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# ImageReady™ MRI Full Body Guidelines for Precision™ Montage™ MRI Spinal Cord Stimulator System

℞ 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 full body scan on patients who are implanted with the Precision Montage MRI System with ImageReady MRI Full Body Technology. Refer to the Precision Montage MRI System product manuals for detailed information about non-MRI aspects of implantation, features, programming, and use of the components of the Precision Montage MRI 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.

Drawings are for illustration purposes only.

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# Table of Contents

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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 Precision Montage™ MRI Spinal Cord Stimulator System with ImageReady™ MRI Full Body Technology, as well as radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

Boston Scientific's ImageReady MRI Full Body Technology makes safe MRI scans possible. The Precision Montage MRI SCS System with ImageReady MRI Full Body 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 Precision Montage MRI Spinal Cord Stimulator System. Other configurations have not been evaluated.*
- *A complete and functional Precision Montage MRI System composed only of components listed in "Table 1. Components that are eligible for Precision Montage MRI System with ImageReady MRI Full Body Technology" on page 2, including IPG, leads, and surgical accessories.*

This manual is a supplement to the Precision Montage MRI System product manuals and focuses specifically on the use of 1.5T horizontal closed bore MRI systems for patients implanted with the Precision Montage MRI System.

> ***MRI*** *procedures should be performed using ONLY a 1.5T horizontal closed bore MRI system. Do not use MRI systems that are open-sided, vertical-field, or are operating at other static magnetic field strengths, the risks of using these MRI systems have not been determined and could be significant.*

# MR Conditional System Description

The following table lists model numbers of components that may comprise a Full Body MR Conditional Precision Montage MRI System.

> ***Warning:*** *The Precision Montage MRI SCS System can be "Full Body MR Conditional" only when exposed to the MRI environment under the specific conditions defined in this manual.*

**Table 1. Components that are eligible for Precision Montage MRI System with ImageReady MRI Full Body Technology**

| Component | Description | Model Number(s) | MRI System Settings |
|---|---|---|---|
| IPG | Precision Montage MRI 16 Contact Implantable Pulse Generator (IPG) | SC-1200 | Follow the MRI System Settings used with the implanted lead(s). |
| Percutaneous Leads | Avista™ MRI Percutaneous Leads, 56 cm | SC-2408-56 | Normal Operating Mode (See "Radiology" on page 6, MRI System Settings, 4a) |
| | Avista MRI Percutaneous Leads, 74 cm | SC-2408-74 | |
| | Linear™ Percutaneous Leads, 50 cm | SC-2158-50, SC-2138-50 | Normal Operating Mode with B1+RMS limits (See "Radiology" on page 6, MRI System Settings, 4b) |
| | Linear Percutaneous Leads, 70 cm | SC-2158-70, SC-2138-70 | |
| | Linear ST Percutaneous Leads, 50 cm | SC-2218-50, SC-2208-50 | |
| | Linear ST Percutaneous Leads, 70 cm | SC-2218-70, SC-2208-70 | |
| | Linear 3-4 Percutaneous Leads, 50 cm | SC-2352-50 | |
| | Linear 3-4 Percutaneous Leads, 70 cm | SC-2352-70 | |
| | Linear 3-6 Percutaneous Leads, 50 cm | SC-2366-50 | |
| | Linear 3-6 Percutaneous Leads, 70 cm | SC-2366-70 | |
| | Infinion™ CX Percutaneous Leads, 50cm | SC-2317-50 | |
| | Infinion CX Percutaneous Leads, 70cm | SC-2317-70 | |
| Surgical Leads | Artisan™ MRI Surgical Leads, 50 cm | SC-8416-50 | |
| | Artisan MRI Surgical Leads, 70 cm | SC-8416-70 | |
| | Artisan Surgical Leads, 50 cm | SC-8216-50, SC-8120-50, SC-8116-50 | |
| | Artisan Surgical Leads, 70 cm | SC-8216-70, SC-8120-70, SC-8116-70 | |
| Surgical Accessories | IPG Port Plugs | SC-4401 | Surgical Accessories should follow the MRI System Settings used with the associated implanted lead(s). |
| | Clik Anchor | SC-4316 | |
| | Clik X Anchor | SC-4318 | |
| | Clik™ X MRI Anchor | SC-4319 | |
| | Silicone Suture Sleeves | N/A, included in kit | |
| | Med-A | SC-4320 | |

***Note:*** *The system must be fully implanted and must include both an IPG and a lead(s), at a minimum, to be MR Conditional. The lead(s) should be connected to the IPG, no extensions, splitters, and adapters are allowed. Leads implanted without the IPG are not MR Conditional.*

## 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.bostonscientific.com/imageready. This manual may be updated from time to time. The www.bostonscientific.com/imageready website has the latest version of this manual.


