WAVEWRITER ALPHA™ IMAGEREADY MRI FULL BODY PATIENT ELIGIBILITY

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This form provides information about the patient's implanted WaveWriter Alpha or WaveWriter Alpha Prime 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 stimulator is placed in MRI Mode.
- Refer to www.bostonscientific.com/imageready for labeling and safety conditions

Patient's Name:_____ Date: _____

Physician's Name: _____ Phone:_____

Physician's Signature:_____

A. MR CONDITIONAL WAVEWRITER ALPHA SYSTEM INFORMATION	MODEL #	MRI FULL BODY ELIGIBLE	NOT MRI ELIGIBLE
1. Implantable Pulse Generator (IPG)			
WaveWriter Alpha IPG (32 contact or 16 contact)	SC-1232 or SC-1216	☐	
WaveWriter Alpha Prime IPG (32 contact or 16 contact)	SC-1432 or SC-1416	☐	
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 or 74 cm)	SC-2408-56 or SC-2408-74	☐	
Linear™ Percutaneous Leads (50 cm or 70 cm)	SC-2158-50, SC-2138-50 or SC-2158-70, SC-2138-70	☐	
Linear ST Percutaneous Leads (50 cm or 70 cm)	SC-2218-50, SC-2208-50 or SC-2218-70, SC-2208-70	☐	
Linear 3-4 Percutaneous Leads (50 cm or 70 cm)	SC-2352-50 or SC-2352-70	☐	
Linear 3-6 Percutaneous Leads (50 cm or 70 cm)	SC-2366-50 or SC-2366-70	☐	
Infinion™ CX Percutaneous Leads (50 cm or 70 cm)	SC-2317-50 or SC-2317-70	☐	
Artisan™ or Artisan MRI Surgical Leads (50 cm or 70 cm)	SC-8416-50, SC-8416-70, or SC-8216-50, SC-8116-50, SC-8120-50, SC-8216-70, SC-8116-70, SC-8120-70	☐	
CoverEdge™ 32 or CoverEdge 32 MRI Surgical Leads (50 cm or 70 cm)	SC-8336-50, SC-8336-70, SC-8436-50, SC-8436-70	☐	
CoverEdge X 32 or CoverEdge X 32 MRI Surgical Leads (50 cm or 70 cm)	SC-8352-50, SC-8352-70, SC-8452-50, SC-8452-70	☐	
Other Lead(s):			☐
Extensions or Splitters:			☐
3. Adapters			
Precision™ Adapter M8, 15cm	SC-9218-15	☐	
Precision Adapter M8, 55cm	SC-9218-55	☐	
Precision Adapter S8, 15cm	SC-9208-15	☐	
Precision Adapter S8, 55cm	SC-9208-55	☐	
4. Medtronic Lead connected to Precision Adapter M8			
Vectris™ SureScan™ MRI 1x8 subcompact Lead, 60cm	977A160	☐	
Vectris SureScan MRI 1x8 subcompact Lead, 75cm	977A175	☐	
Vectris SureScan MRI 1x8 subcompact Lead, 90cm	977A190	☐	
Vectris SureScan MRI 1x8 compact Lead, 60cm	977A260	☐	
Vectris SureScan MRI 1x8 compact Lead, 75cm	977A275	☐	
Vectris SureScan MRI 1x8 compact Lead, 90cm	977A290	☐	
5. St. Jude (Abbott) Lead connected to Precision Adapter S8			
Octrode™, 60cm	3186	☐	
Penta™, 60cm	3228	☐	

Note: Leads should be connected directly into the IPG, Patient should not be implanted with lead extensions or splitters. The Precision Adapter M8, 55cm (SC-9218-55) with 75cm or 90cm Mectronic Leads (977A175, 977A275, 977A190, and 977A290) was not tested for MRI conditionality for the WaveWriter Alpha System.

When connecting to the Adapter M8 or Adapter S8, use one 16 Contact Lead, one 8 Contact Lead, or two 8 Contact Leads, All Leads must be from the same manufacturer. Do not add Boston Scientific Leads. Having a combination of Leads from different manufacturers was not tested for MRI conditionality for the WaveWriter Alpha System.

Do not use Adapters of different lengths (for example, one 15cm and one 55cm) when connecting two of the Adapter M8 or Adapter S8 to the WaveWriter Alpha System. Connecting Adapters of different lengths was not tested for MRI conditionality for this system.

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 WaveWriter Alpha or WaveWriter Alpha Prime 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
1. For patients with a rechargeable IPG (SC-1232 or SC-1216), instruct the patient to fully charge their IPG 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 to enable MRI mode before the MRI Scan
Note: The Charger and Remote Control are MR Unsafe and must not be brought into the MRI Scanner Room.

Indications for Use. The Boston Scientific Spinal Cord Stimulator Systems are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, Complex Regional Pain Syndrome (CRPS) Types I and II, intractable low back pain and leg pain, Diabetic Peripheral Neuropathy of the lower extremities. Associated conditions and etiologies may be: radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, multiple back surgeries.

Contraindications. The Spinal Cord Stimulator systems are not for patients who are unable to operate the system, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, or are pregnant. Boston Scientific's ImageReady™ MRI Full Body Technology makes safe MRI scans possible. The Precision Montage™ MRI, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems with ImageReady™ MRI Full Body Technology are "MR Conditional" only when exposed to the MRI environment under the specific conditions defined in the applicable ImageReady™ MRI Full Body Guidelines for Precision Montage™ MRI or WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems.

Warnings. Patients implanted with Boston Scientific Spinal Cord Stimulator Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Exposure to MRI may result in dislodgement of the stimulator or leads, heating of the stimulator, severe damage to the stimulator electronics and an uncomfortable or jolting sensation. As a Spinal Cord Stimulation patient, you should not have diathermy as either a treatment for a medical condition or as part of a surgical procedure. Strong electromagnetic fields, such as power generators or theft detection systems, can potentially turn the stimulator off, or cause uncomfortable jolting stimulation. The system should not be charged while sleeping. The Spinal Cord Stimulator system may interfere with the operation of implanted sensing stimulators such as pacemakers or implanted cardiac defibrillators. Advise your physician that you have a Spinal Cord Stimulator before going through with other implantable device therapies so that medical decisions can be made and appropriate safety measures taken. Patients should not operate motorized vehicles or potentially dangerous machinery with therapeutic stimulation switched "on." Your doctor may be able to provide additional information on the Boston Scientific Spinal Cord Stimulator systems.

For complete indications for use, contraindications, warnings, precautions, and side effects, call 866.360.4747 or visit Pain.com.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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