MRI SAFETY INFORMATION

SpF®
Implantable Spinal Fusion Stimulators

MRI SAFETY INFORMATION, ARTIFACTS TESTING AND EFFICACY

1.5 Tesla MRI Safety Information

SpF® PLUS-Mini and SpF®-XL IIb Models

Experiments conducted to assess magnetic field interactions, artifacts, and operational aspects of the implantable spinal fusion stimulators combined with experience in patients indicate that MR procedures may be performed safely in patients under the following conditions:

- MR static magnetic field of 1.5 Tesla.
- Maximum spatial gradient 250 gauss/cm for the SpF® PLUS-Mini model and maximum spatial gradient 450 gauss/cm for the SpF®-XL IIb model.
- Gradient magnetic fields of 20 Tesla/second.
- Maximum whole body averaged Specific Absorption Rate (SAR) of 1.1 W/kg for 25 minutes of imaging.

MRI procedures must only be performed according to the following guidelines:

- Plain films (radiographs) must be obtained to assess the site of the implanted SpF® stimulator prior to the MRI examination to verify that there are no broken leads present.
- If this cannot be reliably determined, then the potential risks and benefits to the patient requiring the MRI examination must be carefully assessed in consideration of the possibility of excessive heating to develop in the leads.
- The patient must be continuously observed during the MRI procedure and instructed to report any unusual sensations including any feelings of warming, burning, or neuromuscular excitation or stimulation.
- If these occur, the MRI procedure must be discontinued.

Static Magnetic Field of MR Systems

A patient with a SpF® device may safely undergo an MRI procedure using a shielded MR system with a static magnetic field of 1.5 Tesla (maximum spatial gradient 250 gauss/cm for the SpF® PLUS-Mini model and maximum spatial gradient 450 gauss/cm for the SpF®-XL IIb model).

Gradient Magnetic Fields of MR Systems

Pulse sequences (e.g., echo planar imaging techniques or other rapid imaging pulse sequences), gradient coils or other techniques, and procedures that exceed a gradient magnetic field of 20 Tesla/second must not be used for MRI procedures. The use of unconventional or non-standard MRI techniques must be avoided. Standard or conventional pulse sequences (e.g., spin echo, fast spin echo, gradient echo, etc.) may be used for MRI examinations.

Radio Frequency (RF) Fields of MR Systems

MRI procedures must not exceed exposures to RF fields greater than a whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 25 minutes of imaging. The use of unconventional or non-standard MRI techniques must be avoided.

MRI Artifacts

Artifacts for the SpF® stimulators have been characterized using a 1.5 Tesla MR system (maximum spatial gradient 250 gauss/cm for the SpF® PLUS-Mini model and maximum spatial gradient 450 gauss/cm for the SpF®-XL IIb model) and various pulse sequences. This information is indicated on the table that follows. Based on this information, implantation of the SpF® stimulator (i.e., with reference to the center of the device) a distance of at least 5-8 cm from the imaging area of interest is likely to maintain the diagnostic quality of the MRI examination. Artifact size is dependent on the type of pulse sequence used for imaging (e.g., larger for gradient echo pulse sequences and smaller for fast spin echo pulse sequences), the direction of the frequency encoding direction (larger if the frequency encoding direction is perpendicular to the device and smaller if it is parallel to the device), and the size of the field of view. Positional errors and artifacts on MR images may be larger for MR systems with static magnetic field strengths greater than 1.5 Tesla or smaller for MR systems with lower static magnetic fields strengths using the same imaging parameters.

Implant the SpF® stimulator as far as possible from the spinal canal and bone graft is desirable since this will decrease the possibility that artifacts will affect this area of interest on MRI examinations. The use of fast spin echo pulse sequences will minimize the amount of artifact associated with the presence of the SpF® stimulator compared to the use of other imaging techniques.

The implantable spinal fusion stimulator was positioned parallel to the static magnetic field of the MR system for all conditions indicated below. MRI was performed using a 1.5 Tesla MR system (maximum spatial gradient 450 gauss/cm). Signal void values are indicated in millimeters squared.

Table Key: (T1-SE, T1-weighted spin echo; GRE, gradient echo or FISP, Siemens version of the gradient echo pulse sequence; N/A, not applicable; values for artifact size indicated in mm^2; Note that the T1 and the T2 values for the gadolinium-doped saline.)

