PARTNER SAW A LITTLE OF MY SPARKLE THAT HAD BEEN LOST FOR YEARS; I WAS ME AGAIN.
>
> EVOKE Study patient

# Evoke® System Components

## As you are considering spinal cord stimulation (SCS), it may be helpful for you 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 it generates the electrical signals that interrupt your pain signals.

### Evoke® Pocket Console (EPC)

The Evoke® Pocket Console (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 optimise 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 in your spine. 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

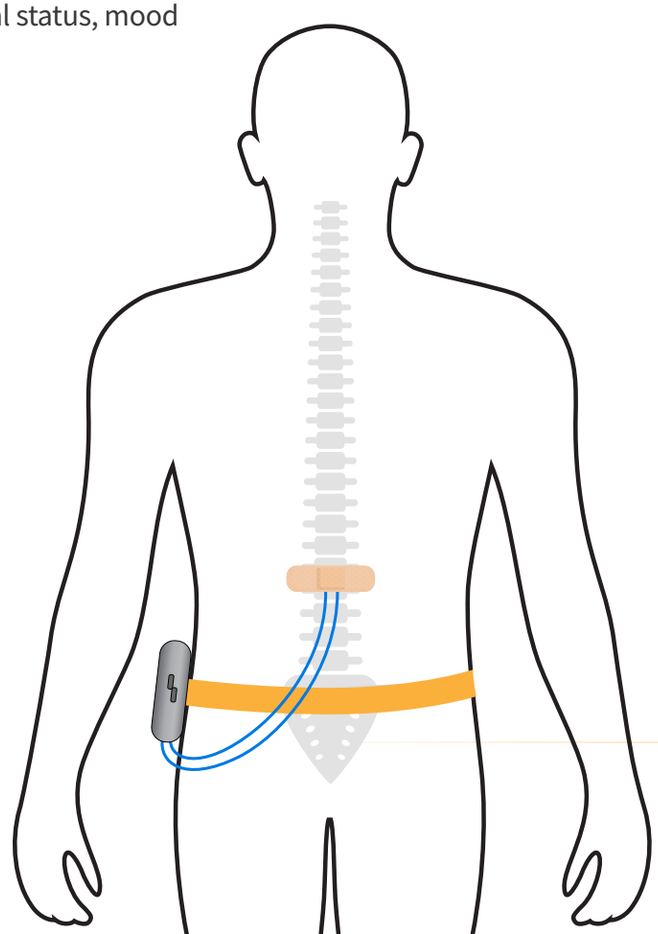
The CLS needs to be recharged to continue delivering therapy. The Evoke® Charger consists of a portable controller and charge coil. The charge coil is placed over the stimulator (on top of your clothes) and held in position until your battery is fully recharged.

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

# The Evoke® System Trial

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

- One of the advantages of SCS therapy is that **you may try it before deciding on a permanent implant.**
- The goal of the trial will be discussed with your healthcare team.
- In the EVOKE Study, **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 stimulation will be delivered by an external pulse generator.
- Your healthcare 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 Evoke®, but some patients report feeling pain relief immediately!

### At home

- You may be asked by your healthcare team to document how you're feeling.
- You may receive calls from your care team throughout your trial to help optimise your experience.

