Prism Surgical Spinal Fusion Implantable Devices

MRI SAFETY INFORMATION

Non-clinical testing has been conducted for the Prism Surgical spinal fusion family of device systems as listed in this document.

PLEASE NOTE: Individual testing of each system or device has not been completed. A worst-case device/s was determined for testing purposes to validate the upper limit of safety in the MRI environment for the device/s listed in this document. Testing standards applied to the worst-case device/s are listed in this document.

The device/s listed in this document are MR conditional and can be scanned safety under the following conditions. Failure to follow these conditions may result in injury.

Static Magnetic Field Strength (Bo)	1.5 T and 3.0 T
Maximum Spatial Field Gradient	38.5 T/m (3,850 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode

RF Conditions for 1.5 T MR Scanner:

- Condition 1: Whole-body SAR £ 1.6 W/kg (30 min continuous scanning), or
- Condition 2: Whole-body SAR £ 2.0 W/kg for 15 min continuous scanning followed by 1 min cooling period (may be repeated up to three times in single imaging session), or
- Condition 3: Whole-body SAR £ 2.0 W/kg for 60 min continuous scanning if landmark limitations listed below are applied.

RF Condition for 3.0 T MR Scanner:

- Condition 1: Whole-body SAR £ 1.3 W/kg (30 min continuous scanning), or
- Condition 2: Whole-body SAR £ 2.0 W/kg for 12 min continuous scanning followed by 3 min cooling period (may be repeated up to three times in single imaging session), or
- Condition 3: Whole-body SAR £ 2.0 W/kg for 60 min continuous scanning if landmark limitations listed below are applied.

Scan Regions if RF Conditions 1 and 2 defined above are applied:

- Any landmark is acceptable.

Scan Regions if RF Condition 3 defined above is applied:

- Patient landmark must assure the implanted device is at least 20 cm from isocentre for scanning at either 1.5 or 3.0 T.

MR Image Artifact

The presence of this implant may produce an image artifact that extends approximately 37 mm from the device.

Standards applied

ASTM Designation F2503-20: "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment" (2020)

ASTM Designation F2182-19e2: "Standard Test Method for Measurement of Radio Frequency Induced Heating on or near Passive Implants During Magnetic Resonance Imaging" (2020)

ASTM Designation F2052-15: "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment" (2015)

ASTM Designation F2213-17: "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment" (2017)

ASTM Designation F2119-07: "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants" (2007, Reapproved 2013)

Prism Surgical Spinal Device System List

System name	System number	Limitations
Centaur Spinal System	131-08	Nil
Aquila Spinal System	131-16	Nil

PRISM SURGICAL

Prism Surgical Pty Ltd
15/43 Lang Parade MILTON QLD 4064
Australia
For more information phone: +61 7 3720 8882
www.prismsurgical.com.au