Summary of MRI Artifact Information for the SpF®-XL IIb model

Parameter	Condition #1	Condition #2	Condition #3	Condition #4
Signal Void Size (mm^2)	16,762	8,918	19,769	12,630
Static Magnetic Field (T)	1.5	1.5	1.5	1.5
Pulse Sequence	T1-SE	T1-SE	GRE(FISP)	GRE(FISP)
TR (msec)	500	500	3	3
TE (msec)	20	20	1	1
Flip Angle	N/A	N/A	55°	55°
Bandwidth	16kHz	16kHz	16kHz	16kHz
Field of View (cm)	30	30	30	30
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10mm	10mm	10mm	10mm
Imaging Plane	parallel	perpendicular	parallel	perpendicular
Phantom Filler	fluid	fluid	fluid	fluid

Summary of MRI Artifact Information for the SpF® PLUS-Mini model

Parameter	Condition #1	Condition #2	Condition #3	Condition #4
Signal Void Size (mm^2)	7,618	5,813	21,871	14,908
Static Magnetic Field (T)	1.5	1.5	1.5	1.5
Pulse Sequence	T1-SE	T1-SE	GRE(FISP)	GRE(FISP)
TR (msec)	500	500	100	100
TE (msec)	20	20	15	15
Flip Angle	N/A	N/A	50°	50°
Bandwidth (HZ/pixel)	100kHz	100kHz	100kHz	100kHz
Field of View (cm)	30	30	30	30
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10mm	10mm	10mm	10mm
Imaging Plane	parallel	perpendicular	parallel	perpendicular
Phantom Filler	fluid	fluid	fluid	fluid

3.0 Tesla MRI Safety Information

Based on testing results, the SpF®-XL IIb and the SpF® PLUS-Mini require unique MR Conditional labels. The primary difference is a patient implanted with the SpF®-XL IIb can be scanned during the device's 24-week therapeutic treatment window or after therapy is over (i.e., "ON" or "OFF" state), whereas a patient implanted with the SpF® PLUS-Mini can only be scanned after the 24-week therapeutic treatment window has been completed (i.e., "OFF" state).

The SpF®-XL IIb

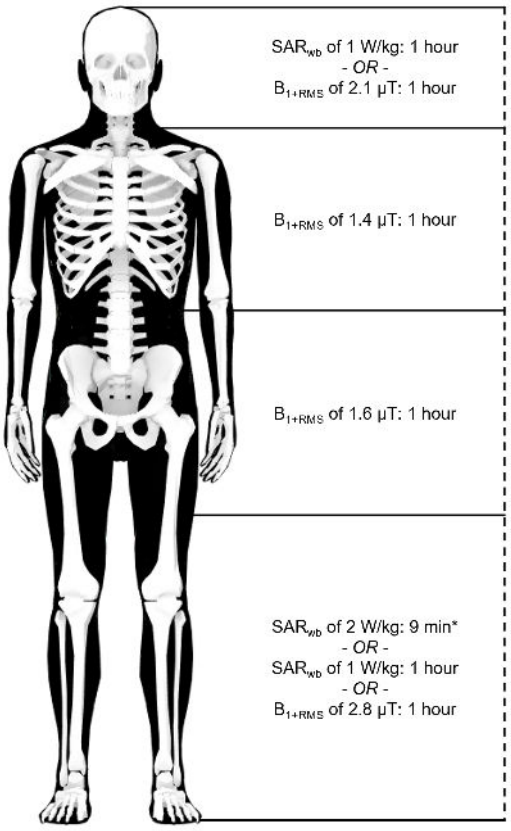
A person implanted with the SpF®-XL IIb may be safely scanned anywhere in the body at 3.0T under the following conditions. Failure to follow these conditions may result in device malfunction or injury.

Parameter	Condition	
Device Name	SpF®-XL IIb 2/DM SpF®-XL IIb 2/DW	
Device Configuration	Stimulation ON or OFF MRI scanning can occur any time after implantation assuming all conditions in this table are met.	
Static Magnetic Field Strength (B_0)	3.0T	
MR Scanner Type	Cylindrical	
B_0 Field Orientation	Horizontal	
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)	
Maximum Gradient Slew Rate	200 T/m/s per axis	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Integrated Whole Body Transmit Coil	
Operating Mode	Normal Operating Mode	
RF Conditions†	Head Scan	Continuous RF with SAR_{WB} of 1 W/kg for 1 hour, or B_{1+RMS} of 2.1 µT for 1 hour
	Chest Scan	Continuous RF with B_{1+RMS} of 1.4 µT for 1 hour
	Pelvic Scan	Continuous RF with B_{1+RMS} of 1.6 µT for 1 hour
	Lower Leg Scan	Continuous RF with SAR_{WB} of 2 W/kg for 9 minutes*, SAR_{WB} of 1 W/kg for 1 hour, or B_{1+RMS} of 2.8 µT for 1 hour
Image Artifact	The presence of the SpF®-XL IIb may produce an image artifact of 6.3 cm at the implantable titanium generator and 1.4 cm at the cathode. Some manipulation of scan parameters may be needed to compensate for the artifact.	

†Continuous RF: A sequence or back-to-back imaging series/scans without breaks.

*For restrictions marked with an asterisk, scan at the specified whole-body average SAR (SAR_{wb}) for the specified duration with continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 7 minutes if the scan duration limit is reached. This sequence of scan and wait time can be repeated for a total duration of up to 60 minutes or 1 hour.

MRI Restricted Zone Summary



Landmark restrictions for time and exposure conditions from the SpF® XL-IIb in 3T scanners.

Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
*For restrictions marked with an asterisk, scan at the specified whole-body average SAR (SAR_{wb}) for the specified duration with continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 7 minutes if the scan duration limit is reached. This sequence of scan and wait time can be repeated for a total duration of up to 60 minutes or 1 hour.

SAR_{wb}: Whole-body averaged specific absorption rate
B_{1+RMS}: Root-mean-squared RF magnetic field (B_{1+})

The SpF® PLUS-Mini

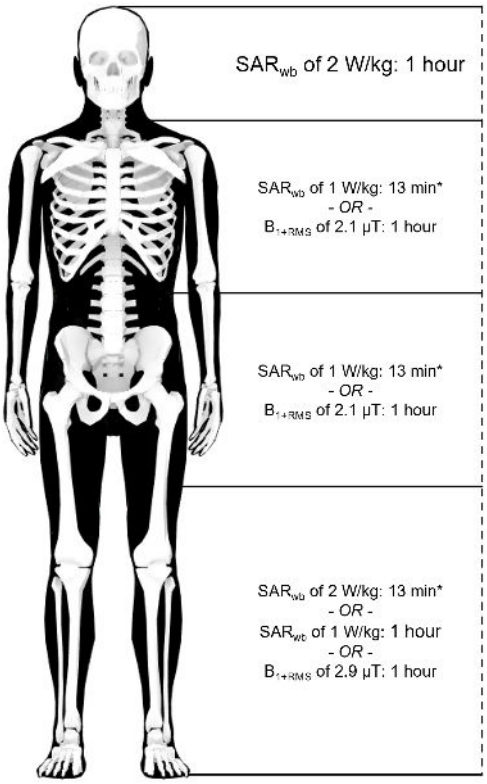
A person implanted with the SpF® PLUS-Mini may be safely scanned anywhere in the body at 3.0T under the following conditions. Failure to follow these conditions may result in device malfunction or injury.

Parameter	Condition	
Device Name	SpF® PLUS-Mini (60µA/M) SpF® PLUS-Mini (60µA/W)	
Device Configuration	Stimulation OFF MRI scanning can only occur after the therapeutic treatment window (i.e., 24 weeks or greater after implantation) has been completed or after the titanium generator has been explanted (i.e., removed)	
Static Magnetic Field Strength (B_0)	3.0T	
MR Scanner Type	Cylindrical	
B_0 Field Orientation	Horizontal	
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)	
Maximum Gradient Slew Rate	200 T/m/s per axis	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Integrated Whole Body Transmit Coil	
Operating Mode	Normal Operating Mode	
RF Conditions†	Head Scan	Continuous RF with SAR_{WB} of 2 W/kg for 1 hour
	Chest Scan	Continuous RF with SAR_{WB} of 1 W/kg for 13 minutes*, or B_{1+RMS} of 2.1 µT for 1 hour
	Pelvic Scan	Continuous RF with SAR_{WB} of 1 W/kg for 13 minutes*, or B_{1+RMS} of 2.1 µT for 1 hour
	Lower Leg Scan	Continuous RF with SAR_{WB} of 2 W/kg for 13 minutes*, SAR_{WB} of 1 W/kg for 1 hour, or B_{1+RMS} of 2.9 µT for 1 hour
Image Artifact	The presence of the SpF® PLUS-Mini may produce an image artifact of 6.3 cm at the implantable titanium generator and 1.4 cm at the cathode. Some manipulation of scan parameters may be needed to compensate for the artifact.	

†Continuous RF: A sequence or back-to-back imaging series/scans without breaks.

*For restrictions marked with an asterisk, scan at the specified whole-body average SAR (SAR_{wb}) for the specified duration with continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 7 minutes if the scan duration limit is reached. This sequence of scan and wait time can be repeated for a total duration of up to 60 minutes or 1 hour.

MRI Restricted Zone Summary



Landmark restrictions for time and exposure conditions for the SpF® PLUS-Mini in 3T scanners.

Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
*For restrictions marked with an asterisk, scan at the specified whole-body average SAR (SAR_{wb}) for the specified duration with continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 7 minutes if the scan duration limit is reached. This sequence of scan and wait time can be repeated for a total duration of up to 60 minutes or 1 hour.

SAR_{wb}: Whole-body averaged specific absorption rate
B_{1+RMS}: Root-mean-squared RF magnetic field (B_{1+})

Nerve Excitation

The cathodes of the implantable spinal fusion stimulator must be positioned a minimum of 1cm from the nerve roots to reduce the possibility of nerve excitation during a MRI procedure.

Torque

To minimize the possibility of magnetically induced torque during MR imaging, the stimulator should be oriented with its broad face (39mm x 27mm plane for the SpF® PLUS-Mini and 36mm x 23mm plane for the SpF®-XL IIb) parallel to the body and to the static field lines inside the bore.

Contact Us

For additional questions regarding MRI Safety Information, please call the EBI® Customer Care team at 800-526-2579.

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