

Dentium Implant System MRI Safety Information

Devices fabricated from metal can be affected by the MRI environment. Devices fabricated from polymers or ceramic are not affected by MRI environment. The MRI compatibility status must consider the clinically relevant construction, which may include assembly with metal devices that can be affected in Magnetic Resonance (MR) environment. For example, Abutment cannot be placed in patients without fixtures placed bone. Considering the clinical situation, all dental implant systems fabricated from metal are deemed to be MR Conditional.

In non-clinical worst-case testing demonstrates that the products of Dentium Implant System are MR conditional.

Note: *MR Conditional* –“a medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time varying gradient magnetic fields, and the radiofrequency fields”

(adopted from ASTM F2503-20 Standard Practice for marking Medical Devices and other Items for Safety in the Magnetic Resonance Environment which defines “an item with demonstrated safety.”)

MR Conditional

A patient with Dentium Implant System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

| <i>Parameter</i> | <i>Condition of Use / Information</i> |
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| Static Magnetic Field Strength (B_0) | 1.5 Tesla or 3.0 Tesla |
| Static Magnetic Field Strength (B_0) Orientation | Horizontal, Cylindrical Bore |
| Maximum Spatial Field Gradient (SFG) | 30 T/m (3,000 gauss/cm) |
| RF Polarization | Circularly polarized (CP) (I.e., quadrature drive) |
| RF Transmit Coil | Any Transmit RF Coil may be used |
| RF Receive Coil | Any Receive RF Coil may be used |
| RF Operating Mode | Normal Operating Mode |
| Maximum Whole-Body SAR | 2 W/kg (Normal operating mode) |
| Maximum Head SAR | 3.2 W/kg (Normal operating mode) |
| Scan Duration | 2 W/kg whole-body average SAR for 60 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) |
| MR Image Artifact | The presence of this implant may produce an image artifact. |