


Magnetic Resonance (MR) Safety Information

MRI Safety Information 	
Non-clinical testing has demonstrated the device is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions mentioned here below. Failure to follow these conditions may result in injury to the patient.	
Nominal value(s) of Static Magnetic Field [T]	1.5-Tesla (1.5 T) 3-Tesla (3 T).
Maximum Spatial Field Gradient [T/m and gauss/cm]	Maximum spatial field gradient of 44.4 T/m (4,440 G/cm).
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil
Maximum Whole-Body SAR [W/kg]	Inferior to the shoulders: 2.0 W/kg Superior to the shoulders: 0.2 W/kg Inferior to the navel: 2.0 W/kg Superior to the navel: 0.1 W/kg
Limits on Scan Duration	Under the scan conditions defined above, the dental implant systems are expected to produce a maximum temperature rise less than 6.0 °C after 15 minutes of continuous scanning.
MR Image Artifact	In non-clinical testing, the image artifact caused by the dental implant systems extend radially approximately 3.0 cm from the devices or device assemblies when imaged in a 3 T MRI system.
Caution	Configurations with more than 2 Zygoma implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of configurations with more than 2 Zygoma implants in the MR environment is unknown. Scanning a patient who has this configuration may result in patient injury.