Pain Physician 2025; 28:451-465 • ISSN 1533-3159

Narrative Review

# Advancements in MRI Conditionality of Spinal Cord Stimulation Systems: A Narrative Review of Recent SCS Systems and Their Associated Risks in MRI Operations

Pravardhan Birthi, MD[1,2], Mahesh Pattabiraman, PhD[1,3], Harish Kalaivanan, MBBS[1], Aparajitha Rajkumar, MBBS[1], Vittal R Nagar, MD, PhD[4], Anterpreet Dua[5], Mittal S. Prajapati, MD[6], Akshay Agarwal[7], and Surabhi Chandra, PhD[1,3]

From: [1]TriCity Research Center, Grand Island, NE; [2]Grand Island Pain Relief Center, Grand Island, NE; [3]University of Nebraska Kearney, Kearney, NE; [4]St. Croix Regional Medical Center, St Croix Falls, WI; [5]Augusta University, Medical College of Georgia, GA; [6]Creighton University, Omaha, NE; [7]Bryan Health, Grand Island, NE

Address Correspondence: Mahesh Pattabiraman, PhD TriCity Research Center, Grand Island, NE E-mail: pattabiramm2@unk.edu

Disclaimer: P. Birthi, M. Pattabiraman, H. Kalaivanan, and A. Rajkumar contributed equally to this manuscript. There was no external funding in the preparation of this article.

Conflict of interest: PB and MP are co-founders of TCRC, a clinical research organization, and funding was received to conduct trials involving spinal cord stimulation technologies. Currently, TCRC is conducting 2 funded studies supported by Saluda Medical Pty Ltd. and Abbott Medical Inc. Other authors certify that he or she, or a member of his or her immediate family, have no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Article received: 10-16-2024
Revised article received: 03-17-2025
Accepted for publication: 06-20-2025

Free full article: www.painphysicianjournal.com

**Background:** Spinal cord stimulation (SCS) has become a vital therapy for managing intractable chronic pain, especially in patients unresponsive to conventional treatments. However, integrating SCS devices with magnetic resonance imaging (MRI) poses significant clinical challenges. The strong magnetic and radio frequency (RF) fields generated by MRI can interact with the implanted SCS devices, leading to potential risks such as device malfunction, heating, and image distortion, which complicate both the safety and efficacy of this essential diagnostic tool. New-generation SCS devices are now designed with modern materials and circuitry, which renders them relatively safe. The plethora of devices and leads available in medical industry market requires practitioners and technicians to develop a comprehensive overview of MRI-conditional technologies and remain aware of the challenges, failures, and safety concerns that still exist, albeit to a much lesser extent.

**Objective:** This review aims to thoroughly evaluate the current advancements and challenges in MRI-conditional SCS devices. The study focuses on the technological innovations that have enhanced the safety of such devices, the specific operational conditions under which these devices are deemed safe, and the clinical implications of these developments. By summarizing pertinent information from manufacturer specifications and coverage of commonly encountered malfunctions and adverse events for devices used in mainstream clinical practice, this review seeks to offer valuable insights for clinicians navigating the complexities of SCS device management in patients requiring MRI diagnostics.

**Methods:** This review was conducted through a comprehensive analysis of device manufacturers' manuals and guidelines; recent literature, including peer-reviewed articles; case studies; and safety data obtained from regulatory bodies and authentic publicly available information. The analysis focused on identifying technological advancements and reported adverse events as well as the clinical implications of using SCS devices in MRI environments. By synthesizing findings from various sources, the review presented an integrated perspective on MRI safety in SCS therapy.

**Results:** The review identified several key advancements in MRI-compatible and conditional SCS devices, with significant improvements in lead design, shielding techniques, and device programming that have enhanced the devices' safety in MRI environments. However, despite these advancements, multiple instances of device malfunction, particularly those related to high lead impedance, heating under MRI exposure, inability to enter or exit MRI modes, and more, were reported across various manufacturers; in some cases, these issues have led to FDA recalls, manufacturers' advisories, and warnings. Additionally, observations were made regarding the prevalence of certain types of operational failures in devices made by specific manufacturers.

**Conclusion:** The evolution of MRI-compatible SCS devices has markedly improved the safety and efficacy of combining SCS therapy with essential diagnostic imaging. Ongoing technological advancements and rigorous safety validations continue to enhance patient outcomes, allowing individuals with chronic pain to receive comprehensive care without compromising on diagnostic accuracy or therapeutic efficacy. Knowledge of operational guidelines and device specifications combined with guarding against commonly encountered safety challenges should protect patients

from serious adverse events. Future developments must tackle the remaining challenges and refine MRI compatibility to further integrate these critical aspects of patient care.

**Key words:** Spinal cord stimulator, Magnetic Resonance Imagine, pain, neuromodulation

**Pain Physician 2025: 28:451-465**

In the realm of neuromodulation, spinal cord stimulation (SCS) represents a cornerstone therapy for managing chronic pain, particularly in cases unresponsive to conventional medical management (1,2). Emerging neuromodulation techniques offer new possibilities for treating chronic neuropathic pain beyond even traditional SCS (3). However, the functionality of SCS devices intersects with the need for magnetic resonance imaging (MRI) and has thus historically presented significant clinical challenges (4). For this reason, traditional SCS systems, despite their effectiveness, have encountered limitations in attempts to integrate them with imaging technologies like MRI, often necessitating complex management protocols.

MRI, a critical diagnostic tool, offers unparalleled soft tissue contrast and detail, which are essential for diagnosing conditions that are often concomitant with chronic pain syndromes. However, the presence of an implanted SCS device has traditionally imposed limitations, due to the risks associated with the interactions that MRI's strong magnetic and radio frequency (RF) fields may have with the ferromagnetic components of the implantable pulse generator (IPG) devices and their leads. The strong magnetic fields required for operating MRI procedures interact with the electronics and device components in SCS systems, resulting in damage to the device, displacement of leads in the device or tissue, lead heating, changes in device settings, and unprogrammed or unintended stimulations (4-7). A device's MRI compatibility status as defined by the FDA is highlighted in Table 1.

Recent advancements in SCS technology have significantly improved the safety profiles of these devices, which is predominantly due to innovation in materials science and electronics utilizing non-ferromagnetic components in the setup. Modern systems are increasingly designed to be MRI-conditional, permitting patients with implants safer access to MRI diagnostics (10,11). Such developments not only enhance patient safety but also expand the utility of SCS therapies by mitigating previous diagnostic and therapeutic limitations.

This review aims to critically evaluate the safety and performance of MRI-conditional SCS devices, examining both the technological advancements that have been made and the ongoing challenges such as device malfunctions and failures that arise during MRI procedures. We will explore the important MRI conditions that need to be considered under which these devices operate safely, highlight the operational guidelines issued by manufacturers, and provide a snapshot of safety profiles of these MRI devices as evaluated based on surveys of scientific, regulatory, and news reports. The tables of MRI-conditional specifications are designed to provide a general and comparative overview between brands and manufacturers. Through this comprehensive analysis, this review seeks to serve as a quick and useful resource for clinicians and MRI technicians serving SCS patients.

## Clinical Relevance of MRI in Chronic Pain Management

MRI holds a pivotal role in the diagnostic process for chronic pain conditions, offering unparalleled insights into the anatomical structures and pathologies of the spine and surrounding tissues (13,14). Chronic pain, often a complex and multifaceted ailment, can be rooted in various spinal abnormalities such as herniated discs, spinal stenosis, nerve root compression, etc. MRI's ability to provide high-resolution images of both hard and soft tissues without ionizing radiation makes it an indispensable tool in the comprehensive evaluation of these conditions (15). MRI uses strong magnetic fields and radio waves to align hydrogens (protons) in the body's water molecules, which are then perturbed by RF pulses. The resulting signal emitted by these protons as they return to their original alignment is captured and transformed into detailed images by sophisticated computer algorithms. This process allows for the visualization of complex structures within the vertebral column and adjacent areas, highlighting abnormalities that may be contributing to a patient's pain syndrome (16). For instance, the soft tissue contrast provided by MRI is critical for identifying and differentiating between diseased and healthy tissue in the spinal cord and nerves.