# MR Conditions of Use

The Precision Montage MRI System with ImageReady MRI Full Body Technology is MR Conditional. A patient with this system may be scanned only under very specific conditions. Scanning under different conditions may result in severe patient injury or device malfunction. The following Conditions of Use must be met in order for a patient with a Precision Montage MRI System with ImageReady MRI Full Body Technology to undergo an MRI 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 scan.

## SCS Implant System Conditions

Appendix A, "ImageReady MRI Full Body 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 Scans as described in this manual.

1. The patient is implanted with a Precision Montage MRI SCS System composed only of components listed in "Table 1. Components that are eligible for Precision Montage MRI System with ImageReady MRI Full Body Technology" on page 2 of this manual.

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

2. The lead implant location is epidural.
3. The patient has no abandoned leads or IPGs (i.e. leads or IPGs that are not connected to the functioning Precision Montage MRI System).
4. The IPG is implanted in the upper buttock or the lower flank.
5. No evidence of fractured leads or compromised IPG-lead system integrity.
6. 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 scan. The patient should bring the Charger (in case charging is necessary) to the MRI center. *The Charger is MR Unsafe and 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 is MR Unsafe and 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: vibration or tugging (moving) sensation in the IPG pocket, warming of the implanted system, 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 “Potential Interactions with MRI Environment” in the Safety Information 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 spatial field gradient less than or equal to 40 T/m (4000 gauss/cm).
2. MRI coil setup:
   - Transmit coil: 1.5T Full Body transmit/receive, Head transmit/receive, or Extremity transmit/receive. RF quadrature[1] only.
   - Receive-only coil: Any type.
   - Hydrogen/proton imaging only.
3. Patient status and positioning:
   - The patient is in supine or prone position only.
   - The lead implant location is epidural.
   - 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:

   **a. Only for Patients Implanted with Precision Montage MRI IPG and Avista MRI Leads:**
   Scanner operation at or below Normal Operating Mode limits for RF and gradient exposure: Whole body SAR must be ≤ 2.0 W/kg, Head SAR must be ≤ 3.2 W/kg

   **b. For Patients Implanted with Precision Montage MRI IPG and any other leads listed in Table 1:**
   Scan sequence throughout the scan must have B1+rms less than or equal to (≤) 2.0 μT

   If B1+rms is not available then scan sequence must have Whole body and head SAR less than or equal to (≤) 0.2 W/kg

   ***Note:*** *Using the SAR value may result in a more restrictive MRI scan.*

***Warning:*** *Apply the required B1+rms (or SAR) limit in the Normal Operating Mode. Do not conduct MRI scans in the First Level and Second Level Controlled Operating Modes as it may increase the risk of unintended stimulation and excessive heating.*

5. Monitoring:
   - The patient must be under continuous audio/visual monitoring during the MRI.

1 RF Quadrature coil– RF Quadrature Coils produce an RF field with circular polarization perpendicular to the static magnetic field.

# Safety Information

## Warnings

The Precision Montage MRI System with ImageReady MRI Full Body 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.

If an MRI scan is performed in a condition other than advised in the MR Conditions of Use section it may result in serious risks such as tissue damage or severe patient injury.

**Only use 1.5T Full Body transmit/receive, Head transmit/receive, or Extremity transmit/receive coils. RF quadrature only. Hydrogen/proton imaging only:** Do not use other transmit/receive coils (eg, linear coils). Local receive-only coils may be used. Only 1.5T coils have been evaluated.

**Gradient Systems:** Do not use gradient systems producing gradient slew rates per axis greater than 200 T/m/s because they have not been tested and could cause increased risk of induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or warming of the neurostimulator.

