

IMAGEREADY™ MRI HEAD ONLY PATIENT ELIGIBILITY

This form provides information about the patient's implanted Precision Spectra™ or Spectra WaveWriter™ Spinal Cord Stimulator Systems 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.
- For additional assistance contact Boston Scientific Customer Service at 866.360.4747

Patient Name: _____

Date: _____

Physician Name: _____

Physician Signature: _____

Office Address: _____

(optional)

Phone: _____

A.	MR CONDITIONAL PRECISION SPECTRA SYSTEM INFORMATION	MODEL #	MRI ELIGIBLE	NOT MRI ELIGIBLE
1.	Implantable Pulse Generator (IPG)			
	• Precision Spectra IPG, 32-Contact IPG	SC-1132	<input type="checkbox"/>	
	• Spectra WaveWriter IPG, 32-Contact IPG	SC-1160	<input type="checkbox"/>	
	• Precision IPG, 16-Contact IPG	SC-1110-xx		<input type="checkbox"/>
	• Other: _____			<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 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.

B.	PATIENT IMPLANT CONFIGURATION INFORMATION (ALL QUESTIONS MUST BE ANSWERED)	MRI ELIGIBLE	NOT MRI ELIGIBLE
1.	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	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 Spectra or Spectra WaveWriter 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 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)	<input type="checkbox"/>
2.	Instruct the patient to bring their Remote Control to the MRI exam and turn stimulation off before the MRI Head Scan	<input type="checkbox"/>

Note: The Charger and Remote Control must not be brought into the MRI Scanner Room

US 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. 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, warnings, precautions, side effects. The SCS Systems are contraindicated for patients who: are unable to operate the SCS System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, or are pregnant. Refer to the Instructions for Use provided with the SCS System or ControlYourPain.com for potential adverse effects, warnings, and precautions prior to using this product. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Outside of US Indications for Use: CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.