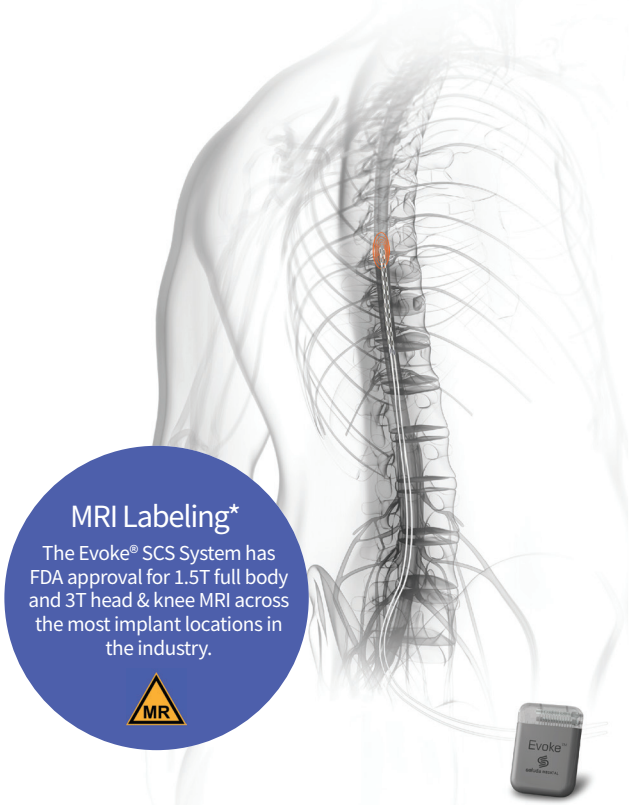

MRI Labeling*

The Evoke® SCS System has FDA approval for 1.5T full body and 3T head & knee MRI across the most implant locations in the industry.

MR

A Smarter Way to Treat Chronic Pain

With help from the world's first and only SmartSCS™ Therapy there's renewed hope that you can treat chronic pain. Like your home's smart thermostat, the unique and advanced technology found in the Evoke® System constantly listens to your body as you move and automatically adjusts your therapy 4+ million times a day to provide you long-term pain relief.**

***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.*

Important Safety Information

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

MR

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

1. 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.
2. 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.
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.

SCAN ME

For more information, visit www.saludamedical.com.

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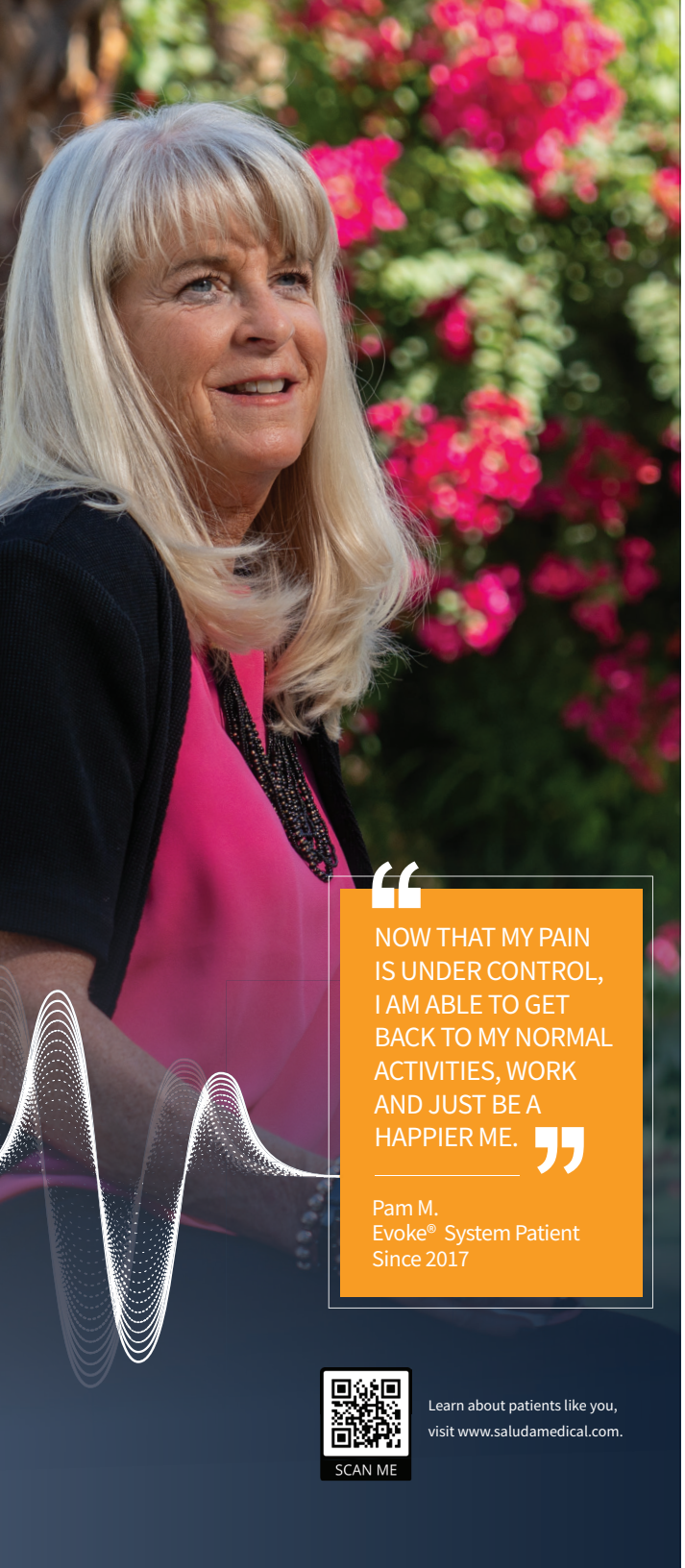
CLIN-MKT-010044 Rev. 2.0

EVOKE®
SmartSCS™ System

As Unique As You.

Finally, a smarter way to treat chronic pain.

saluda MEDICAL



> 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

SCAN ME

Learn about patients like you, visit www.saludamedical.com.

Experience The Evoke® System Difference

The EVOKE Study showed that the Evoke® System provided clinically superior treatment as well as the most durable patient outcomes from a randomized controlled trial in SCS history.[1]

93% Patient **satisfaction**

83% experienced long-term pain relief

55% voluntarily reduced or eliminated their opioid use

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

85% improved ability to perform daily activities

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

68% showed clinically significant improvements in sleep time and quality. ***EVOKE Study patients gained on average an additional 1.2 hours of sleep per night.***[3]

How Does It Work?

The Evoke® System is a spinal cord stimulation system. Spinal cord stimulation (or SCS therapy) is a safe and effective treatment that has been in use for over 55 years.[2]

- 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.
- One of the advantages of SCS therapy is that **you can try it before deciding on a permanent implant.**