However, the integration of MRI examinations into the management of patients with implanted medical devices, such as SCS systems, introduces a layer of complexity. Traditional SCS devices, which include metal components and electronic circuits, can interact with MRI's magnetic and electromagnetic fields, potentially leading to adverse effects such as device malfunction, displacement, or harm to the surrounding tissue due to induced currents or heat (20). These risks necessitate rigorous testing and modification of both new and existing SCS technologies to ensure MRI compatibility. As a result, the development of MRI-conditional SCS devices represents a significant advancement in the engineering of medical devices, bridging the gap between effective pain management and essential diagnostic imaging.

The evolution of MRI-compatible SCS devices underscores a critical shift toward safer, more versatile treatment modalities in pain management. By accommodating the need for regular and emergent MRI scans, these devices ensure that patients receive not only ongoing therapeutic benefits but also continual access to the best diagnostic resources. This dual capability is essential for dynamic pain management strategies, particularly in cases in which pain patterns change or evolve, requiring periodic reassessment of underlying conditions and therapeutic responses.

## Challenges of MRI with Implanted Devices

The integration of SCS devices with MRI systems presents a series of technical and safety challenges that stem primarily from the interaction between the MRI systems' magnetic fields and the electronic and metallic components of the implanted devices (20). MRI scanners operate using a strong static magnetic field, gradient magnetic fields, and RF fields, each of which can adversely affect an implanted SCS device.

Magnetic Field Interactions. The static magnetic field of an MRI scanner, typically ranging from 0.5T to 3T in clinical settings, can exert forces on ferromagnetic materials found in some older or non-MRI-compatible SCS devices. This effect can lead to torque or displacement of the device, potentially causing patient discomfort or injury and displacement of the device from its therapeutic position (23,24). Even in devices designed without ferromagnetic materials, the presence of any metallic component can distort the MRI's magnetic field, leading to significant imaging artifacts that obscure diagnostic information around the implant site. The inherent technological incompatibility between MRI and SCS devices is further complicated by the need for strong magnetic fields for better imaging resolution, which also increases the risks due to interference.

Table 1. *Major terms and their commonly accepted definitions.*

| Status | Definition |
|---|---|
| MRI-safe | A medical device that poses no known hazards resulting from exposure to any MR environment. MR-safe medical devices are composed entirely of materials that are electrically nonconductive, nonmetallic, and nonmagnetic. |
| MRI-conditional | A medical device with demonstrated safety in the MR environment within defined conditions, including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the RF fields. |
| MRI-unsafe | A medical device that poses unacceptable risks to the patient, medical staff, or other persons within the MR environment. |

Note: The term "MR-compatible," which appeared in a 1997 FDA draft guidance document and was frequently misinterpreted, is obsolete and should not be used. (ASTM F2503-20 Standard Practice for Marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment. ASTM International.)
ASTM = American Society for Testing and Materials

RF Field-Induced Heating. One of the most major risks involves the RF fields used during MRI scans, which can induce currents in conductive materials such as the leads of SCS devices (25). This phenomenon can cause significant heating at the tip of the lead or along the lead body, potentially resulting in tissue damage if the heating is not controlled adequately. The extent of RF-induced heating depends on several factors, including the design of the lead, its positioning relative to the RF coil, and the specific MRI conditions, such as the scanner's operating frequency and the type of sequence used (20,26).

Image Distortions. SCS devices are known to create imaging artifacts, particularly around the electrode leads, which can impact the quality of MRI scans significantly (27). These artifacts, which often present as signal voids or distortions, are typically caused by signal loss around the metallic components of the leads, disturbances in the homogeneity of the magnetic field, and changes in resonance frequencies near the implant site. The artifacts are generally localized to areas surrounding the electrode leads, such as the dorsal epidural space, but can obscure important diagnostic information, especially in cases requiring detailed imaging of spinal cord lesions, inflammation, or other abnormalities. The extent and severity of these artifacts can vary depending on such factors as the design of the

SCS leads, their position relative to the MRI coil, and the specific MRI settings being used.

Device Functionality and Malfunction. Beyond physical risks, the interference of the electromagnetic environment and incident RF on the electronic functionality of implantable devices in general has been documented in a study by Brown et al (28) that provides an understanding of the mechanisms behind RF-induced malfunctions, such as unintended stimulation or device failure, during MRI exposure. The possible results of interference can range from temporary malfunctions to permanent damage, affecting the device's ability to deliver therapy. For instance, the gradient magnetic fields and the radio frequencies, the former of which change rapidly to produce images, can induce voltages in electronic circuits that may lead to inappropriate responses or reprogramming of the device (29).

Given these challenges, the designing and testing of SCS devices for MRI compatibility requires meticulous engineering to mitigate risks. Manufacturers must employ robust shielding techniques, use nonferrous materials, and design circuits that can tolerate or avoid the induction currents (30). Additionally, the development of leads that minimize RF-induced heating has been a focal point of recent innovations in device design. Recent comparative analyses of MR-conditional SCS devices have also highlighted several failure modes that can arise even when designs adhere to manufacturer guidelines. These problems include issues such as unexpected device lockups in MRI mode, lead impedance varying in ways that affect conditionality status, and inconsistent RF shielding performance, all of which pose potential safety concerns during MRI exposure (31). Additionally, mismatches in device responses to MRI protocols across different manufacturers are also well-documented matters of concern.

## Technological Innovations Enabling MRI Compatibility in SCS Devices

The conjunction of SCS and MRI technologies in treatment and diagnostics has significantly advanced due to innovations in device materials, lead technology, and electronic safety features. Modern SCS systems are constructed with non-ferromagnetic materials that minimize magnetic interference and reduce risk during MRI scans. Leads are now designed to mitigate RF-induced heating, a critical challenge in earlier designs, through improved structural configurations and protective coatings. These enhancements have established a new standard in patient care, allowing individuals with implanted SCS devices to gain access to essential MRI diagnostics without compromising their pain management therapy. This shift not only reflects significant technological progress but also improves clinical outcomes by ensuring continuous compatibility with evolving medical imaging techniques. The subsequent sections of this article will explore specific devices from various manufacturers, detailing their unique MRI compatibility features and the conditions under which they operate safely.

## Comparative Review of Current MRI-Compatible SCS Technologies

As the intersection of SC stimulation technologies and MRI evolves, it becomes essential for clinicians and patients to understand the specific capabilities and limitations of various MRI-compatible SCS systems. This knowledge is crucial not only for ensuring the safety of patients during MRI scans but also for optimizing therapeutic outcomes by selecting the most appropriate device tailored to individual clinical needs. The present section of this study provides a comparative review of the latest MRI-compatible SCS devices, drawing from an extensive compilation of data on device specifications, lead compatibilities, and the safe MRI operating conditions. Each device's entry is obtained from manufacturer guidelines and clinical evaluations available online, which are compiled here. By organizing the IPGs and leads based on their manufacturers, we aim to provide an overview of the diverse range of options available on the market currently and the prominent details of their MRI operational conditions. The ensuing analysis will delve into the core features of each system, discussing their design innovations, MRI-conditional statuses, and specific operational guidelines as outlined in Tables 2 through 9, organized in accordance with SCS brands on the market. These tables are for cursory reference, and practitioners are highly recommended to consult the device manufacturers' manuals for a comprehensive understanding of safe operating profiles.

