Important Safety Information

Indications for Use
For U.S. — Consult product manuals prior to use. 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, highoutput 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

Full guidelines and conditions can be found at https://www.saludamedical.com/manuals
D102263 Evoke SCS System MRI Guidelines

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CLIN-MKT-009824 Rev 1.00

EVOKE® The First SmartSCS™ System

Confidence in Enduring SCS Therapy + Access to MRI

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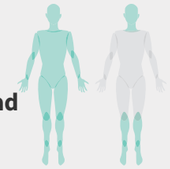
How does the Evoke® SmartSCS™ System differ from other SCS systems?

Patients Implanted with the Evoke® System, the first and only FDA approved smart spinal cord stimulation (SCS) system that has demonstrated the most enduring outcomes from the only double-blind, pivotal randomized clinical trial out to 36 months, now have access to MRI scans. Patients may undergo 1.5T full body scans and 1.5T and 3.0T head and knee scans if they and their implanted devices meet the specified conditions, including implant location and device functionality. Scan conditions and safety information are provided in the Evoke® SCS System MRI Guidelines manual.

MR Conditional System Components



Evoke® CLS

- REF 0002 , 3002, 3042
- Only radiopaque marker (SME BYY and SME EYY)

60 cm CAP12 Perc Lead

- REF 0008, 0026, 3008
- 1 or 2 leads

90 cm CAP12 Perc Lead

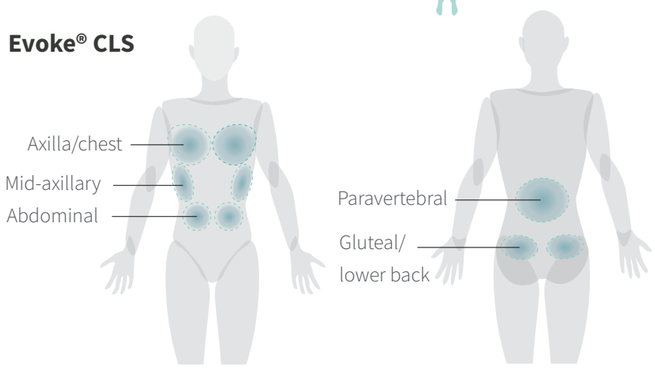
- REF 0009, 0027, 3009
- 1 or 2 leads

*Evoke® port plug and anchors approved for use with leads are MR Conditional

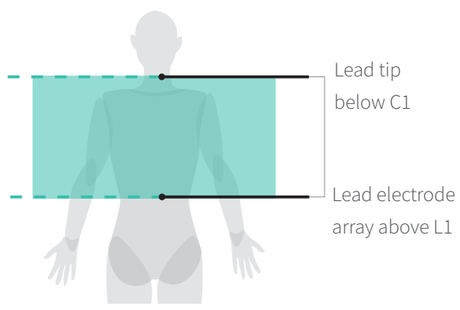
Full Body – 1.5T MRI Scans

Implant Locations

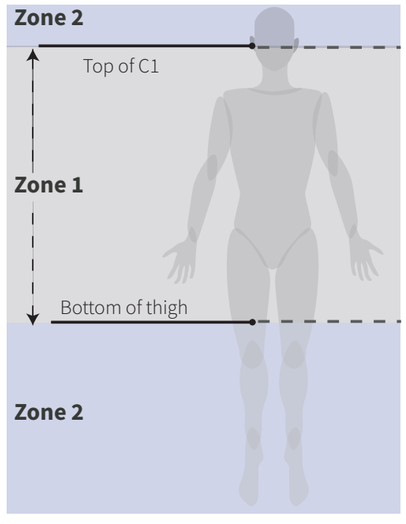
Evoke® CLS



CAP12C Percutaneous Lead



MRI Scanning Conditions



Full Body Scans

- Active scan time 30 minutes
- Maximum 1 scan per day

Zone 1: Top of C1 to bottom of thigh

- 1.5T MRI Scanner
- Body transmit coil
- Any receive coil
- SAR ≤ 1.0 W/kg

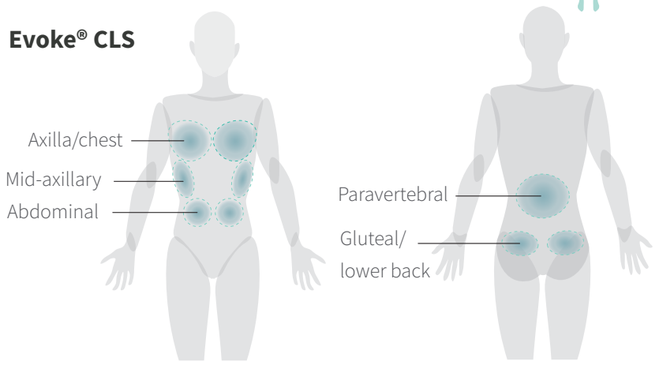
Zone 2: Head above C1, knee below thigh

- 1.5T MRI Scanner
- Body transmit coil
- Any receive coil
- Head: ≤ 2.0 W/kg
- Knee: ≤ 2.0 W/kg

Head and Knee – 1.5T and 3T MRI Scans

Implant Locations

Evoke® CLS



Head Scans

- Lead tip below C7
- No part of the Lead or CLS directly underneath the head transmit coil

Knee Scans

- No part of the lead or CLS directly underneath the knee transmit coil

MRI Scanning Conditions

Head Scans

- 1.5T or 3T MRI scanner
- Head transmit coil only
- SAR ≤ 3.2 W/kg (normal mode)
- Active scan time 30 minutes Maximum 1 scan per day

Knee Scans

- 1.5T or 3T MRI Scanner
- Knee transmit coil only
- SAR ≤ 10 W/kg (normal mode)
- Active scan time 30 minutes
- Maximum 1 scan per day

Additional Considerations for All Implant Locations

- No disconnected or shorted electrodes
- Patient does not have fever

Please consult the Evoke® SCS System MRI Guidelines US, D102263