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ImageReady™ MRI Head Only Guidelines for Spectra WaveWriter™ Spinal Cord Stimulator System

Rx ONLY

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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Read this manual in its entirety before performing a head scan on patients who are implanted with the Spectra WaveWriter System with ImageReady MRI Technology. Refer to the Spectra WaveWriter System product manuals for detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the Spectra WaveWriter System.

Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

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Additional Information

Refer to the *Information for Prescribers* manual for contraindications, warnings, precautions, adverse events summary, Physician Instructions, sterilization, component disposal, contact information for Boston Scientific, information regarding the Patient Identification card, FCC rules and clinical studies supporting clinical use of the neuromodulation system.

For other device-specific information not included in this manual, labeling symbols, and warranty information, refer to the appropriate DFU for your SCS System as listed on your *Reference Guide*.

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Introduction

About this Manual

This manual is intended for use by physicians and other healthcare professionals (HCPs) involved in managing patients with a Spectra WaveWriter™ Spinal Cord Stimulator System with ImageReady™ MRI Technology, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

Boston Scientific's ImageReady MRI Technology makes safe MRI head scans possible. The Spectra WaveWriter SCS System with ImageReady MRI Technology is "MR Conditional" only when exposed to the MRI environment under the specific conditions defined in this manual.

Caution: *The instructions in this manual apply **only** to the following:*

- *On-label indications (epidural placement) of the Spectra WaveWriter Spinal Cord Stimulator System. Other configurations have not been evaluated.*
- *A complete and functional Spectra WaveWriter System comprised only of components listed in "Table 1. Components that are eligible for Spectra WaveWriter System with ImageReady MRI Technology" on page 2, including Implantable Pulse Generator (IPG), leads, and surgical accessories.*

This manual is a supplement to the Spectra WaveWriter System product manuals and focuses specifically on the use of a transmit/receive radio frequency (RF) head coil of an Eligible 1.5T MRI Head Coil Setup for patients implanted with the Spectra WaveWriter System.

Throughout this manual, the term "Eligible 1.5T MRI Head Coil Setup" is used to indicate *specifically* a 1.5 Tesla horizontal closed-bore whole-body MRI system that is configured to use its transmit/receive RF head coil for the MRI examination.

Warning: *Before using the head coil, check to ensure it is clearly labeled as a "Transmit/Receive radio frequency head coil" (for example, via a label fixed to the body of the coil). Receive-only head coils are not safe because they require the use of a radio frequency body coil to transmit.*

MRI procedures should be performed using ONLY a transmit/receive RF head coil in an Eligible 1.5T MRI Head Coil Setup. Do not use MRI systems that are open-sided, vertical-field, or are operating at other static magnetic field strengths. The risks of using MRI systems operating at other static magnetic field strengths or using an RF body coil have not been determined and could be significant.

MR Conditional System Description

The following table lists model numbers of components that may comprise an MR Conditional Spectra WaveWriter System.

Warning: The Spectra WaveWriter SCS System can be “MR Conditional” only when exposed to the MRI environment under the specific conditions defined in this manual.

Table 1. Components that are eligible for Spectra WaveWriter System with ImageReady MRI Technology

Component	Model Number(s)
Spectra WaveWriter Implantable Pulse Generator	SC-1160
IPG Port Plugs	SC-4401
Linear™ Leads, 30 cm and 50 cm only	SC-2158-30, SC-2158-50
Linear ST Leads, 30 cm and 50 cm only	SC-2218-30, SC-2218-50
Linear 3-4 Leads, 50 cm only	SC-2352-50
Linear 3-6 Leads, 50 cm only	SC-2366-50
Artisan™ Surgical Paddle Leads, 50 cm only	SC-8216-50
CoverEdge™ 32 Surgical Paddle Leads, 50 cm only	SC-8336-50
CoverEdge X 32 Surgical Paddle Leads, 50 cm only	SC-8352-50
Clik™ Anchor	SC-4316
Clik X Anchor	SC-4318
Silicone Suture Sleeves	Not applicable, included in the lead kit.
Med-A	SC-4320

Note: Leads should be connected directly to the IPG, no extension, splitters and adapters are allowed.

Patient ID card

Advise the patient to bring the most up-to-date patient ID card to all MRI appointments. MRI personnel can then use the patient ID card to identify Boston Scientific as the manufacturer of the patient’s spinal cord stimulator system and to confirm the model number of the implanted IPG and Leads.