In the realm of neuromodulation, significant strides have been made to ensure that SCS devices are not only effective in pain management but also compatible with MRI. Abbott's recent developments in MRI-compatible SCS devices exemplify this progression. The Eterna series, with model numbers 3666 and 3770, showcases advanced MRI-safe protocols that facilitate full-body scanning under 1.5T conditions without compromising patient safety or device functionality. The

Table 2. *Boston Scientific SCS devices and their features relevant to their operational safety under MRI (8,9).*

| Model # and Name | Compatible Leads with Model Numbers | Scan Reg. | Static Mag. Str. | Max Grad. Slew Rate | Max Spatial Grad. | 1.5T SAR Limit | Battery | Additional Notes |
|---|---|---|---|---|---|---|---|---|
| SC-1232, SC-1216 (WaveWriter™ Alpha) | a - j | Full body | 1.5 T | ≤200 T/m/s | ≤ 40 T/m | B1+rms ≤ 3.2 μT† | Rechargeable, fully charge (≥ 3 bars) before MRI | Enable MRI mode before MRI. |
| SC-1416, SC-1432 (WaveWriter™ Alpha Prime) | a – j | Full body | 1.5 T | ≤200 T/m/s | ≤ 40 T/m | B1+rms ≤ 3.2 μT† | Non-rechargeable. If battery enters ERI, MRI mode cannot be enabled. | Enable MRI mode before MRI. |
| SC-1200 (Precision Montage™ MRI) | a – i | Full body | 1.5 T | ≤200 T/m/s | ≤ 40 T/m | B1+rms ≤ 2.0 μT† | Rechargeable, fully charge (≥ 3 bars) before MRI | Turn off stim during MRI. |
| SC-1128, SC-1126 (Spectra WaveWriter™) | a – i | Full body | 1.5 T | ≤200 T/m/s | ≤ 40 T/m | B1+rms ≤ 2.0 μT† | Rechargeable, fully charge (≥ 3 bars) before MRI | Turn off stim during MRI. |
| SC-1110 and SC-1112 (Precision Spectra™) | a – i | Full body | 1.5 T | ≤200 T/m/s | ≤ 40 T/m | B1+rms ≤ 2.0 μT† | Rechargeable, fully charge (≥ 3 bars) before MRI | Turn off stim during MRI. |

MRI-compatible leads from Boston Scientific • Percutaneous leads: [(a) Avista™ SC-2408 – 56 cm, 74 cm; (b) Linear™ SC-2158, SC-2138 – 50 cm, 70 cm; (c) Linear™ ST SC-2218, SC-2208 – 50 cm, 70 cm; (d) Linear™ 3-4 SC-2352 – 50 cm, 70 cm; (e) Linear™ 3-6 SC-2366 50 cm, 70 cm; (f) Infinion™ CX SC-2317– 50 cm, 70 cm; (g) Infinion™ Pro SC-2318 – 50 cm, 70 cm] • Surgical leads: [(h) Artisan™ MRI SC-8416 – 50 cm, 70 cm; (i) Artisan™ SC-8216, SC-8120, SC-8116 – 50 cm, 70 cm; (j) CoverEdge™ 32 MRI SC-8436, SC-8452 – 50 cm, 70 cm].
† • For Avista™ MRI leads: whole body ≤ 2.0 W/kg, head ≤ 3.2 W/kg. • All other leads: WaveWriter™ Alpha & Alpha Prime whole body and Head ≤ 0.4 W/kg. Precision Montage™ whole body & Head ≤ 0.2 W/kg.
All Boston Scientific models listed in the table (i) allow full-body scanning with caveats based on leads as listed above, (ii) offer supine or prone positioning and must operate in Normal Operating Mode, and (iii) have a 30-minute active scan time limit, followed by a 60-minute cooling period.

integration of leads like Octrode 3186, Penta 3228, and Tricentrus 3775, which are specifically designed to minimize RF-induced heating and magnetic interference, underscores the ability of these devices to enhancing patient care (33). Similarly, Medtronic's SureScan™ technology was one of the first developments in MRI-safe SCS devices. SureScan™ has been implemented in all of Medtronic's models since 2017 (34). This technology has also been used in designs for MRI safety leads. To address the most common problem of lead heating, SureScan™ leads incorporate braided bodies, which act as RF shields and surfaces for heat dissipation. The design has been established as reducing the accumulation of RF energy and heat at the lead electrodes (34).

Similarly, Abbott's Proclaim™ XR series illustrates how manufacturers are adapting to clinical needs by offering devices that ensure robust performance during MRI scans. These devices leverage technology that adjusts automatically to MRI settings, a feature that not only streamlines the clinical workflow but also mitigates the risk of manual errors during device programming prior to MRI procedures. This series highlights the crucial balance between therapeutic efficacy and diagnostic accessibility, ensuring that patients undergoing chronic pain management can access MRI diagnostics safely, a necessity in comprehensive pain management strategies.

Boston Scientific's WaveWriter™ Alpha and Alpha Prime systems further reflect this trend by incorporating INGEVITY MRI leads, which are known for their operational safety in both 1.5T and 3T MRI environments, enabling their use for full-body scan under MRI conditionality. The design of these systems emphasizes patient-centric innovations, such as Bluetooth-enabled adjustments and FAST™ therapy, which enhance daily usability and patient autonomy. These features not only cater to patient comfort but also align with modern health care practices that prioritize personalized care plans and patient engagement in managing chronic conditions.

The clinical implications of these advancements are profound. By integrating SCS devices that are compatible with MRI, clinicians no longer need to choose between effective pain management and the diagnostic clarity offered by MRI scans. This integration has been shown to improve the quality of life for patients with chronic pain by providing detailed imaging that can inform more targeted adjustments to SCS therapy,

Table 3. *Abbott SCS devices and their features relevant to their operational safety under MRI conditions (12).*

| Model # And Name | Compatible Leads with Model Numbers | Scan Reg. | Static Mag. Str. | Max Grad. Slew Rate | Max Spatial Grad. | Whole Body 1.5T SAR Limit | Battery | Additional Notes |
|---|---|---|---|---|---|---|---|---|
| 32400 (Eterna™ SCS System) | a, b, e, f | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 30 T/m | ≤ 0.1 W/kg | Rechargeable | Enable MRI mode before MRI procedure |
| 3660, 3662 (Proclaim™ XR) 3670, 3672 (Proclaim™ XR Plus) | a, b, e | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 30 T/m | ≤ 0.1 W/kg | Non-rechargeable | Enable MRI mode before MRI procedure. Expanded MRI labelling allows for higher quality images with faster scan times. |
| 3664 (Proclaim™ DRG SCS System) | c, d | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 30 T/m | ≤ 0.1 W/kg | Non-rechargeable | Enable MRI mode before MRI procedure |
| 3772 (Prodigy MRI™ SCS System) | a, e | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 30 T/m | ≤ 0.1 W/kg | Rechargeable | Enable MRI mode before MRI procedure |
| 3771 (Protégé MRI™ SCS System) | a,e | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 30 T/m | ≤ 0.1 W/kg | Rechargeable | Enable MRI mode before MRI procedure |

MRI-compatible leads from Abbott • Percutaneous leads: [(a) Octrode™ 3186 – 60 cm; (b) Octrode™ 3189 – 90 cm; (c) MN20450-50 – 50 cm; (d) MN20450-50A – 50 cm] • Surgical leads: [(e) Penta™ 5-Column Paddle Lead 3228 – 60 cm; (f) TriCentris™ 3-Column Paddle Lead 3292 – 60 cm]
All Abbott models listed in the table: (i) allow full-body scans with caveats based on leads as listed above, (ii) offer supine positioning only and must operate in Normal Operating Mode, (iii) have a 30-minute active scan time limit, followed by a mandatory 30-minute cooling period, (iv) are applicable only to circularly polarized transmit coils, and (v) have a 1.5-T cylindrical-bore magnet and horizontal field orientation.
For Proclaim™ SCS and DRG systems, a paired patient controller or clinician programmer is required to enable and disable MRI Mode.
1.5T SAR for head scans for integrated whole-body transmit coil with any receive coil is 1.5 W/kg; detachable transmit-receive coils for head or extremity scan for hip and shoulder are to be consistent with Normal Operating Mode.

