

MRI Safety Information

EndoLIF® Cages and Percusys® Plus Pedicle Screws and Rods

The following conditions must be complied with in the case of an MRI examination:

A patient with the "Percusys® Plus pedicle system" and/ or "EndoLIF® cages" may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

The information is based on US FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment" and based on ASTM F2503.

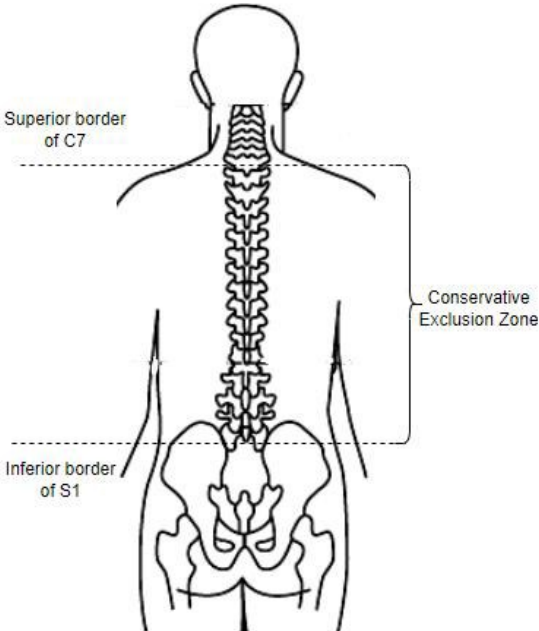
Parameter	Condition of Use/Information
Device Name	Percusys® Plus pedicle system and/ or EndoLIF® cages
Static Magnetic Field Strength (B0)	1.5 T, 3 T
Static Magnetic Field (B0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	129 T/m (12,900 gauss/cm)
Radio frequency (RF) Polarization	Circular Polarized (CP)
RF Transmit Coil	Integrated Whole Body Transmit RF Coil
RF Receive Coil	Any Receive RF coil may be used
MR System (RF) Operating or Constraints	1.5 T: Device-Specific RF Operating Constraints 3 T: Normal Operating Mode
Maximum Whole-Body Specific absorption rate (SAR)	1.5 T (Option 1): 1.3 W/kg or 1.5 T (Option 2): 1.0 W/kg 3 T: Normal Operating Mode
Maximum Head SAR	1.5 T (Option 1): 2.1 W/kg or 1.5 T (Option 2): 1.6 W/kg 3 T: Normal Operating Mode
B1 ⁺ _{rms}	1.5 T (Option 1): 3.8 µT or 1.5 T (Option 2): 3.3 µT 3 T: 3.5 µT Note: B1 ⁺ _{rms} shall be used on all MR systems with this limitation parameter. Use SAR only on MR systems not providing B1 ⁺ _{rms} limitation.

Abbreviations:

RF	Radio frequency
SAR	Specific absorption rate

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Anatomy scan region restrictions	1.5 T: Any anatomic location at isocenter is acceptable. 3 T: Any scan landmark is acceptable with the exclusion zone placed outside the MR bore. The Exclusion Zones are defined as follows: <u>Conservative Exclusion Zone:</u> It extends from the superior border of C7 to the inferior border of S1.  or <u>Clinically Determined Exclusion Zone:</u> It is based on the actual location of the implanted components and determined by X-ray imaging. The Conservative Exclusion Zone must be used if the implanted components cannot be unambiguously identified.
Item Configuration	The Percusys® Plus pedicle system and the EndoLIF® cages can be scanned singly or in combination.
Scan Duration	1.5 T (Option 1): 4:10 minutes of continuous RF (a sequence or back-to-back series) followed by a wait time of 2 minutes before resuming scanning. 1.5 T (Option 2): 8:20 minutes of continuous RF (a sequence or back-to-back series) followed by a wait time of 2:10 minutes before resuming scanning. 3 T: 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 38.8 mm.