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 email us at info@saludamedical.com.

Full guidelines and conditions can be found at https://www.saludamedical.com/manuals
CLIN-UMAN-002427 Evoke SCS System MRI Guidelines

saluda MEDICAL®

CLIN-MKT-010151 Rev 1.00

EVOKE® The First SmartSCS™ System

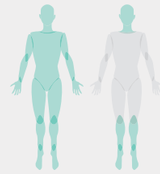
Confidence in Enduring SCS Therapy + Access to MRI

saluda MEDICAL®

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

Patients implanted with the Evoke® System, the first and only 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 1002
- Only radio opaque marker Rev B – (SME BYY)

60 cm Evoke® 12C Lead

- REF 1008
- 1 or 2 leads

90 cm Evoke® 12C Lead

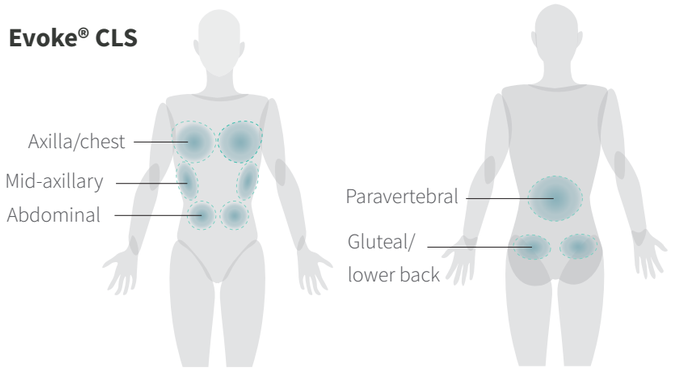
- REF 1009
- 1 or 2 leads

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

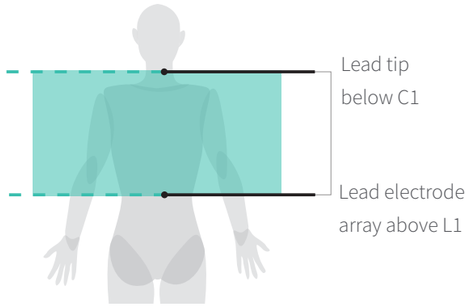
Full Body – 1.5T MRI Scans

Implant Locations

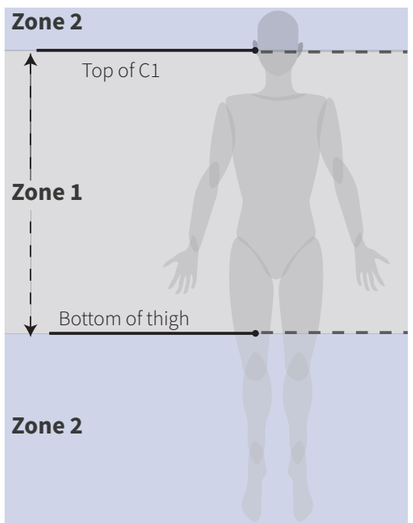
Evoke® CLS



CAP12C Percutaneous Lead



MRI Scanning Conditions



Full Body Scans

- 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 ≤ 0.9 W/kg or B1+rms ≤ 1.96 uT

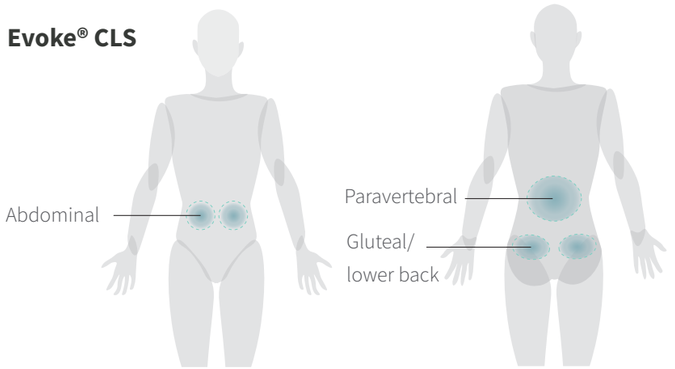
Zone 2: Head above C1, knee below thigh

- 1.5T MRI Scanner
- Body transmit coil
- Any receive coil
- SAR ≤ 2.0 W/kg or B1+rms ≤ 3.87 uT

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)
- 15 minute scan time with 15 minutes between scans
- 2 scans per day

Knee Scans

- 1.5T or 3T MRI Scanner
- Knee transmit coil only
- SAR ≤ 3.2 W/kg (normal mode)
- 15 minute scan time with 15 minutes between scans
- 2 scans 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 CLIN-UMAN-002427