Table 4. *Medtronic SCS devices and their features relevant to their operational safety under MRI conditions (17-19).*

| Model # And Name | Scan Reg. | Static Mag. Str. | Max Grad. Slew Rate | Max Spatial Grad. | Whole Body 1.5T SAR Limit | Battery | Additional Notes |
|---|---|---|---|---|---|---|---|
| 977117, 977118, 977119 (Inceptiv™) | Any body part | 1.5 T, 3 T | ≤ 200 T/m/s | ≤ 40 T/m | Whole body: ≤ 2.0 W/kg, Head: ≤ 3.2 W/kg | Rechargeable | Enable MRI mode before MRI. |
| 97715, 97716 (Intellis™) | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 40 T/m | Whole body: ≤ 2.0 W/kg, Head: ≤ 3.2 W/kg | Rechargeable | Fully charge before MRI. |
| 977005, 977006 (Vanta™, Sequentia™) | Any body part | 1.5 T | ≤ 200 T/m/s | ≤ 40 T/m | Whole body: ≤ 2.0 W/kg, Head: ≤ 3.2 W/kg | Non-rechargeable | Enable MRI mode before MRI. |
| 97702, 97712, 97713, 97714 (Restore™ Series) | Head only | 1.5 T | ≤ 200 T/m/s | ≤ 40 T/m | Head: ≤ 3.2 W/kg | Non-rechargeable | Use detachable head transmit/receive volume coil. |
| 37701, 37702, 37703, 37704 (Itrel™ Series) | Head only | 1.5 T | ≤ 200 T/m/s | ≤ 40 T/m | Head: ≤ 3.2 W/kg | Non-rechargeable | Enable MRI mode before MRI. |
| 37711, 37712, 37713, 37714 (Restore™ Series) | Head only | 1.5 T | ≤ 200 T/m/s | ≤ 40 T/m | Head: ≤ 3.2 W/kg | Non-rechargeable | Use detachable head transmit/receive volume coil. |
| 7479, 7479B, 7427, 7427V | Head only | 1.5 T | ≤ 200 T/m/s | ≤ 40 T/m | Head: ≤ 3.2 W/kg | Non-rechargeable | Use detachable head transmit/receive volume coil. |

IPG-leads-compatible model combinations: Intellis™ Series 97715, 97716, Inceptiv™ Series 977119, Restore™ Series 37713, 37714, 97713, 97714, Itrel™ Series 37703, 37704, Vanta™ Series 977006, Sequentia™ Series 977005, PrimeAdvanced™ Series 97702. Some model numbers, such as 977117, 977118, 97712, 37701, 37702, 37711, 37712, 7479, 7479B, 7427, 7427V, and 7425 are unnamed.

Table 5. *Saluda SCS devices and their features relevant to their operational safety under MRI conditions (21).*

| Model # And Name | Compatible Leads with Model Numbers | Scan Reg. | Static Mag. Str. | Whole Body 1.5T SAR Limit | Head/Knee 1.5 T or 3.0 T SAR Limit | Battery | Additional Notes |
|---|---|---|---|---|---|---|---|
| P190002 Evoke™ | 12C 60 cm, 90 cm | Full body (1.5T) | 1.5 T | ≤ 0.9 W/kg or B1+rms ≤ 1.96 μT | ≤ 2.0 W/kg or B1+rms ≤ 3.87 μT (Zone 2) ≤ 3.2 W/kg (Normal Mode) | Rechargeable | Maximum 30 min scan time One scan per day |
| | | Head and knee | 1.5 T and 3.0 T | | | | |

Evoke™ is also referred to as a closed-loop system (CLS); model number for 60 cm lead is 1008, 90 cm is 1009, and lead extension is 1011.
Time of MRI-compatibility notificaiton: Feb 2022, FDA. Check latest MRI guidelines at Saludamedicals.com before procedure.
Max gradient slew rate and max spatial gradient are not provided.

Table 6. *Biotronik SCS devices and their features relevant to their operational safety under MRI conditions (22).*

| IPG Model # And Name | Compatible Leads with Model Numbers | Scan Reg. | Static Mag. Str. | Max Grad. Slew Rate | Max Spatial Grad. | SAR Limits 1.5 T and 3.0 T | RF Excitation | Battery | Additional Notes |
|---|---|---|---|---|---|---|---|---|---|
| 457849 Prospera™ (with Embrace One™) | Resilience™ percutaneous leads | Full body and head | 1.5 T, 3.0 T | ≤ 200 T/m/s | ≤ 30 T/m (3,000 gauss/cm) | Whole body ≤ 2.0 W/kg, head ≤ 3.2 W/kg | 1.5 T: CP 3.0 T: CP or MC-2, 2-channel | Rechargeable | MRI mode enabled. Max scan durations specified.† |

MRI-compatible leads with IPGs: Resilience™ models 457852 (55 cm), 457853 (75 cm). Lead accessories 457858 (anchor), 463926 (TrueLock anchor), 457854 (SCS Port Plug).
CP: circularly polarized. MC: multi-channel RF excitation mode(s). †Max 60 min per 90 min for 1.5 T, and max 30 min per 60 min for 3.0 T. Information as of Revision E dated July 24, 2023, published on Feb 17, 2024.

leading to better overall pain management outcomes. The latest technology in SCS development is the introduction of closed-loop systems that automatically adjust stimulation parameters to compensate for this variability (35). Closed-loop SCS devices that are compatible with MRI include Medtronic's Inceptiv® and Saluda's Evoke®. Both devices support MRI scanning even under high impedance conditions and across a wide range of MRI settings. Notably, Inceptiv® is safe for MRI procedures in 3T even when the device is fully charged. These technological advancements have consistently demonstrated positive outcomes.

## Evaluation of MRI Safety Outcomes for SCS Devices in the Last Decade (2016 to 2024)

Despite the improvements in the MRI conditionality of SCS devices, the industry continues to face challenges related to MRI compatibility, predominantly due to the increase in volume of its usage. The heightened use of MRI-compatible devices is attributable to the integration of MRI therapy in mainstream pain management. Issues such as devices that fail to exit MRI mode, device/lead heating, and other safety concerns have led to recalls and additional interventions across various manufacturers. Recent comparative studies have demonstrated that MRI-conditional failure modes in SCS devices are not limited to isolated cases but are observed across multiple manufacturers, with common issues including high lead impedance, device lockups in MRI mode, and unintended RF-induced heating (31). These findings highlight the importance of the continuous post-market surveillance and systematic evaluation of SCS performance under real-world MRI conditions to mitigate patient risk. This section will delve into prominent and recent instances of adverse events, safety recalls, and concerns that are found in scientific literature, documented by regulatory bodies, and/or reported in news media. Due to the comprehensive reviews analyzing such instances in the past decade (7,10) and similar available resources (37,38), this section will focus on instances reported since 2018.

Abbott: Table 3 lists Abbott's MRI-conditional SCS devices that have defined safety parameters for their MRI-conditional use. Abbott's MRI-conditional SCS devices, including the Proclaim™ and Infinity™ IPGs, have encountered significant safety issues, particularly concerning their performance during MRI procedures. In 2023, those concerns culminated in a Class I recall

