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MRI Safety Information - SpF® PLUS-Mini Spinal Fusion Stimulator

SpF PLUS-Mini 60µA/W and 60µA/M

Safety information for the use of Magnetic Resonance Imaging (MRI) procedures (i.e., imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems with static magnetic fields of 1.5 Tesla or less (maximum spatial gradient 250 gauss/cm), gradient magnetic fields of 20 Tesla/second or less, and a maximum whole body averaged Specific Absorption Rate (SAR) of 1.1 W/kg for 25 minutes of imaging. The effects of MRI procedures using MR systems and conditions above these levels have not been determined.

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** 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** PLUS-Mini 60µA/W and 60µA/M may safely undergo an MRI procedure using a shielded MR system with a static magnetic field of 1.5 Tesla or less (maximum spatial gradient 250 gauss/cm).

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) and various pulse sequences. This information is indicated on the table that follows. Based on this information, implantation of the **SpF** (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.

Implantation of the **SpF** generator as far as possible from the spinal canal and bone graft is desirable since this will decrease the likelihood that artifacts will affect this area of interest on MRI examinations. Implantation of the generator (i.e., with reference to the center of the device) a distance of at least 5 to 8 cm from the imaging area of interest is likely to maintain the diagnostic quality of the MRI examination. The MRI of the area close to the generator case may be distorted.

MRI Safety Information - SpF® PLUS-Mini Spinal Fusion Stimulator (continued)

The use of fast spin echo pulse sequences will minimize the amount of artifact associated with the presence of the **SpF** 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 250 gauss/cm).
Signal void values are indicated in millimeters squared.

Nerve Excitation
The cathodes of the implantable spinal fusion stimulator must be positioned a minimum of 1 cm from 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 (39 mm x 27 mm plane) parallel to the body and to the static field lines inside the bore.

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 mm2; Note that the T1 and the T2 values for the gadolinium-doped saline.)

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

Parameter	Condition #1	Condition #2	Condition #3	Condition #4
Signal Void Size (mm2)	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