Obtain the latest MRI guidelines labeling

Always obtain the latest MRI guidelines. Refer to the contact information at the back of this manual, or go to www.controlyourpain.com/dfu. This manual may be updated from time to time. The www.controlyourpain.com/dfu website has the latest version of this manual.



MR Conditions of Use

The following Conditions of Use must be met in order for a patient with a Spectra WaveWriter System with ImageReady MRI Technology to undergo an MRI head scan. Adherence to the Conditions of Use must be verified prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MRI head scan.

SCS Implant System Conditions

Appendix A, "Spectra WaveWriter ImageReady MRI Patient Eligibility," contains a form that may be used by the physician managing the patient's SCS system to confirm the patient meets the SCS Implant System Conditions for MRI Head Scans as described in this manual.

1. The patient is implanted with a Spectra WaveWriter SCS System comprised only of components listed in "Table 1. Components that are eligible for Spectra WaveWriter System with ImageReady MRI Technology" on page 2 of this manual.
2. The patient is implanted with lead lengths of 50 cm or shorter, as listed in Table 1.

Note: *Leads should be connected directly into the IPG. Patient should not be implanted with lead extensions, splitters, or adapters.*

3. The lead implant location is epidural.
4. The patient has no abandoned leads or IPGs (such as leads or IPGs that are not connected to the functioning Spectra WaveWriter System).
5. No component of the Spectra WaveWriter SCS System (such as the implanted leads, IPG, etc) comes within 10 cm of the head coil. One way to verify this is:
 - a. The lead distal tip placement is at or below the T5 thoracic spinal level. Only distal lead tip placement between T12 and T5 is allowed.
 - b. The IPG is implanted in the upper buttock or the lower flank.
6. No evidence of fractured leads or compromised IPG-lead system integrity
7. The patient has been informed of what to do or expect in preparation for their MRI scan:
 - a. Prior to arrival at the MRI Center, the patient should ensure that the IPG is fully charged (IPG charge shown as three (3) bars on the Remote Control.) for the MRI head scan. The patient should bring the Charger (in case charging is necessary) to the MRI center. *The Charger must not be brought into the MRI scanner room.*

- b. At the MRI Center, prior to entering the scanner room, the patient should turn the stimulation “off” using the Remote Control. *The Remote Control must not be brought into the MRI scanner room.*
- c. The patient should be aware of the potential perceptible effects of undergoing MRI with an SCS System, which are as follows: tugging (moving) sensation in the IPG pocket, warming or vibration of the device in the pocket, and sensation of stimulation. The patient should be directed to immediately notify the MRI personnel if any of these effects become uncomfortable or intolerable. Refer to the “Risks and Potential Interactions” section of this manual for additional information.

Radiology

1. MRI systems that meet the following criteria:
 - MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems)
 - Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s.
 - Maximum static field spatial gradient less than or equal to 40 T/m (4000 gauss/cm).
2. MRI coil setup:
 - 1.5T transmit/receive RF quadrature head coil only
 - No other local or whole body transmit or transmit/receive coils may be used.
 - Hydrogen/proton imaging only
3. Patient status and positioning:
 - The patient is in supine position only, with head at isocenter within the Head Transmit/Receive coil.
 - Confirm that no component of the Spectra WaveWriter SCS System (such as the implanted leads, IPG, etc) comes within 10 cm of the head coil. One way to verify this is:
 - a. The lead distal tip is inferior to T5 (between T12 and T5) at the thoracic spinal level.
 - b. The IPG is implanted in the upper buttock or the lower flank.
 - Confirm with the patient that their IPG is fully charged (IPG charge shown as three (3) bars on the Remote Control).
 - The patient has turned stimulation “Off” using their Remote Control.
4. MRI system settings:
 - Scanner operation at or below Normal Operating Mode limits for RF and gradient exposure: RF Head SAR < 3.2 W/Kg (Note: Whole Body averaged SAR is not applicable for Head Transmit/Receive scanning.)
5. Monitoring:
 - The patient must have continuous audio/visual monitoring during the MRI.

Warnings, Limitations, and Risks

Warnings

Do not use with RF Body Transmit Coil: Patients implanted with the Spectra WaveWriter System should not be subjected to a MRI transmit or transmit/receive RF body coil. RF body coil exposure may result in significant heating and/or tissue damage, especially near the proximal and distal portions of the implant. RF body coil exposure can also damage the IPG electronics, potentially requiring device replacement.

Do not use with Receive-only Head Coil or Surface Coils: Ensure that the head coil being used is not a receive only head coil and the scanner settings are set to use the head coil only. Receive-only head coils are not part of an Eligible 1.5T MRI Head Coil Setup, as defined in this manual, because these require the use of a RF body coil to transmit.

