Important Safety Information

U.S. 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, Diabetic peripheral neuropathy of the lower extremities. **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. Surgical complications and adverse events may be more frequent and severe in diabetic patients. The physiologic closed-loop controlled (PCLC) stimulation mode and frequencies greater than 1200 Hz have not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population. **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. The severity of any surgical complication may be greater in diabetic patients, particularly those with inadequate pre-operative glycemic control. **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.

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

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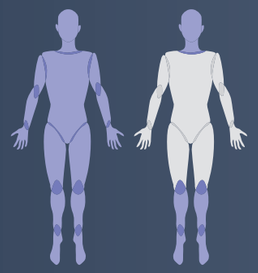
Enduring SCS Therapy + Access to MRI



EVOKE®

Evoke® System MRI Access

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® System MRI Guidelines manual.



MR Conditional System Components

CAP12® 60 cm Percutaneous Lead
- REF 0008, 0026, 3008
- 1 or 2 leads

CAP12® 90 cm Percutaneous Lead
- REF 0009, 0027, 3009
- 1 or 2 leads



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



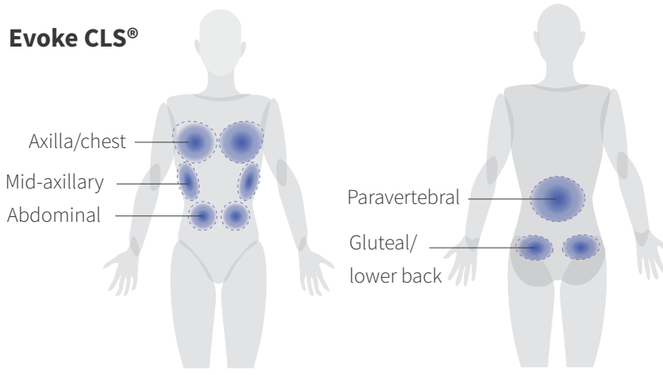
CAP24™ 70 cm Paddle Lead
- REF 3053
- 1 paddle lead

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

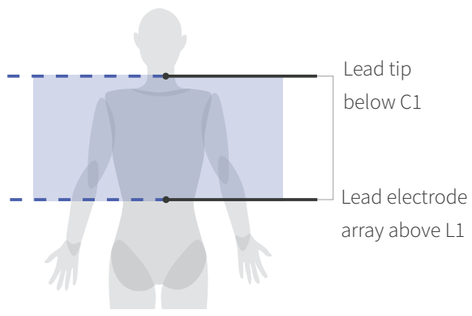
Full Body – 1.5T MRI Scans

Implant Locations

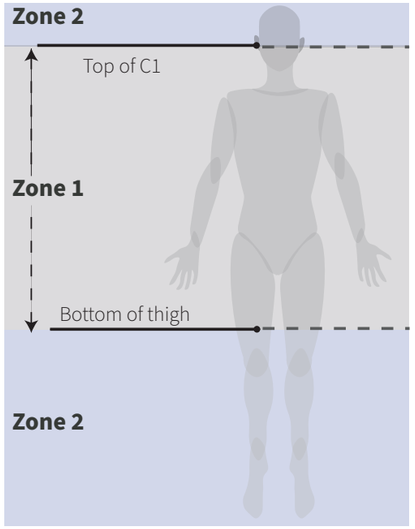
Evoke CLS®



CAP12® Percutaneous Lead and CAP24™ Paddle Lead



MRI Scanning Conditions



Full Body Scans
- 30 minute scan time
- 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, below thigh
- 1.5T MRI Scanner
- Body transmit coil
- Any receive coil

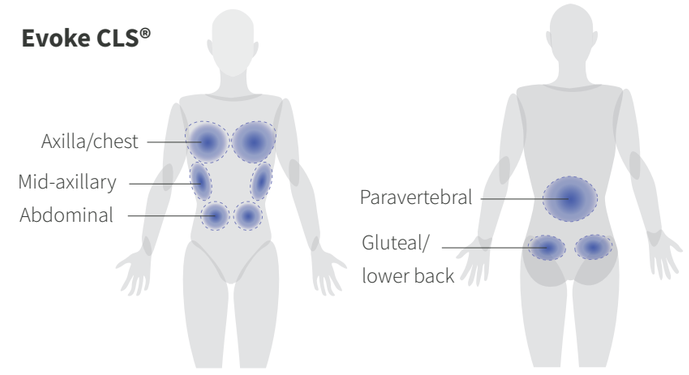
CAP12® Percutaneous Lead
- Head: SAR ≤ 2.0 W/kg
- Knee: SAR ≤ 2.0 W/kg

CAP24™ Paddle Lead
- Head: SAR ≤ 1.0 W/kg
- Knee: SAR ≤ 1.0 W/kg

Head and Knee – 1.5T and 3T MRI Scans

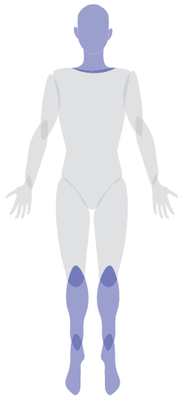
Implant Locations

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
- Any receive coil
- 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
- Any receive coil
- 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
- The CLS must be placed into 'Stock Mode' before entering the MRI suite

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