

Can I Get an MRI Scan?

You may be eligible for an MRI Scan with your Evoke[®] SmartSCS[™] System. Your system is MR Conditional depending on the version of your system, how your system is implanted, and how the MRI scan is performed.



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.

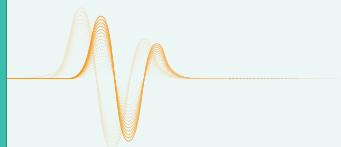
Warnings/Precautions

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

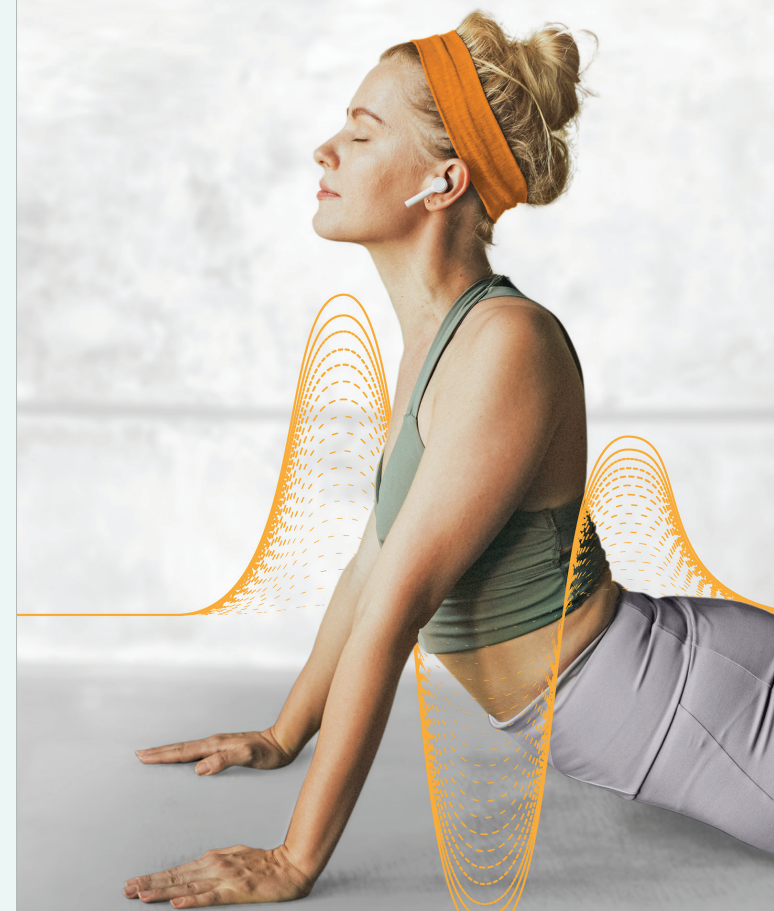
May include: undesirable changes in stimulation sensation and/or location; uncomfortable changes in stimulation (over and/or under stimulation); persistent post-surgical pain at hardware implantation sites; CLS migration, which may result in pain or difficulty in charging; seroma or haematoma at surgery 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.



Getting an MRI Scan

With the Evoke[®] SmartSCS[™] System



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Scheduling Your MRI Scan

Here are the first steps:

- ✔ Tell the doctor who prescribes your MRI scan that you are implanted with a Saluda Medical Evoke® System.
- ✔ Contact your Pain Specialist to discuss your prescribed MRI scan.
- ✔ Your Pain Specialist may provide you or your radiologist at the MRI center a copy of the **Evoke® SCS System MRI Scanning Checklist**.
- ✔ When scheduling your MRI, provide the MRI Center with the following information, which can be found on your Patient ID Card and on the **Evoke® SCS System MRI Scanning Checklist**:
 - Model (REF) numbers of your Evoke® System
 - Implant location of your Evoke® System
 - Your Pain Specialist's contact information
- ✔ Contact your Healthcare team at your implanting center, once you have scheduled your MRI.



Scan this code to access the MRI Checklist and MRI Guidelines.

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The Day Before Your MRI Scan

Remember to prepare your devices:

- ✔ Charge your Evoke® Closed Loop Stimulator.
- ✔ Charge your Evoke® Charging System (if needed).
- ✔ Ensure your Evoke® Patient Controller (Remote Control) batteries do not need to be replaced (EPC Low Battery Indicator light on).
- ✔ If you have any questions prior to your MRI contact your Healthcare team at your implanting center.

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The Day Of Your MRI Scan

Things to bring with you to your MRI:

- ✔ Evoke® Patient Controller (Remote Control)
- ✔ Magnet that came with your Patient Controller
- ✔ Evoke® Charger
- ✔ Patient ID Card
- ✔ **Evoke® SCS System MRI Scanning Checklist** (if provided by your Pain Specialist)

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After Your MRI Scan

The Evoke® Stimulator should be taken out of stock mode:

- ✔ Hold the Charger coil over the implanted stimulator, press and hold the “start charging button” green button.
- ✔ Once the Evoke® Stimulator starts charging, the stimulator has been taken out of stock mode.

Confirm your Evoke® Stimulator functionality using your Patient Controller:

- ✔ Connect your Patient Controller to your Evoke® Stimulator.
- ✔ Turn stimulation on and adjust stimulation.

NOTE: Do not bring your Evoke® Patient Controller, Charger, or Magnet into the room where your MRI will be performed. The implanted components of your Evoke® System may be MR Conditional, but your external patient devices are not.