**Potential Interactions with MRI Environment:** During an MRI examination there are potential interactions with the system that may result in heating, magnetic field effects, induced stimulation, or damage to the device, requiring its replacement. Following the safety conditions designated in this manual will minimize potential interactions described in this section.

- **Heating** – The MRI fields may interact with the Spinal Cord Stimulation System causing warming of the IPG and leads. This may cause discomfort, pain, or burns.
- **Mechanical effects:** The MRI magnetic field may exert force or torque on the Spinal Cord Stimulation System. Patients may feel a tugging or vibration sensation. Patients with recent implant incisions may feel surgical wound discomfort.
- **Induced stimulation:** An MRI may induce energy onto the implanted leads, potentially causing unintended or uncomfortable sensations (e.g., tingling, shocking, or jolting).

If these interactions cause the patient discomfort, stop the MRI scan.

**Body Temperature:** The MRI conditional evaluation has been performed for patients with a typical body temperature of 37°C. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.

**No Blankets:** Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.

**Patient Positioning:** Only place the patient in the prone or supine position. Do not position the patient in other positions, e.g., on his or her side (called the lateral decubitus position) within the MRI bore. Scanning patients in positions other than prone or supine has not been evaluated and could cause excessive tissue heating during an MRI scan.

**External Devices:** External components (i.e., External Trial Stimulator and OR Cables, Remote Control and accessories, and Battery Charger) are **MR Unsafe**. They must not be taken into any MR environment such as the MRI Scanner Room.

**Supervision:** A person with expert knowledge about MRI must ensure all procedures in this manual are followed and that the MRI scan parameters during both the pre-scan and the actual MRI examination are within the recommended settings listed in this manual.

# Cautions

Stimulation system must be turned off: Before conducting the MRI scan, confirm that the patient's implanted neurostimulation system is off. Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.

# Limitations

- Boston Scientific has not evaluated the effect of other implanted devices in combination with or in proximity to the Boston Scientific System described in this manual. Contact the appropriate device manufacturers with questions regarding other systems.
- Physicians should not prescribe MRI for patients undergoing trial neurostimulation and/or having systems that are not fully implanted.

# Image Artifacts and Distortion

The Precision Montage MRI system has minimal image distortion when the device is out of the field of view. Significant image distortion can result from the presence of the device within the field of view. Image artifacts and distortion resulting from the presence of the device and the leads within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

Careful choice of pulse sequence parameters and location of the imaging plane may minimize MR image artifacts. However, the reduction in image distortion obtained by adjustment of pulse sequence parameters will usually compromise signal-to-noise ratio.

The following general principles should be followed

- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use imaging sequences with stronger gradients for both slice and read encoding directions. Use higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for the read-out axis that minimizes the appearance of in- plane distortion.
- Use a shorter echo time for gradient echo technique, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to the presence of the field disturbance of the neurostimulator.
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted neurostimulator.

## *Warnings*

- If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator to obtain an image, or use alternate imaging techniques. MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted neurostimulation system components, especially near the neurostimulator.
- If the neurostimulator is removed, remove the entire neurostimulation system. Do not remove the neurostimulator and leave the lead system implanted as this can result in higher than expected lead heating under MRI exposure. Testing has not been completed to demonstrate safety of this configuration under MRI exposure. Excessive heating can result in tissue damage or serious patient injury.

# Patient Screening and Preparation

The following table summarizes the Precision Montage MRI System/Patient-related Conditions of Use that must be met in order for an MR Conditional 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, "ImageReady MRI Full Body 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 Scans as described in this manual.