Table 7. *Nevro SCS devices and their features relevant to their operational safety under MRI conditions (32).*

| IPG Model | Lead Information | Scan Reg. | Static Mag. Str. | Max Grad. Slew Rate | Max Spatial Grad. | SAR Limits | | RF Excitation | MRI Mode Activation | Additional Notes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Zone A | Zone B | | | |
| Senza® NIPG1000, NIPG1500 | a, b, c | Full body (1.5 T), head and extremity (1.5 T and 3T) | 1.5 T and 3 T | 200 T/m/s | 2000 G/cm (20 T/m | Whole body ≤ 0.4 W/kg, head ≤ 0.6 W/Kg | Whole body ≤ 2.0 W/kg, head ≤ 3.2 W/Kg | Only circularly polarized (CP) mode | Patient remote | 3T: use only a transmit/ receive head or local coil.* |
| Senza II® NIPG2000 | a, b, c | Full body (1.5 T), head and extremity (1.5 T and 3T) | 1.5 T and 3 T | 200 T/m/s | 2000 G/cm (20 T/m | Whole body ≤ 0.4 W/kg, head ≤ 0.6 W/Kg | Whole body ≤ 2.0 W/kg, head ≤ 3.2 W/Kg | Only CP mode | Patient remote | 3T: use only a transmit/ receive head or local coil.* |
| Senza® Omnia™ NIPG2500 | a, b, c, | Full body (1.5 T), head and extremity (1.5 T and 3T) | 1.5 T and 3 T | 200 T/m/s | 2000 G/cm (20 T/m | Whole body ≤ 0.4 W/kg, head ≤ 0.6 W/Kg | Whole body ≤ 2.0 W/kg, head ≤ 3.2 W/Kg ) | Only CP mode | Patient remote | 3T: use only a transmit/ receive head or local coil.* |
| Senza® HFX iQ™ NIPG3000 | a, b, c | Full body (1.5 T), head and extremity (1.5 T and 3T) | 1.5 T and 3 T | 200 T/m/s | 2000 G/cm (20 T/m | Whole body ≤ 0.4 W/kg, head ≤ 0.6 W/Kg | Whole body ≤ 2.0 W/kg, head ≤ 3.2 W/Kg | Only CP mode at 1.5 T Both CP and MC2 at 3T | HFX patient app or patient remote control | 3T: use only a transmit/ receive head or local coil.* |

All Nevro-compatible leads with all Nevro IPG for MRI: (a) percutaneous LEAD10x8-xx(B), (b) Surpass™ Surgical LEAD3005-xx(B), (c) Surpass-C™ Surgical LEAD2005-xx(B). All leads available in 50 cm, 70 cm, and 90 cm. *Do not use integrated body coil. MRI is not usable with Lead Extension 2008-xx(B). All Nevro batteries are rechargeable. Maximum 30 min scan per study, and minimum 60 min cooldown duration between scans. Information as of Revision D, July 2024, for Senza® HFX iQ™ and Revision R, year 2024, for all other Senza models. Zone A is the localization of laser light between the tip of nose and 8 inches above the knee. Zone B is any position outside Zone A.

Table 8. *Curonix® (previously Stimwave Tech Inc.) SCS devices and their features relevant to their operational safety under MRI conditions (36).*

| IPG Model | Lead Information | Scan Reg. | Static Mag. Str. | Max Grad. Slew Rate | Max Spatial Grad. | SAR Limits | Temperature Increase | MRI Mode Activation | Additional Notes |
|---|---|---|---|---|---|---|---|---|---|
| Freedom®-8A | FR8A-A1, FR8A-B1 | Full body (1.5 T with restrictions), and head & extremity (1.5 T and 3.0 T) | 1.5 T and 3.0 T | ≤ 200 T/m/s | ≤ 10 T/m (1000 gauss/cm) | 1.5T whole body ≤ 2.0, 3.0T head & extremity ≤ 2.0, 3.0T torso ≤ 0.3 | Maximum of $4^0$ C for 15 mins of continuous scanning | Manual activation required via external controller | 3T: Use only a transmit/ receive head, local, or torso coil. No integrated body coil at 3 T. |

Information as of Revision 5, released on Dec 2023. CP: circularly polarized mode. All leads are percutaneous cylindrical type, 45 cm in length.

by the FDA, the most serious type of recall, affecting a large number of devices (39). The recall was initiated after numerous reports that the devices could become stuck in MRI mode, preventing the resumption of normal therapy after the scan. This malfunction, which was linked to software glitches and issues with the patient controllers, led to 73 reported injuries and, in many cases, required additional surgeries for device replacement (40). This situation necessitated device replacement surgery, as detailed in the patient notification letters from Abbott in mid-2023 (41). The documents highlight instances in which the device re-

Table 9. *Nalu SCS devices and their features relevant to their operational safety under MRI conditions (46).*

| IPG Model | Lead Information | Scan Reg. | Static Mag. Str. | Max Spatial Grad. | Temperature Increase | SAR Limits | RF Excitation Mode† | Additional Information |
|---|---|---|---|---|---|---|---|---|
| 11002-040 (Dual Integrated) | 40 cm Nalu lead 12001-040 | Head and extremities | 1.5 T and 3.0 T | 2000 gauss/cm (20 T/m) | 2.5°C* | 10 W/kg (partial-body SAR), 3.2 W/kg (head) | Transmit/ receive head & extremity coils | Remove all external components. |
| 11001-040 (Single Integrated) | 40 cm Nalu lead 12001-040 | Head and extremities | 1.5 T and 3.0 T | 2000 gauss/cm (20 T/m) | 2.5°C* | 10 W/kg (partial-body SAR), 3.2 W/kg (head) | Transmit/ receive head & extremity coils | Remove all external components. |
| 11004-002 (Dual Ported) | Two 40 cm Nalu leads 12001-040 | Whole body | 1.5 T | 2000 gauss/cm (20 T/m) | 6°C* | 1.0 W/kg (whole body) | Whole-body RF transmit coil | Remove all external components. Verify lead integrity, impedance checks, and RF coil config. |
| 11003-002 (Single Ported) | 40 cm Nalu lead 12001-040 | Whole body | 1.5 T | 2000 gauss/cm (20 T/m) | 6°C* | 1.0 W/kg (whole body) | Whole-body RF transmit coil | Remove all external components. Verify lead integrity, impedance checks, and RF coil config. |

Version and release date not mentioned. Date of web update is Nov 2024. *Maximum 15 min continuous scanning with transmit/receive head & extremity coils, 10 W/kg partial-body SAR, 3.2 W/kg head SAR. Nalu IPGs are non-rechargeable and powered wirelessly by external, rechargeable therapy discs. No specific MRI mode activation procedure to follow. †Excitation mode not explicitly specified.

mained in MRI mode due to such issues as damaged or lost patient controllers, locked controllers, or software issues during MRI mode activation. In those cases, additional surgeries were required to replace the IPGs to restore normal operation and therapy (42). The scope of this recall underscores the widespread nature of the problem. Beyond these immediate concerns, studies have pointed out that SCS leads, including those from Abbott and other leading brands, may experience elevated lead impedances over time. A detailed retrospective analysis by Mullins et al (30), based on a single-site study, showed that approximately 8% of the 568 MRI-conditional Abbott SCS systems experienced lead issues. This problem may compromise the devices' MRI conditionality over time, making them unsafe for MRI procedures in the long term.

Boston Scientific: Table 2 lists Boston Scientific's MRI-conditional SCS devices that have defined safety parameters pertaining to their MRI conditionality. Boston Scientific's MRI-conditional SCS devices have encountered some safety and performance issues that were reported to oversight bodies, including glitches while entering or exiting MRI mode, problems with rechargeability/battery life, and high impedances (43-45). The concern regarding elevated lead impedance has been that long-term issues can cause the devices to fail to enter or maintain MRI-conditional mode. The issue of high lead impedance also corresponded with the findings reported in a retrospective review by Mullins et al (30), wherein about one percent of the 1,184 leads in the patients studied experienced elevated impedance (30). This increase in impedance could be expected to compromise the devices' MRI conditionality, which might require some patients to undergo alternative imaging methods or even device explantation and replacement.

Saluda Medical™: Table 5 lists Saluda Medical's™ MRI-conditional SCS devices that have defined safety parameters for their MRI-conditional use. In September 2023, Saluda's™ Evoke® SCS system received FDA approval for use in the United States of America. A recent report highlights a case of a patient who could not proceed with an MRI due to the unavailability of contacts in the Evoke® 12c percutaneous lead. Although no immediate safety failure occurred, the device was explanted because the patient was unable to undergo the necessary MRI procedure. During the revision surgery, excessive scar tissue was found around the implant site, complicating the procedure and ultimately leading to the removal of the entire system (47). Compared to other device manufacturers, Saluda™ is a newcomer to the field, with only one model of SCS system. The MRI-conditional Evoke® system has not been associated with any major safety failures during MRI exposure or issues with device performance over time; given the limited number of available models, the relatively recent intro-

duction to the market, and minimal market penetration, the absence of significant safety concerns should be interpreted with caution, since long-term data and broader clinical experience are still developing.

