



MR Conditional

Nevro® Senza® Spinal Cord Stimulation System 1.5 Tesla Magnetic Resonance Imaging (MRI) Guidelines

This document is a supplement to the Senza SCS system physician and patient manuals and is related only to the use of a transmit/receive radio frequency (RF) head coil of a 1.5 Tesla horizontal bore MRI system for patients implanted with the Nevro Senza Spinal Cord Stimulation (SCS) system.

The implanted components of the Senza system may include Nevro percutaneous leads (Model No.: LEAD10x8-xxB), lead extensions (Model No.: LEAD2008-xxB), lead anchors (Model No.: ACCK5xxx), and the Senza implantable pulse generator (Model Nos: NIPG1000 or NIPG1500).

Please note that MR Conditional components of the Senza system **shall not** include S8 lead adaptors (Model No.: SADP2008-xxB) and M8 lead adaptors (Model No.: MADP2008-xxB).

It is important to read this full document prior to conducting or recommending an MRI examination on a patient with the Nevro Senza SCS system. These instructions only apply to the Senza system, and do not apply to other products. If you have any questions, please contact Nevro at the address or phone number at the end of this document. These instructions can also be found at Nevro website (www.nevro.com/ous/mri).

Introduction

Magnetic Resonance Imaging (MRI) uses a powerful static magnetic field, gradient magnetic fields, and RF energy to construct an image of a section of the body used for diagnosis of various diseases and conditions. Benchtop tests have shown that patients implanted with the Nevro Senza system can be safely exposed to MR environments specified in this guideline.

However, MR scans performed outside the guidelines may result in MRI field interacting with implanted devices, which may potentially cause movement and/or excessive heating of or around the implanted device components, tissue damage, damage to the device, and uncomfortable jolting sensation. Additionally, the metallic components of the implanted device could add an image artifact resulting in a less effective image for diagnostic purposes. Due to these risks associated with using an MRI with an implanted device, it is important to read, understand, and comply with these instructions to prevent harm to the patient and device undergoing MRI examination.

Definition of terms used in this document

*MR Conditional*¹: an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

Radio frequency (RF) magnetic field: the magnetic field in MRI that is used to flip the magnetic moments.

*Specific absorption rate (SAR)*¹: the mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg.

*Tesla, (T)*¹: the SI unit of magnetic induction equal to 10⁴ gauss (G).

*Transmit/Receive RF head coil*¹: a coil used to transmit and receive RF energy that is limited to the head only.

Intended Use

MRI examinations of the head can be safely conducted in patients with the Nevro® Senza® Spinal Cord Stimulation system if all the instructions in this document are followed. Non-clinical testing has shown the Nevro Senza SCS system to be MR conditional when exposed to the MRI environment under the specific conditions listed below:

- Stimulation must be turned off
- Use only a transmit/receive RF head coil
- Use only a 1.5-Tesla horizontal bore MRI system
- No part of the implanted system (implantable pulse generator (IPG), extensions, leads) may be within the RF transmit/receive head coil
- Limit the gradient dB/dt field to 20 Tesla per second or less
- Use MRI examinations parameters that limit the Head Specific Absorption Rate (SAR) level lower than 1.5 W/kg
- MRI scan duration shall not exceed a total of 15 minutes of active scan time.

Risks and Warnings Associated with MRI

Instructions in this document were determined by thorough non-clinical testing and should result in a safe MRI examination with the Senza SCS system. However, as many variables can impact safety, the safety of patients and continued functionality of the device exposed to MRI cannot be absolutely ensured.

¹ ASTM F2503-08, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"

Use only a transmit/receive RF head coil. The risk of using a transmit or transmit/receive RF body coil have not been determined.

Use only a 1.5-Tesla horizontal bore MRI system. Do not use open-sided MRI systems or systems operating at other static magnetic field strengths. Do not use higher or lower static magnetic field strengths (0.5, 1.0, or 3.0T). The risks of using MRI systems operating at other static magnetic field strengths have not yet been determined.

The trial stimulator (TSM), patient remote, charger, and physician programmer are MR Unsafe and should not be allowed into the MRI scanner (magnet) room.

Prior to MRI Examination

- If the patient has a device or device component (lead, extension, etc) from a different manufacturer attached to the Nevro® IPG using a Nevro adaptor, do not perform an MRI. The risks of performing MRI scan with a Nevro IPG connected to a lead manufactured by a different company have not been evaluated.
- An individual with proper knowledge of MRI equipment such as an MRI-trained radiologist or MRI physician must confirm that MRI examination will be conducted according to the information in this document.
- Identify if the patient has any other medical device implants. The most restrictive MRI exposure requirements must be used if the patient has multiple medical device implants. Consult with the manufacturers of the devices.
- Do not conduct an MRI if there are any orphan leads, or additional leads not connected to the Nevro Senza® IPG in the patient.
- Do not conduct an MRI if the leads are not connected to the IPG or Lead Extensions.
- Do not conduct an MRI with a trial stimulator (TSM). Only conduct an MRI with an implanted system.
- Confirm no part of the implanted system (IPG, extensions, leads) are within the RF transmit/receive head coil.
- Inform the patients of all the risks associated with undergoing an MRI examination as stated in this document.
- Perform an impedance check. Do not perform an MRI if any impedance is greater than 10 KΩ.
- Document the patient's programming parameters.
- Turn stimulation off. This can be done using either the programmer, patient remote, or patient charger.
- Allow at least two weeks' time between the date of IPG implantation to the time of the MRI examination.
- If possible, do not sedate the patient so the patient can inform the MRI operator of any problems during the examination.

- Instruct the patient to immediately inform the MRI operator if any discomfort, stimulation, shocking, or heating occurs during the examination.
- There are no restrictions regarding blankets.
- MRI images may be distorted or blocked if near implanted system components.

During the MRI Examination

- Carefully monitor the patient throughout the MRI examination both visually and audibly. Discontinue the MRI examination immediately if the patient cannot respond to questions or reports any problems.
- The radiologist or MRI physician must verify all proposed examination parameters comply with this document. If the parameters cannot be changed to comply with this document, do not perform the MRI examination.
- Once the Senza[®] SCS system is off, the MRI will not cause the device to begin stimulation.

After the MRI Examination

- Confirm the patient feels normal.
- Switch on the device and restore the programmer parameters.
- Confirm the patient is programmed to the prior settings.

Throughout and after the MRI examinations, if there are any adverse events or issues please contact Nevro Corp.

NEVRO CORP.

All questions or concerns about Nevro products should be forwarded to:



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IMPORTANT: Changes or modification to any component of the Nevro® Spinal Cord Stimulation system, unless expressly approved by Nevro Corp., could void your authority to operate this product.

FOR USA:

CAUTION: Investigational Device. Limited by Federal (USA) law to investigational use.