**Table 2. Precision Montage MRI System/Patient Screening and Preparation Conditions**

| # | Condition for Scanning | Suggested Methods to Determine Eligibility |
|---|---|---|
| 1. | The patient is implanted with a Precision Montage MRI SCS System composed only of components listed in "Table 1. Components that are eligible for Precision Montage MRI System with ImageReady MRI Full Body Technology" on page 2 of this manual.<br>***Note:*** *Leads should be connected directly into the IPG. Patient should not be implanted with lead extensions, splitters, or adapters.* | • Check patient records<br>• Check the Patient ID card<br>• Check model numbers in Table 1 of this manual or by contacting Boston Scientific Neuromodulation Technical Services.<br>• Confirm with the physician responsible for managing the Patient's SCS System. |
| 2. | The lead implant location is epidural. | • Check patient records<br>• Verify by X-Ray |
| 3. | The patient has no abandoned leads or IPGs (i.e. leads or IPGs that are not connected to the functioning Precision Montage MRI System). | • Check patient records<br>• Verify by X-Ray |
| 4. | The IPG is implanted in the upper buttock or the lower flank | • Check patient records<br>• Examine the patient by palpation to determine the location of the IPG<br>• Ask the patient where on their body they charge the IPG<br>• Verify by X-Ray |
| 5. | No evidence can be found of fractured leads or compromised IPG-lead system integrity. | • Check patient records<br>• Test lead integrity by using the patient Remote Control or clinician programmer. From the **Main Menu**, select **System Settings,** then select **Lead Check**. The **Lead Check** screen will display green check boxes. If a red "X" displays, do not proceed, contact Boston Scientific.<br>• Verify by X-Ray |

| # | Condition for Scanning | Suggested Methods to Determine Eligibility |
|---|---|---|
| 6. | IPG is fully charged prior to the MRI scan. | Make sure three bars are displayed  at the top right of the Home screen on the Remote Control. |
| 7. | Stimulation is “Off”  prior to the MRI scan. | • 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. The Remote Control is MRI Unsafe and must not be brought into the MRI Scanner Room.<br>• Confirm with the patient that Stimulation is off. |
| 8. | The patient should be aware of the potential perceptible effects of undergoing MRI with an SCS System, which are as follows: vibration or tugging (moving) sensation in the IPG pocket, warming of the implanted system, and sensation of stimulation. Refer to the “Potential Interactions with MRI Environment” in the Safety Information section of this manual for additional information.<br><br>Direct the patient to immediately notify the MRI personnel if any of these effects become uncomfortable or intolerable. | 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 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:<br>• MRI magnet strength of 1.5T only, in a horizontal closed bore system (no vertical-field, standing, or extremity systems).<br>• Gradient systems with a maximum gradient slew rate per axis less than or equal to 200 T/m/s.<br>• Maximum spatial field gradient less than or equal to 40 T/m (4000 gauss/cm). | Check the technical specifications of the MRI Scanner. |
| 2. | 1.5T Full Body transmit/receive, Head transmit/receive, or Extremity transmit/receive coils. RF quadrature only. Hydrogen/proton imaging only | Check the technical specifications of the MRI Coil. |
| 3. | MRI System Settings<br>**a. Only for Patients with Implanted Avista MRI Leads:** Scanner must be at or below Normal Operating Mode limits for RF and gradient exposure: Whole body SAR must be ≤ 2.0 W/kg, Head SAR must be ≤ 3.2 W/kg<br>**b. For Patients Implanted with any other leads listed in Table1:**<br>Scan sequence throughout the scan must have B1+rms less than or equal to (≤) 2.0 µT<br>If B1+rms is not available then scan sequence must have Whole body and head SAR less than or equal to (≤) 0.2 W/kg<br>***Note:*** *Using the SAR value may result in a more restrictive MRI scan.* | Ensure MRI Scanner is operated at or below Normal Operating Mode.<br>Ensure MRI Scanner is operated at or below B1+rms of 2.0 µT throughout the scan.<br>If B1 + rms is not available then ensure MRI scanner is operated at or below Whole body and head SAR of 0.2 W/kg |
| 4. | Patient must be positioned in supine or prone position during the scan. | 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 any adverse effects listed in the Safety Information Section of this manual.

# Post-MRI Examination Review

1. Verify that the patient has not experienced any adverse effects as a result of the MRI. The potential adverse effects are listed in the Safety Information Section of this manual. 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 Precision Montage MRI System are eligible for MRI scans. Precision Montage patients can undergo MRI 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 Conditional**[2] – 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)**[2]– 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 Quadrature Body Coil** – a coil used to transmit and to receive RF energy that encompasses the entire body region within the MR system bore, and configured to use circular polarization (CP).

**MRI Transmit/Receive RF Quadrature Extremity Coil** - a coil used to transmit and to receive RF energy that is constrained to an extremity, and configured to use circular polarization (CP).