Medtronic: Table 4 lists Medtronic's MRI-conditional SCS devices that have defined safety parameters for their MRI-conditional use. The Manufacturer and User Facility Device Experience (MAUDE) database contains adverse reports on MRI-related failures in malfunctioning Medtronic devices, and these reports sporadic and varied in category; however, a prevalent theme among them (some of which are cited here) is the correlation between battery recharge inconsistencies and irregular charge level thresholds, which ultimately prevented the device from entering or maintaining MRI mode successfully (48-51). A case report of 3 patients published by Takahashi et al (52) documented the introduction of artifacts in MR images in 2 of the instances. In 2 of the 3 cases, the researchers observed metal-induced artifacts around the electrode leads on MR images, likely caused by signal loss and magnetic field disturbances around the electrode materials. These artifacts were limited to the dorsal epidural space and did not affect the ventral epidural space or critical structures such as the spinal cord and nerves.

Biotronik: Table 6 lists Biotronik's MRI-conditional SCS devices that have defined safety parameters for their MRI-conditional use. The Prospera® system with Embrace One™ has recently gained attention since its FDA approval in March 2023. This system, which includes RESONANCE™, a novel multiphase stimulation paradigm, is designed to treat chronic pain with lower power requirements than those of other SCS therapies. Because the technology is relatively new, no significant FDA recalls have been reported for the Prospera® system or its associated leads to date. The ongoing BENEFIT-03 study aims to further evaluate the long-term safety and effectiveness of the system, which will provide more comprehensive data on its performance over time.

Nevro: Table 7 lists Nevro's MRI-conditional SCS devices that have defined safety parameters for their MRI-conditional use. These devices have been reported for device malfunctions and other minor reports of safety concerns, though they have not faced major recalls, perhaps due to their relatively recent advent and limited market penetration. Nonetheless, the frequency of their post-market device malfunction and reporting of adverse events related to the devices shows that they may have a tendency to undergo heating during or shortly after MRI exposure (53-56). This issue potentially indicates vulnerability in Nevro's MRI-conditional systems, which justifies further analysis to understand key factors (57). Hagedorn et al (58) retrospectively reviewed 327 patients implanted with Nevro's 10 kHz systems and found that elevated lead impedance led to MRI ineligibility in 4% of the patients. The authors ascertained that there was no specific link to patient demographics or implant factors. Interestingly, however, in the aforementioned article by Mullins et al (30), Nevro's leads were noted to have a relatively low incidence of elevated lead impedance compared to other those of manufacturers. While impedance and heating issues were documented, they were less frequent, and the study suggested that Nevro's high-frequency (10 Khz) stimulation technology might contribute to better lead stability and fewer impedance-related complications over time. However, ongoing monitoring is essential to ensure the long-term efficacy and safety of these devices, particularly in MRI settings.

Nalu, Curonix, and Other Devices: Currently, no significant safety concerns or failures under MRI conditions have been reported widely in association with several other SCS devices, including those from manufacturers like Nalu Medical, Curonix, and others. While these devices are marketed as MRI-conditional and have received FDA clearance for specific MRI use, the available reports do not indicate widespread or critical issues related to MRI safety. Again, this phenomenon could be due to these devices' limited market share, shorter presence, and shallower penetration into the clinical space. Adverse events documented in databases such as MAUDE typically focus on device functionality or patient outcomes unrelated to MRI exposure. As a result, these devices have not been subject to major FDA recalls or widespread safety alerts concerning their performance in MRI environments. Table 8 and 9 list the MRI-conditional SCS of Nevro and Curonix devices that have defined safety parameters for their MRI-conditional use.

Publications by Mullins et al (30) and Jotwani et al (57) provide an overview of impedance-related challenges and considerations. Mullins et al (30) noted that a significant percentage of SCS devices from various manufacturers, including Nevro, Abbott, Boston Scientific, and others, showed elevated lead impedances over time, which could compromise those devices' MRI-conditional status, potentially making them ineligible for MRI procedures under certain conditions (30). The authors concluded that if a patient was likely to undergo MRI in the future, patients and clinicians

should consider implanting impedance-independent MRI-conditional systems, such as Medtronic SureScan™, and the possible failure of MRI conditionality should be incorporated routinely into patient consent prior to the implantation. The 2021 paper by Jotwani et al (57) focuses on impedance-related complications to MRI safety in SCS devices manufactured by Medtronic and Boston Scientific (57). Jotwani et al's (57) report presents the overall details of a study involving 3 cases in which elevated lead impedance in Medtronic's Intellis and Boston Scientific's Precision models resulted in patients being ineligible for MRI scans despite those models' MRI-conditional status. Unfortunately, Jotwani et al (57) did not specifically indicate which devices were associated with each case or with the details of which adverse event. The findings from their study necessitated either alternative imaging techniques and/or device explantation. The paper emphasizes that lead design and individual patient factors can influence impedance levels over time, affecting the MRI-conditional status of these devices, and stresses the need for continuous impedance monitoring to maintain MRI safety.

These issues, though relatively rare, indicate that MRI procedures can pose risks of heating and unintended stimulation, which may affect patients' safety. Case studies and review articles suggest that while MRI-compatible SCS devices generally perform well under the approved conditions, there are instances in which high impedance or device-specific limitations can prevent safe MRI scans, leading to alternative diagnostic approaches or, in some cases, the explanation of the SCS system. In terms of the overall performance of SCS technology, reports indicate that these devices, while beneficial, have documented adverse events, indicating a significant rate of device malfunctions that lead to surgical interventions, highlighting areas for ongoing technological improvements in MRI-conditional SCS systems (59,60).

While there are still several instances of MRI-conditional devices posing safety failures, malfunctions, and image distortions, qualitative deduction may indicate that these incidents represent a very small proportion of the cases reported and an even smaller proportion of the broader SCS patient population. To the best of our knowledge, there have been no widespread reports to date of heating, displacement of the device, or significant MRI image distortion directly caused by the devices under normal operation conditions, which suggests that these devices' core MRI compatibility features perform as expected in preventing these specific types of incidents. Although these failures highlight critical risks associated with the MRI-conditional devices manufactured by the major brands, real-world clinical data provides additional context on MRI safety outcomes in patients with both MRI-conditional and non-MRI-approved SCS systems. For example, though Abbott devices have appeared prominently in the context of malfunctioning SCS system, a report by Reining et al (61) paints an interesting picture: A retrospective analysis of 149 MRI scans of 86 patients with Abbott SCS devices (2011–2019) found that only 10.1% of the implanted devices were officially MRI approved at the time of scanning. Despite this figure, the overall complication rate was 8.1%, with no serious adverse events reported. These findings suggest that, when strict safety protocols are followed, MRI can be performed on non-MRI-approved SCS devices without significant risk, though this should not be interpreted as justification for routine MRI on nonconditional devices.

This outcome aligns with the ongoing efforts to enhance device safety and MRI compatibility in modern SCS systems, ensuring that they can be used safely in conjunction with MRI scans when the specified guidelines and precautions are followed. Our literature review indicates a consistent theme of earlier versions of SCS devices facing challenges with MRI procedures, including heating, potential displacement, and setting changes. However, the lack of long-term effects of the safety profiles of these devices, in addition to the number of reported incidents (albeit very small) and the potential for serious injury, presents a compelling need for continued monitoring, rigorous post-market surveillance, and further clinical research.

## MRI Safety of SCS Leads

Though much attention is given to the IPGs when evaluating MRI safety, the leads themselves might introduce unique challenges that impact MRI compatibility, patient safety, and device longevity. The interaction of MRI's magnetic and RF fields with implanted leads can lead to excessive heating, unintended stimulation, and loss of device function if impedance thresholds are exceeded. The durability, design, and integrity of SCS leads are key factors in ensuring that MRI scanning remains a viable diagnostic option for patients implanted with these devices. One of the primary considerations in MRI safety is the impact of lead fractures or high impedance on conditionality. Across major manufacturers, MRI conditionality is typically voided if a lead fracture occurs, since impedance changes can significantly alter

the system's response to RF energy. High impedance, which can develop over time due to lead microfractures or insulation degradation, has been reported to increase the risk of heating during MRI. While manufacturers such as Abbott, Boston Scientific, and Nevro currently require intact leads within an acceptable impedance range for MRI safety, Medtronic stands apart as the only company that allows MRI scanning regardless of impedance status. Notably, Abbott has recently sought FDA approval for MRI scanning with fractured leads, which, if approved, could represent a significant shift in MRI accessibility for SCS patients.