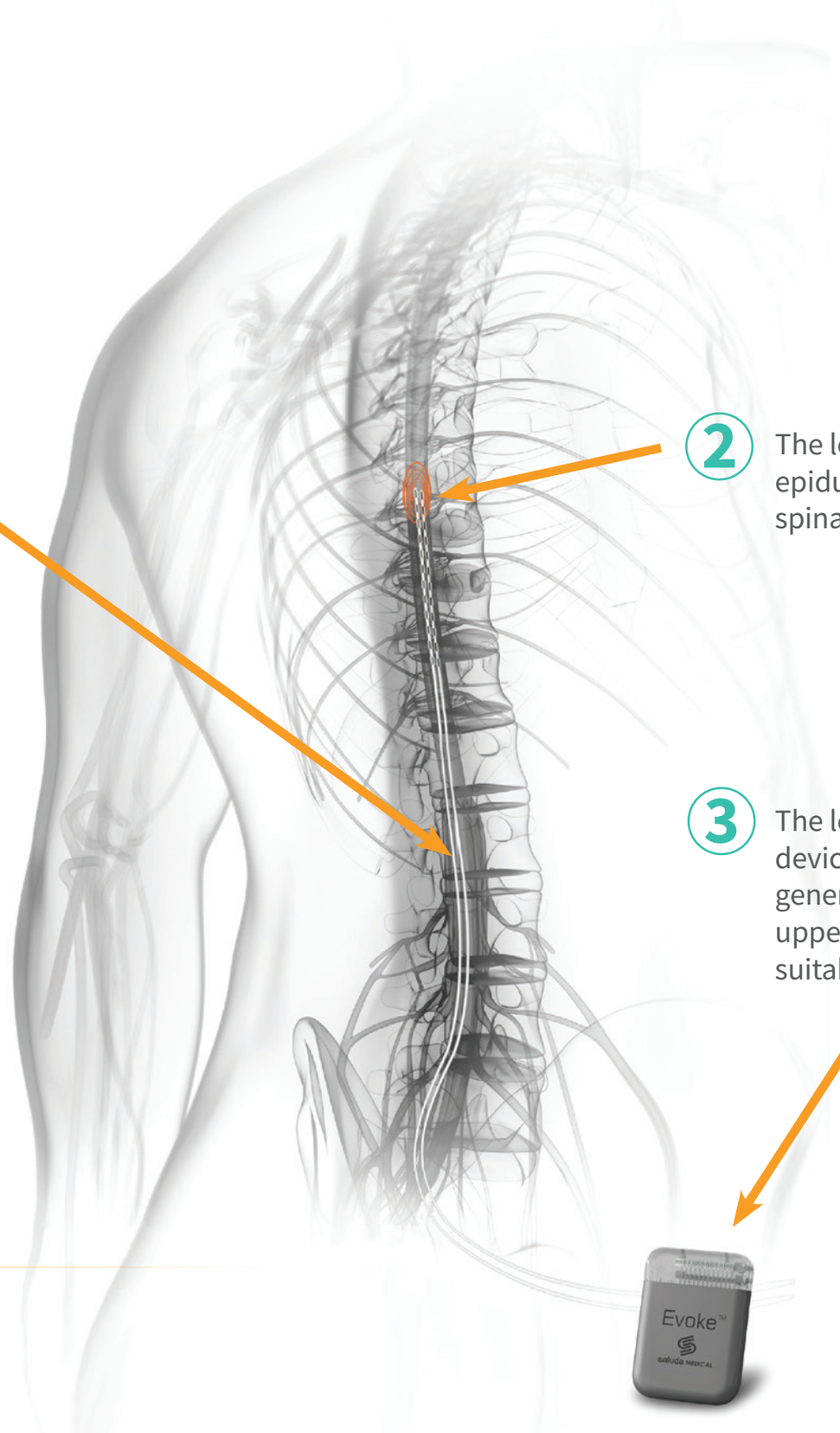
# Implanting the Evoke® System

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

The procedure is **minimally invasive.**

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

Your healthcare team 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 another suitable area.


# Get all your questions answered

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

## Why is my healthcare team recommending Evoke® over other devices?

Your healthcare team generally makes therapeutic recommendations based on each 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 that Evoke® 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 Evoke® has been 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 healthcare team 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 in 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 off your stimulator first.

## Can I stop all other treatments once my Evoke® System has been implanted?

You will continue to work with your pain-management healthcare team to ensure that 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 healthcare team so that they can check whether the items you are allergic to are used in the stimulation system.

## Can I drive?

Yes, if done in accordance with the patient manual.

For more information,
visit www.saludamedical.com.

# Important safety information

**Indications for Use**
The Saluda Medical Evoke® 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:
- Do not receive effective pain relief during the trial stimulation
- Are unable to operate the system
- Are unsuitable surgical candidates

**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 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 the details above or email us at info@saludamedical.com.

**Rx-only**

**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.