Only use 1.5T transmit/receive RF quadrature head coils: Do not use other transmit/receive coils (eg, linear coils). Only 1.5T transmit/receive quadrature head coils have been evaluated.

MRI Exposure: MRI fields may potentially interact with implanted Spinal Cord Stimulation Systems to cause tugging (moving) sensation of implanted components, warming of the neurostimulator, damage to the device electronics and/or voltage induction through the leads and Stimulator causing unintended stimulation, which the patient could experience as a tingling, shocking, or jolting sensation. Therefore, it is very important to follow the instructions in this manual to minimize the potential interactions with MRI. Refer to the section in this manual titled “Risks and Potential Interactions” for additional information.

External Devices: Spectra WaveWriter external components (such as the External Trial Stimulator, Remote Control, Battery Charger) are **MR Unsafe**. They must not be taken into any MR environment such as the MRI scanner room.

Limitations

- If the patient has any other active or passive medical implant from a manufacturer that prohibits or contraindicates an MRI examination, follow the instructions from the manufacturer. The instructions in this manual apply only to the Spectra WaveWriter System with ImageReady MRI Technology described herein.
- Physicians should not prescribe MRI for patients undergoing trial neurostimulation and/or having systems that are not fully implanted.

Risks and Potential Interactions

The Spectra WaveWriter System with ImageReady MRI Technology has been shown through non-clinical testing to minimize the potential interactions with MRI when the appropriate conditions described in this manual are followed. Risks related to SCS implant geometries or locations outside the directions for use have not been evaluated.

The known potential residual risks include:

- The Spectra WaveWriter IPG may move within the implant pocket or become warm, which may cause patient discomfort.
- Induced electrical stimulation of the patient could cause an uncomfortable sensation.

Factors that increase these residual risks include, but are not limited to, the following:

- Lead lengths longer than 50 cm and/or use of extensions, adapters, or splitters may increase the risk of stimulation or jolting sensations.
- Performing MRI scans above Normal Operating Mode exposure limits or in scanners with higher maximum slew rate limits may increase the risk of stimulation or uncomfortable sensations or implant pocket temperature rise.
- Any component of the Spectra WaveWriter System (such as the implanted leads, IPG, etc) extending into the Transmit/Receive RF Head Coil or within 10cm of the Head Coil may increase the risk of stimulation or jolting sensations.




Patient Screening and Preparation

The following table summarizes the Spectra WaveWriter System/Patient-related Conditions of Use that must be met in order for an MR Conditional head scan to be performed. For each condition or requirement, suggested methods to determine eligibility are listed. It is not required to use all suggested methods. Any or a combination of the suggested methods may be used.

Appendix A, “Spectra WaveWriter ImageReady MRI Head Only Patient Eligibility,” contains a form that may be used by the physician managing the patient’s SCS system to confirm the patient meets the SCS Implant System Conditions for MRI Head Scans as described in this manual.

Table 2. Spectra WaveWriter System/Patient Screening and Preparation Conditions

#	Condition for Scanning	Suggested Methods to Determine Eligibility
1.	The patient is implanted with a Spectra WaveWriter SCS System comprised only of components listed in “Table 1. Components that are eligible for Spectra WaveWriter System with ImageReady MRI Technology” on page 2 of this manual.	<ul style="list-style-type: none"> • Check patient records • Check the Patient ID card • Check model numbers in Table 1 of this manual or by contacting Boston Scientific Neuromodulation Technical Services. • Confirm with the physician responsible for managing the Patient’s SCS System.
2.	The patient is implanted with lead lengths of 50 cm or shorter, as listed in Table 1. <i>Note: Leads should be connected directly into the IPG. Patient should not be implanted with lead extensions, splitters, or adapters.</i>	<ul style="list-style-type: none"> • Check patient records • Check model numbers in Table 1 of this manual or by contacting Boston Scientific Neuromodulation Technical Services • Confirm with the physician responsible for managing the Patient’s SCS System.
3.	The lead implant location is epidural.	<ul style="list-style-type: none"> • Check patient records • Verify by X-Ray
4.	The patient has no abandoned leads or IPGs (such as leads or IPGs that are not connected to the functioning Spectra WaveWriter System).	<ul style="list-style-type: none"> • Check patient records • Verify by X-Ray

