

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

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.

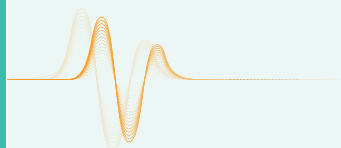
Potential Risks:

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

EVOKE[®]
powered by SmartLoop

Getting an MRI Scan With the Evoke[®] SmartSCS[™] System



 **saluda** MEDICAL

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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 Saluda Medical representative or call 952-491-4256, 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 Saluda Medical representative or call 952-491-4256.

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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 Evoke® Patient Controller:

- ✔ Connect your Evoke® 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.

