### EVERE CLOSED-LOOP SPINAL CORD STIMULATION PATIENT BROCHURE



Only to be distributed to potential candidates for treatment by a treating physician.

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#### Overview

Spinal Cord Stimulation (SCS) is a way of managing pain by interrupting pain signals, carried by the spinal cord, before they reach the brain. This is achieved by positioning 1 or 2 stimulation leads (wires) next to the spinal cord. The leads are connected to a battery-powered stimulator and carry tiny electrical pulses (stimulation) to the spinal cord. The stimulation then interrupts the pain messages to the brain, thereby helping to manage your pain.

Approximately 50,000 people across the world receive SCS systems each year to manage their chronic pain.<sup>1</sup>

Since the introduction of SCS in the 1960's, a major drawback to the systems has been the inability to account for the constant movements of the spinal cord relative to the leads. Everyday activities such as breathing, laughing, sneezing, coughing, moving around and even your heart beating can affect the distance the spinal cord is from the leads. These movements can affect the performance of your SCS therapy.





The Evoke<sup>®</sup> Closed-Loop SCS System is the only SCS system designed to measure the response of your spinal cord to stimulation and automatically adjust the stimulation.

This Closed-Loop SCS System is designed to account for the constant movements of your spinal cord and automatically keep the therapy near your preferred level.<sup>2</sup> In a recent clinical study, patients treated with the Evoke Closed-Loop SCS System received significant and long-lasting improvement in their pain intensity, disability, and sleep.<sup>2,3\*</sup>

This booklet explains how the Evoke Closed-Loop SCS System may help to reduce your pain and what you can expect if you choose this method of pain management.<sup>2-4</sup>

#### Nearly 9 out of 10

of patients received significant pain relief<sup>3,4\*</sup> >3 out of 4 people reported improvement in disability<sup>3,5\*</sup>

9 out of 10 subjects report

that the stimulator helps them sleep<sup>3,6\*</sup>



\*All patients do not respond the same way to spinal cord stimulation (SCS) and experiences may vary.

### What is Spinal Cord Stimulation (SCS)?

Chronic pain is a complicated condition to treat. The reason why this pain happens is not fully understood, but we know that pain signals are carried along the spinal cord to the brain via electrical impulses.

SCS works by interrupting the pain signals in the spinal cord before they reach the brain. Thin, flexible leads (wires) are inserted through a needle, placed next to the spinal cord, and connected to a battery-powered stimulator. These leads carry small electrical pulses (stimulation) to the spinal cord, which interrupt the pain signals.

The level of spinal cord stimulation that a person needs continuously changes with each and every pulse as the spinal cord moves with everyday activities such as walking, lying down, breathing, coughing, and even your heart beating.

Conventional SCS systems provide a fixed output of stimulation regardless of these movements, which can result in too little or too much stimulation at any time and inconsistent and/or undesirable therapy.<sup>2</sup>





### What is the Evoke Closed-Loop SCS System?

Evoke is a closed-loop spinal cord stimulation system. The Evoke System measures and records your spinal cord's response to stimulation as the spinal cord constantly moves. The system uses this measurement to adjust the stimulation and automatically keep the therapy near your preferred level millions of times per day.<sup>7</sup>

### The measurement and adjustment of output of the Evoke System is referred to as Closed-Loop SCS.



#### **Fixed-Output SCS** Requires manual adjustment of your therapy to keep stimulation comfortable (This can be up to 30 x per day for conventional SCS)<sup>9</sup>



In a recent clinical study, the Evoke System has been shown to keep your therapy near your preferred level 88% of the time.<sup>3</sup>



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All patients do not respond the same way to spinal cord stimulation (SCS) and experiences may vary.

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# Can I try the Evoke® System?

Once you and your doctor have decided that the Evoke System could help to manage your pain, you may be offered the chance to evaluate the system. This evaluation, also known as a SCS trial, will help you to decide if the Evoke System is right for you before the system is implanted.

Your doctor will place 1 or 2 leads (thin, flexible wires) next to your spinal cord. This is a minimally-invasive procedure. Once the leads are in place, they will be connected to an external stimulator, which will be programmed by your doctor or nurse to deliver the optimal stimulation to help manage your pain. This will allow you to use the Evoke System at home on an evaluation basis.

Your doctor will give you a remote control that you can use at home to adjust your preferred level of stimulation, and to turn the stimulator on and off.

The evaluation will allow you to determine whether the Evoke System helps you to manage your pain and the impact it has on your quality of life.

Please note that if you feel that the Evoke System is not right for you at any point, the system can be fully removed. You can then discuss other options with your doctor.

### What is the next step after the evaluation of the Evoke System?

If you and your doctor feel the Evoke System will make a meaningful difference to your pain and quality of life, it can be fully implanted. This is another minimally-invasive procedure.

During this procedure, the implantable Evoke Closed-Loop Stimulator will be connected to the leads and then placed under your skin.

Please note that, as in the evaluation, if you feel that the Evoke System is not right for you at any point, the system can be fully removed. You can then discuss other options with your doctor.

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### What will happen after my Evoke System is implanted?

Once you have had the Evoke System implanted and programmed, it will take measurements and adjust the stimulation to automatically keep the therapy near a preferred level for you.

There are certain physical activities that you shouldn't undertake during the first 6-8 weeks after the Evoke System is fully implanted – this helps the leads remain in the correct position while your body heals. Your doctor and/or nurse will advise.