#	Condition for Scanning	Suggested Methods to Determine Eligibility
5.	<p>No component of the Spectra WaveWriter SCS System (such as the implanted leads, IPG, etc) comes within 10 cm of the head coil. One way to verify this is:</p> <ol style="list-style-type: none"> The lead distal tip placement is at or below the T5 thoracic spinal level. Only distal lead tip placement between T12 and T5 is allowed. The IPG is implanted in the upper buttock or the lower flank. 	<ul style="list-style-type: none"> Check patient records Examine the patient by palpation to determine the location of the IPG Verify by X-Ray
6.	<p>No evidence can be found of fractured leads or compromised IPG-lead system integrity.</p>	<ul style="list-style-type: none"> Check patient records Measure impedances using the patient Remote Control or clinician programmer. From the Clinician Menu, select Impedances to display the Impedances screen, then select Measure to check the impedances. If a red "X" displays, do not proceed. For instructions on accessing the Clinician Menu, refer to the Clinician Remote Control DFU listed in your <i>Reference Guide</i>. Verify by X-Ray
7.	<p>IPG is fully charged prior to the MRI head scan.</p>	<p>Make sure three bars are displayed   at the top right of the Home screen on the Remote Control.</p>
8.	<p>Stimulation is "Off"  prior to the MRI head scan.</p>	<ul style="list-style-type: none"> Prior to entering the scanning room, verify stimulation is off by using the Remote Control. The Stimulation "Off" symbol displays as an orange circle surrounded by grey sunbursts. <i>The Remote Control must not be brought into the scanning room.</i> Confirm with the patient that Stimulation is off.

#	Condition for Scanning	Suggested Methods to Determine Eligibility
9.	<p>The patient should be aware of the potential perceptible effects of undergoing MRI with an SCS System, which are as follows: tugging (moving) sensation in the IPG pocket, warming or vibration of the device in the pocket, and sensation of stimulation. Refer to the “Risks and Potential Interactions” section of this manual for additional information.</p> <p>Direct the patient to immediately notify the MRI personnel if any of these effects become uncomfortable or intolerable.</p>	N/A.

MR System Preparation

Table 3 summarizes the MR Scanner-related Conditions of Use that must be met in order for an MR Conditional head scan to be performed. For each condition or requirement, recommended actions to determine conformance are listed.

Table 3. MR System Conditions

#	Condition for Scanning	Actions
1.	MRI systems that meet the following criteria: <ul style="list-style-type: none"> • MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems). • Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s. • Maximum static field spatial gradient less than or equal to 40 T/m (4000 gauss/cm). 	Check the technical specifications of the MRI Scanner.
2.	1.5T Transmit/receive RF quadrature head coil only, and Hydrogen/proton imaging only	Check the technical specifications of the MRI Head Coil.
3.	No other local or whole body transmit or transmit/receive coils may be used.	Ensure that only the head transmit/receive coil is used throughout the examination.
4.	Scanner must be at or below Normal Operating Mode limits for RF and gradient exposure: Head SAR < 3.2W/kg (Note: Whole Body averaged SAR is not applicable for Head Transmit/Receive scanning.)	Ensure MRI Scanner is operated at or below Normal Operating Mode.
5.	Patient must be positioned for head scanning and must be in supine position during the scan, with head at isocenter within the Head Transmit/Receive coil.	Continuously monitor the patient to ensure the patient is in the correct position during scan.

Supervision

Note: *The patient should be in a psychological condition and mental state in which the patient is able to provide immediate feedback of any problems during the examination.*

Maintain visual and audio monitoring of the patient throughout the MRI examination. Verify that the patient is feeling normal and is responsive during and between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences excessive heating, pain, or shocking sensations/uncomfortable stimulation.

Post-MRI Examination Review

1. Verify that the patient has not experienced any adverse effects as a result of the MRI. Contact Boston Scientific if the patient has experienced any adverse effects.
2. Instruct the patient to use the Remote Control (outside of the scanner room) to turn on the neurostimulator. Verify that the neurostimulator is functional. If the patient's Remote Control cannot turn stimulation back on, or displays any error messages, instruct the patient to contact the clinician managing the patient's neurostimulator system.

MRI Basic Concepts

MRI is a diagnostic tool that uses three types of magnetic and electromagnetic fields to image soft tissue in the body:

- A static magnetic field generated by a superconducting electromagnet coil, typically 1.5 Tesla (T) in strength.
- Gradient magnetic fields of much lower intensity, but with high rates of change over time. Three sets of gradient coils are used to create the gradient fields.
- A pulsed radio frequency (RF) field produced by transmission RF coils (approximately 64 MHz for 1.5 T Hydrogen/proton).