A secondary factor influencing MRI conditionality is the potential for older leads to become MRI compatible when paired with newer-generation IPGs. Some manufacturers, such as Boston Scientific, allow certain legacy leads to be used safely with newer MRI-conditional IPGs. In contrast, other manufacturers retain strict compatibility limitations, requiring that both the leads and IPG be designed together for the sake of MRI safety. This discrepancy in compatibility highlights the importance of reviewing manufacturer guidelines for specific model combinations rather than assuming that an upgraded IPG confers MRI conditionality onto older leads.

Another critical consideration is the process for enabling and disabling MRI mode, which varies among manufacturers. Some SCS systems, such as Boston Scientific's WaveWriter™ Alpha, allow patients to activate and exit MRI mode independently via their remote controls, eliminating the need for a clinician or device representative to intervene. Others, such as devices manufactured by Abbott and Medtronic, require device interrogation or impedance checks prior to MRI scanning, with post-MRI system interrogation sometimes necessary before resuming therapy. The need for these extra steps can complicate access to MRI in emergency or urgent care settings, wherein a device representative may not be immediately available.

Beyond these practical concerns, there is an emerging discussion around long-term MRI safety in SCS systems due to lead durability issues. Recent studies, including a 2023 report comparing the durability of various manufacturers' SCS-system leads to one another, suggest that Boston Scientific leads exhibit superior longevity over time, with Abbott and Nevro leads showing higher rates of impedance-related complications. Additionally, the Mullins MRI study found that 43% of MRI-conditional leads from Abbott, Boston Scientific, and Nevro develop impedance issues within 5 years, potentially compromising MRI eligibility (30). These findings raise questions about whether MRI-conditional labeling should account for the evolving impedance status of leads over time, rather than assuming that a device remains MRI compatible for the duration of its implantation.

Given these complexities, the role of SCS leads in MRI conditionality warrants further in-depth exploration. The present review focuses primarily on the MRI compatibility of entire SCS systems, including manufacturer guidelines, operational considerations, and regulatory updates. However, the authors recognize that the topic of the design, impedance variability, and durability of SCS-system leads and their direct impact on MRI safety is an area of growing clinical significance. To address this gap, a dedicated narrative review focusing exclusively on the MRI safety of SCS leads and their durability and evolving conditionality status will be submitted in a follow-up publication. This forthcoming review will provide a detailed comparative analysis of lead-specific considerations across manufacturers and offer further insight into the ongoing challenges associated with maintaining MRI accessibility for SCS patients.

## Conclusions

This review provides a comprehensive examination of the advancements in MRI-compatible SCS systems, focusing on the key technological innovations and operational conditions that define their safety in MRI environments. We have compiled detailed data on various device models, their leads, and the specific MRI operating conditions under which they are deemed safe, covering brands such as Medtronic, Abbott, Boston Scientific, Nevro, and newer entrants like Saluda™ and Nalu. The review evaluates critical aspects such as lead designs, static magnetic strength, specific absorption rates, and gradient slew rates, all of which contribute to the devices' performance during MRI procedures. The analysis presented above also addresses the instances of device malfunctions and safety failures reported in post-market surveillance and regulatory data. This information includes failures related to elevated lead impedance, heating during or after MRI exposure, difficulties entering or exiting MRI modes, and other operational challenges. We have identified and discussed failures across multiple manufacturers, including Abbott and Boston Scientific, which have encountered glitches related to rechargeability, battery life, and lead impedance, sometimes leading to

FDA recalls. Additionally, though their number was relatively lower, some noteworthy reports concerning Medtronic and Nevro devices were explored. In those documents, certain frequently encountered conditions led to adverse events that compromised MRI safety. Our coverage of these device failures has highlighted the types of malfunctions that may occur in these devices, such as heating, lead displacement, and system lockups during MRI, offering a useful understanding of the risks the devices pose in MRI settings. While these failures represent a small proportion of the broader SCS-patient population, and SCS safety profiles have improved significantly in recent years, the potential for injury these devices pose underscores the importance of adhering to guidelines during MRI procedures. It should also be noted that the available data on device failures and complications is inherently limited by underreporting and undercounting in regulatory databases and published literature. Because adverse event reporting is often voluntary or inconsistent across different surveillance systems, the true frequency of MRI-related complications may be underestimated. The aim of the present effort is to serve as an overall qualitative introduction to MRI-conditional SCS systems and the key considerations associated with them and to summarize the current state of MRI safety in SCS IPG technology.

Acknowledgements: MP thanks GIPRC staff for helping with clinical studies conducted at TriCity Research Center (TCRC).

## References


1. Atkinson L, Sundaraj S, Brooker C, et al. Recommendations for patient selection in spinal cord stimulation. *J Clin Neurosci* 2011; 18:1295-1302.
2. Hong A, Varshney V, Hare GM, Mazer CD. Spinal cord stimulation: A nonopioid alternative for chronic pain management. *CMAJ* 2020; 192:E1264-E1267.
3. Tanei T, Maesawa S, Nishimura Y, et al. Efficacy of the latest new stimulation patterns of spinal cord stimulation for intractable neuropathic pain compared to conventional stimulation: Study protocol for a clinical trial. *Trials* 2023; 24:604.
4. Thornton JS. Technical challenges and safety of magnetic resonance imaging with in situ neuromodulation from spine to brain. *Eur J Paediatr Neurol* 2017; 21:232-241.
5. Jabehdar Maralani P, Schieda N, Hecht EM, et al. MRI safety and devices: An update and expert consensus. *J Magn Reson Imaging* 2020; 51:657-674.
6. Practice advisory on anesthetic care for magnetic resonance imaging: An updated report by the american society of anesthesiologists task force on anesthetic care for magnetic resonance imaging. *Anesthesiology* 2015; 122:495-520.
7. De Andres J, Martinez-Sanjuan V, Fabregat-Cid G, Asenio-Samper JM, Sanchis-Lopez N, Villaneuva-Perez V. MRI-compatible spinal cord stimulator device and related changes in patient safety and imaging artifacts. *Pain Med* 2014; 15:1815-1819.
8. MR-conditional spinal cord stimulator systems. Boston Scientific. www.bostonscientific.com/imageready/en-EU/scs-systems.html
9. Boston Scientific. Product literature. www.bostonscientific.com/elabeling/us/en/home.html
10. Rubino S, Adepoju A, Kumar V, et al. MRI conditionality in patients with spinal cord stimulation devices. *Stereotact Funct Neurosurg* 2016; 94:254-258.
11. Lam CM, Latif U, Sack A, et al. Advances in spinal cord stimulation. *Bioengineering (Basel)* 2023; 10:185.
12. Abbott. Abbott manuals. www.neuromodulation.abbott/us/en/healthcare-professionals/mri-support.html
13. Chou R, Qaseem A, Snow V, et al; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: A joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Annals Intern Med* 2007; 147:478-491.
14. Westbrook C, Roth CK, Talbot J. *MRI in Practice*. Wiley-Blackwell, 2021.
15. Chiu CC, Chuang TY, Chang KH, Wu CH, Lin PW, Hsu WY. The probability of spontaneous regression of lumbar herniated disc: A systematic review. *Clin Rehabil* 2015; 29:184-195.
16. Modic MT, Obuchowski NA, Ross JS, et al. Acute low back pain and radiculopathy: MR imaging findings and their prognostic role and effect on outcome. *Radiology* 2005; 237:597-604.
17. Medtronic. Vanta SCS brochure. www.medtronic.com/content/dam/medtronic-com/products/neurological/spinal-cord-stimulation/documents/vanta-scs-brochure-hcp.pdf
18. Medtronic. Determining MRI eligibility for spinal cord stimulation systems. www.medtronic.com/en-us/l/patients/treatments-therapies/chronic-pain-spinal-cord-stimulation/getting-mri.html
19. Medtronic. Manual library: Instructions for use and product manuals for healthcare profressionals. https://manuals.medtronic.com/manuals/main/en_US/home/index
20. Shellock FG, Crues JV. MR procedures: Biologic effects, safety, and patient care. *Radiology* 2004; 232:635-652.
21. Medical S. Saluda Medical Evoke System Manual of Page. https://manuals.saludamedical.com/hcp/saludamed/US/evoke
22. BIOTRONIK. BIOTRONIK manual library. https://manuals.biotronik.com/emanuals-professionals/?country=US
23. Nyenhuis JA, Park SM, Kamondetdacha R, Amjad A, Shellock FG, Rezai AR. MRI and implanted medical devices: Basic interactions with an emphasis on heating. *IEEE Trans Device Mater Reliab* 2005; 5:467-480.
24. Simopoulos TT, Gill JS. Magnetic resonance imaging of the lumbar spine in a patient with a spinal cord stimulator.