**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.

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

# Appendix A

## Precision Montage MRI ImageReady MRI Full Body Patient Eligibility

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

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

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

**A. <u>MR Conditional Precision Montage MRI System Information</u>**

| | Model # | MRI Full Body Eligible | Not MRI Eligible |
|---|---|---|---|
| 1. Implantable Pulse Generator (IPG) | | | |
| • Precision Montage MRI IPG, 16-contact IPG | SC-1200 | ☐ | |

***NOTE:*** *If you have another model number IPG, please refer to the labeling specific to your IPG model number.*

2. Percutaneous and/or surgical paddle leads (check all that apply)

| | | |
|---|---|---|
| • Avista MRI Percutaneous Lead, 8-contact lead, 56 cm | SC-2408-56 | ☐ |
| • Avista MRI Percutanious Lead, 8-contact lead, 74 cm | SC-2408-74 | ☐ |
| • Linear™ Percutaneous Leads, 50 cm | SC-2158-50 | ☐ |
| | SC-2138-50 | ☐ |
| • Linear Percutaneous Leads, 70 cm | SC-2158-70 | ☐ |
| | SC-2138-70 | ☐ |
| • Linear ST Percutaneous Leads, 50 cm | SC-2218-50 | ☐ |
| | SC-2208-50 | ☐ |
| • Linear ST Percutaneous Leads, 70 cm | SC-2218-70 | ☐ |
| | SC-2208-70 | ☐ |
| • Linear 3-4 Percutaneous Leads, 50 cm | SC-2352-50 | ☐ |
| • Linear 3-4 Percutaneous Leads, 70 cm | SC-2352-70 | ☐ |
| • Linear 3-6 Percutaneous Leads, 50 cm | SC-2366-50 | ☐ |
| • Linear 3-6 Percutaneous Leads, 70 cm | SC-2366-70 | ☐ |
| • Infinion™ CX Percutaneous Leads, 50cm | SC-2317-50 | ☐ |
| • Infinion CX Percutaneous Leads, 70cm | SC-2317-70 | ☐ |
| • Artisan™ MRI Surgical Leads, 50 cm | SC-8416-50 | ☐ |
| • Artisan MRI Surgical Leads, 70 cm | SC-8416-70 | ☐ |

| | | | |
|---|---|---|---|
| • Artisan Surgical Leads, 50 cm | SC-8216-50 | ☐ | |
| | SC-8120-50 | ☐ | |
| | SC-8116-50 | ☐ | |
| • Artisan Surgical Leads, 70 cm | SC-8216-70 | ☐ | |
| | SC-8120-70 | ☐ | |
| | SC-8116-70 | ☐ | |
| • Other Lead(s) _____ | | | ☐ |
| • Adapters, Extensions, or Splitters: | | | ☐ |

3. Surgical Accessories (check all that apply)

| | | |
|---|---|---|
| • Clik X MRI Anchor | SC-4319 | ☐ |
| • Clik X Anchor | SC-4318 | ☐ |
| • Clik Anchor | SC-4316 | ☐ |
| • Med-A | SC-4320 | ☐ |
| • Silicone Suture Sleeves | | ☐ |
| • Other:_____ | | |

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

| B. | **Patient Implant Configuration Information (ALL QUESTIONS MUST BE ANSWERED)** | **MRI Full Body Eligible** | **Not MRI Eligible** |
|---|---|---|---|
| 1. | The lead implant location is epidural. | Yes | No |
| 2. | The IPG is implanted in the upper buttock or lower flank | Yes | No |
| 3. | Patient has no abandoned leads or IPGs (i.e. leads or IPGS that are not connected to the functioning Precision Montage MRI System) | Yes | No |
| 4. | No evidence can be found of fractured leads or compromised IPG-lead system integrity | Yes | No |

| C. | **Instructions for the patient prior to the MRI Exam** | **MRI Full Body Eligible** | **Not MRI Eligible** |
|---|---|---|---|
| 1. | Instruct the patient to fully charge their IPG (IPG charge shown as 3 bars on the Remote Control) and bring the Charger to the MRI Center (in case charging is necessary) | | |
| 2. | Instruct the patient to bring their Remote Control to the MRI exam and turn stimulation off before the MRI Scan | | |

***Note:*** *The Charger and Remote Control are MR Unsafe and must not be brought into the MRI Scanner Room.*

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