These fields may create physical forces or electrical currents that can affect the functioning of active implantable medical devices (AIMDs) such as implantable pulse generators and leads. Therefore, only patients implanted with specific configurations of the Spectra WaveWriter System are eligible for MRI head scans. Spectra WaveWriter patients can undergo MRI head scans *only* by complying with all of the MRI Conditions of Use outlined in this manual.

Glossary

Hertz (Hz) – a unit of frequency in Hertz or cycles per second. One Megahertz (MHz) is one million cycles per second.

MR Conditional¹ – an item with demonstrated safety in the MR environment within defined conditions. At a minimum, these address the conditions of the static magnetic field, the switched gradient magnetic field and the radio frequency fields. Additional conditions, including specific configurations of the item, may be required.

MRI – Magnetic Resonance Imaging.

Radio Frequency (RF) – high frequency electrical fields whose frequencies are in the range of 10,000 Hz and above. The RF used in the 1.5T MRI Scanner is ~64MHz.

Specific Absorption Rate (SAR)¹– radio frequency power absorbed per unit of mass (W/kg). IEC 60601-2-33

Tesla (T) – the unit of measure of magnetic field strength. One T is equal to 10,000 Gauss.

MRI Transmit/Receive RF Body coil – a coil used to transmit and to receive RF energy that encompasses the entire body region within the MR system bore.

MRI Transmit/Receive RF Quadrature Head coil – a coil used to transmit and to receive RF energy that is constrained to the head region, and configured to use circular polarization (CP).

W/kg – Watts per kilogram, a measure of the power that is absorbed per kilogram of tissue.

¹ ASTM F 2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"

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Appendix A

Spectra WaveWriter ImageReady MRI Head Only Patient Eligibility

This form provides information about the patient's implanted Spectra WaveWriter Spinal Cord Stimulator System and MRI head scan eligibility. It may be provided to the radiologist to support the confirmation of the patient's scan.

- Prior to performing and MRI Head Scan, confirm that the patient's stimulation is OFF
- Refer to www.controlyourpain.com/dfu for labeling and safety conditions

Patient Name:		Date:	
Physician Name,			
Office, Address			
Phone:			

A. <u>MR Conditional Spectra WaveWriter System Information</u>	Model #	MRI Eligible	Not MRI Eligible
1. Implantable Pulse Generator (IPG)			
• Spectra WaveWriter IPG, 32-Contact IPG	SC-1160	<input type="checkbox"/>	
• Other IPG _____			<input type="checkbox"/>
2. Percutaneous and/or surgical paddle leads (check all that apply)			
• Linear Lead, 8-contact lead, 30 cm	SC-2158-30	<input type="checkbox"/>	
• Linear Lead, 8-Contact lead, 50 cm	SC-2158-50	<input type="checkbox"/>	
• Linear ST Lead, 8-Contact Lead, 30 cm	SC-2218-30	<input type="checkbox"/>	
• Linear ST Lead, 8-Contact Lead, 50 cm	SC-2218-50	<input type="checkbox"/>	
• Linear 3-4 Lead, 8-Contact Lead, 50 cm	SC-2352-50	<input type="checkbox"/>	
• Linear 3-6 Lead, 8-Contact Lead, 50 cm	SC-2366-50	<input type="checkbox"/>	
• Artisan Paddle Lead, 16-Contact Paddle, 50 cm	SC-8216-50	<input type="checkbox"/>	
• CoverEdge 32 Paddle Lead, 32-Contact Paddle, 50 cm	SC-8336-50	<input type="checkbox"/>	
• CoverEdge X 32 Paddle Lead, 32-Contact Paddle, 50 cm	SC-8352-50	<input type="checkbox"/>	
• Infinion Lead, 16-Contact Lead, 50 cm or 70 cm	SC-2316-xx		<input type="checkbox"/>
• Leads longer than 50 cm, other leads, Adapters, Extensions, or Splitters:			<input type="checkbox"/>
3. Surgical Accessories (check all that apply)			
• Klik Anchor	SC-4316	<input type="checkbox"/>	
• Klik X Anchor	SC-4318	<input type="checkbox"/>	
• Med-A	SC-4320	<input type="checkbox"/>	
• Silicone Suture Sleeves		<input type="checkbox"/>	
• Other: _____			

Note: Leads should be connected directly into the IPG, Patient should not be implanted with lead extensions, splitters, or adapters.

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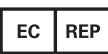
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