

i. MRI Safety Information



MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

ii. Conditions

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	KATANA Zirconia ONE for IMPLANT*
Static Magnetic Field Strength (B ₀)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

* This device made of ceramic is considered to be MR safe. However, if the restoration consists of multiple parts, it must be classified according to the part with the lowest safety level.