As with all pain treatments, the Evoke System will need to be maintained by your doctor and nurse. They will invite you to attend follow-up visits and, if required, will alter your stimulation settings. Your doctor or nurse will arrange these appointments with you.



### Frequently asked questions

#### How does the Evoke System differ from other SCS systems?

Conventional SCS systems can also be effective treatments for chronic pain. However, unlike the Evoke Closed-Loop SCS System they are unable to adjust their stimulation after each and every pulse to account for the constant movements of your spinal cord relative to the leads. These movements can affect the level of the performance of the SCS therapy.<sup>2</sup> The Evoke Closed-Loop SCS System is the only SCS system designed to measure the response of your spinal cord to stimulation and automatically adjust the stimulation. The therapy is maintained near the preferred level set by you. If needed, you can also adjust your stimulation level using your remote control.

#### Will I be able to control my stimulation while at home?

Yes, you will be provided with your own remote control (Evoke Pocket Console) so that you can adjust the level of stimulation at home. The Evoke Closed-Loop SCS System is designed to measure the response of your spinal cord to the stimulation and maintain therapy near your preferred level. You may want to adjust your preferred level as it may differ over time or during the day.

#### Is it easy to recharge the stimulator?

Yes, the Evoke Closed-Loop Stimulator is charged using the Evoke Charger kit, which consists of a portable controller and charging coil. The coil is placed over the stimulator (on top of your clothes) and held in position until your battery is fully charged.

Recharging the Evoke System can be incorporated into your routine, for example, while watching your favourite television show.

### Will security gates, such as those in airports, affect my system?

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.

### What risks are associated with having an SCS system implanted?

All surgical procedures carry risks. Your doctor will discuss the risks associated with SCS systems with you prior to your procedure.<sup>10</sup>

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

No, the Evoke System works as part of your pain treatment and is not intended to replace other treatments. All changes to your pain treatments, including reducing medication, should be discussed with your doctor and nurse.

### Will I be able to have an MRI scan if I have the system implanted?

Yes, but there are specific recommendations for when MRI scans can be used once an SCS system has been implanted.

If you need to have an MRI scan, it is extremely important that you inform the doctor and staff that will perform your MRI that you have an implanted Evoke Closed-Loop SCS System, and let your pain treating doctor and/or nurse know.

Your doctor should refer to the Saluda Medical 'MRI Guidelines' manual to determine whether an MRI scan is appropriate for you.<sup>11</sup>

#### References

1. American Association of Neurological Surgeons. Spinal Cord Stimulation. American Association of Neurological Surgeons Website. http://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Cord-Stimulation. 2018.

2. Russo M, Cousins MJ, Brooker C, Taylor N, Boesel T, Sullivan R, Poree L, Shariati NH, Hanson E, Parker J. Effective Relief of Pain and Associated Symptoms With Closed-Loop Spinal Cord Stimulation System: Preliminary Results of the Avalon Study. Neuromodulation: Technology at the Interface. 2018 Jan;21(1):38-47. Sponsored by Saluda Medical.

3. Russo M, Brooker C, Sullivan R, Taylor N, Holford L, Boesel T, Gmel G, Shariati N, Poree L, Parker J. Avalon study: long-term impact of ECAPcontrolled closed-loop SCS on pain, patient wellbeing and clinical practice. Presented at: North American Neuromodulation Society (NANS) 2020 Annual Meeting; Las Vegas, NV.

4. Deer T, Hagedorn J, Jameson J, Mekhail N. A new horizon in neuromodulation. Pain Medicine. 2020 Jun 28. doi: https://doi. org/10.1093/pm/pnaa197.

5. Russo M, Brooker C, Cousins Mj, Taylor N, Boesel T, Sullivan R, Holford L, Hanson E, Gmel Ge, Shariati Nh, Poree L, and Parker J. 2020. 'Sustained Long-Term Outcomes With Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study'. Neurosurgery 87(4).

6. At 12 months, 90% of those subjects that report using their stimulation while they sleep reported that the stimulator improves their sleep. Reported on Office Visit CRF. Data on file.

7. The Evoke Closed-Loop SCS system takes measurements and adjusts stimulation output at each and every stimulation pulse delivered. SCS delivered at 40 Hz running for 24 hours, represents over 3.4 million stimulation pulses and therefore over 3.4 million measurements and adjustments per day.

8. Conventional SCS data at 7.69 mA, 240 us, and 60 Hz with the Evoke System. Data on file.

9. Schultz DM, Webster L, Kosek P, Dar U, Tan Y, and Sun M. 2012. 'Sensor-Driven Position-Adaptive Spinal Cord Stimulation for Chronic Pain'. Pain Physician 15(1). (https://pubmed.ncbi.nlm.nih. gov/22270733/).

10. Further information on risks associated with SCS can be found in the EvokeTM SCS System User Manual (CLIN-UMAN-002426).

11. Evoke<sup>™</sup> SCS System MRI Guidelines (CLIN-UMAN-002427).







#### THIS PRODUCT MAY NOT BE RIGHT FOR YOU. READ THE WARNINGS BEFORE PURCHASE

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.

#### **Participation in a Clinical Trial**

Saluda Medical is conducting a clinical trial to improve the products that treat you and your condition, therefore, we ask that you consider clinical study involvement if/when approached. Your participation is entirely your choice, you may or may not benefit, but knowledge gained from your participation may help others.

#### 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, 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 hematoma 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.

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