*Pain Physician* 2013; 16:E295-E300.

25. Jeon HY, Shin JW, Kim DH, et al. Spinal cord stimulator malfunction caused by radiofrequency neuroablation -A case report-. *Korean J Anesthesiol* 2010; 59:S226-S228.
26. Winter L, Seifert F, Zilberti L, Murbach M, Ittermann B. MRI-related heating of implants and devices: A review. *J Magn Reson Imaging* 2021; 53:1646-1665.
27. Rampini PM, Locatelli M, Alimehmeti R, et al. Multiple sequential image-fusion and direct MRI localisation of the subthalamic nucleus for deep brain stimulation. *J Neurosurg Sci* 2003; 47:33-39.
28. Brown JE, Qiang R, Stadnik PJ, Stotts LJ, Von Arx JA. *RF-induced unintended stimulation for implantable medical devices in MRI*. In: Makarov SN, Noetscher GM, Nummenmaa A (eds). Brain and Human Body Modeling 2020: Computational Human Models Presented at EMBC 2019 and the BRAIN Initiative® 2019 Meeting. Springer, 2021, pp 283-292.
29. Brown JE, Qiang R, Stadnik PJ, Stotts LJ, Von Arx JA. *Calculation of MRI RF-induced voltages for implanted medical devices using computational human models*. In: Makarov S, Horner M, Noetscher G (eds). Brain and Human Body Modeling: Computational Human Modeling at EMBC 2018. Springer, 2019, pp 283-294.
30. Mullins CF, Harris S, Pang D. A retrospective review of elevated lead impedances in impedance-dependent magnetic resonance-conditional spinal cord stimulation devices. *Pain Pract* 2024; 24:270-277.
31. Fisher KA, Jenkins TC, Singh V, Li R, Qadri YJ. MR-conditionality failure modes: A comparison across various spinal cord stimulators. *Pain Management* 2024; 14:431-435.
32. Nevro. Product manuals for healthcare professionals. www.nevro.com/English/au/providers/product-manuals/default.aspx
33. Abbott Medical. MRI support for Proclaim™ XR 5 & XR 7 IPGs with Proclaim™ Plus IPGs 5 & 7. www.neuromodulation.abbott/us/en/healthcare-professionals/mri-support/mri-proclaim-xr5-xr7-octrode.html
34. Davies C, Komoroski C, Roy L. Evaluation of an innovative spinal cord stimulator platform for the treatment of chronic pain. *Pain Manag* 2018; 8:167-174.
35. Vallejo R, Chakravarthy K, Will A, Trutnau K, Dinsmoor D. A new direction for closed-loop spinal cord stimulation: Combining contemporary therapy paradigms with evoked compound action potential sensing. *J Pain Res* 2021; 14:3909-3918.
36. Curonix. Curonix Freedom® PNS Neurostimulator System: Implantation of neurotransmitter: Instructions for use. www.curonix.com/wp-content/uploads/2023/12/05-20200-Rev.-6-Freedom-PNS-Neurostimulator-Instructions-for-Use-US.pdf
37. Garg I, Wang D. Complications of spinal cord stimulator trials and implants: A review. *Curr Pain Headache Rep* 2023; 27:837-842.
38. Elster LLC, MRI Safety: Spinal Cord Stimulators. Updated 2025. https://mriquestions.com/spinal-cord-stimulators.html
39. United States Food and Drug Administration. Abbott Medical recalls Proclaim and Infinity IPGs due to inability to exit magnetic resonance imaging (MRI) mode. United States Food and Drug Administration. Updated 09/13/2023. www.fda.gov/medical-devices/medical-device-recalls/abbott-medical-recalls-proclaim-and-infinity-ipgs-inability-exit-magnetic-resonance-imaging-mri-mode
40. Walter M. FDA announces recall of Abbott neurostimulation devices after MRI-related issues lead to 73 injuries. Health Imaging. Updated 09/14/2023. www.healthimaging.com/topics/medical-imaging/magnetic-resonance-imaging-mri/fda-class-i-recall-abbott-neurostimulation-devices
41. Abbott. Abbott product advisories, 2023. www.neuromodulation.abbott/us/en/product-advisories.html
42. United States Food and Drug Administration. Abbott Medical recalls Proclaim and Infinity IPGs due to inability to exit magnetic resonance imaging (MRI) mode. United States Food and Drug Administration. Updated 09/13/2023. www.neuromodulation.abbott/content/dam/nm/neuromodulation/downloadables/AttachmentF_USLetterv3_updatedJul182023.pdf
43. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=20017920&pc=LGW
44. Medical Device Databases. US Food and Drug Administration; 2025. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19990977&pc=LGW
45. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19945006&pc=LGW
46. Nalu Medical Inc. Nalu Neuromodulation System: Patient eligibility form and pre-MRI checklist. Nalu Medical Inc. https://nalumed.com/wp-content/uploads/2021/04/Nalu-MRI-Checklist-MA-000064-Rev-E.pdf
47. Medical Device Databases. US Food and Drug Administration; 2023. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=17658195&pc=LGW
48. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=20076739
49. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=20070816
50. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19938359
51. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=18683667
52. Takahashi K, Sawada A, Iwasaki S, et al. Three cases of implantation of a SureScan® system and MRI for investigating causes of pain. *J Anesth* 2017; 31:915-917.
53. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19852386
54. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19639613
55. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19288997

56. Medical Device Databases. US Food and Drug Administration; 2024. Updated 07/31/2025. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=19160576
57. Jotwani R, Abd-Elsayed A, Villegas K, et al. Failure of SCS MR-conditional modes due to high impedance: a review of literature and case series. *Pain Ther* 2021; 10:729-737.
58. Hagedorn JM, Parmele JB, Wolff JS, Bendel MA, D'Souza RS. The prevalence of elevated impedances and magnetic resonance imaging ineligibility following implantation of 10 kHz spinal cord stimulation devices: A retrospective review. *Neuromodulation* 2022; 25:719-723.
59. Jones CM, Shaheed CA, Ferreira G, et al. Spinal cord stimulators: An analysis of the adverse events reported to the Australian therapeutic goods administration. *J Patient Safe* 2022; 18:507-511.
60. D'Souza RS, Olatoye OO, Butler CS, Barman RA, Ashmore ZA, Hagedorn JM. Adverse events associated with 10-kHz dorsal column spinal cord stimulation: A 5-year analysis of the manufacturer and user facility device experience (MAUDE) database. *Clin J Pain* 2022; 38:320-327.
61. Reining M, Winkler D, Bottcher J, Meixensburger J, Kretzschmar M. Magnetic resonance imaging in patients with implanted spinal cord stimulation systems. *Dtsch Arztebl Int* 2022; 119:408-409.