# Evoke® SCS System MRI Scanning Checklist

**NOTE:** Before conducting an MRI scan, always ensure that you are using the most recent version of the Evoke MRI Guidelines. This is available online at **https://www.saludamedical.com**.

**Appendix A. Checklist for MR Conditional Scans**

Complete this form to help determine if a patient implanted with an Evoke SCS System may be eligible for an MRI scan.

**Patient name**

**Physician name and contact information** (facility name, address, phone number)

**Date of eligibility assessment**

| Implanted Component | Quantity | Model (REF) | Location |
|---|---|---|---|
| **CLS** (1 maximum, always with 1 or 2 leads) | | ☐ 1002 | Serial:<br>OR Radiopaque ID:<br>Location: |
| **Lead** (1 or 2, always with 1 CLS) | | **60cm** ☐ 1008 | |
| | | **90cm** ☐ 1009 | |
| **Lead Extension** (0 or 1, per 60 cm lead) | | ☐ 1011 | |
| **Port Plug** | | N/A | |
| **Suture Anchor** (0 or 1 per lead) | | N/A | |
| **Active Anchor** (0 or 1 per lead) | | N/A | |

⚠ **WARNING:** If the patient has another MR conditional implant, then the scanning instructions for the other system should be compared to these and the least intensive MRI scan settings should be used. If it is unclear what implants are present, perform an X-ray to determine the implant type and location.

| | MRI Guidelines Section | Eligibility Condition | Yes | No / Unknown |
|---|---|---|---|---|
| **1.** | | Identify the RF coil type for the scan:<br>☐ Head: 1.5 or 3T ☐ Knee: 1.5 or 3T ☐ Full-body: 1.5T | | |
| **2.** | 3.1 and 3.2 | The patient has only CLS and lead models that are MR Conditional. (See the patient's ID card or records for CLS and lead models.) | ☐ | ☐ |
| **3.** | 3.2 | Only one CLS is implanted. | ☐ | ☐ |
| **4.** | 3.2 | MR Conditional components are the only components that are implanted. | ☐ | ☐ |
| **5.** | 3.3 | Identify the location of the implanted components (including lead tips). The CLS and implanted leads are within acceptable areas for scanning. | ☐ | ☐ |
| **6.** | 5.1 | The patient's temperature is normal. | ☐ | ☐ |
| **7.** | 5.1 | All implanted components are properly connected and functional. | ☐ | ☐ |
| **8.** | 5.1.1 | Impedance measurement shows no channels are disconnected or shorted. | ☐ | ☐ |
| **9.** | 5.1.2 | The CLS has been placed into Stock Mode. | ☐ | ☐ |
| **10.** | 5.2 | The scan settings are appropriate for the intended scan region and for the RF coil that will be used. | ☐ | ☐ |

If all of the eligibility conditions are confirmed "Yes", refer to the **Evoke MRI Guidelines** for complete information on conducting an MRI scan. If any of the answers are "No" or "Unknown", do not perform the scan. Contact the patient's physician or the patient's Saluda Representative for help.

# 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.

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