

Patient: _____
Location: _____
Facility: _____
Physician: _____
Physician Phone #: _____
Product Catalog #: _____
Date: _____



MR Safety Information



The DuraClip is determined to be MR-Conditional.

Non-clinical testing has demonstrated that the DuraClip is MR Conditional according to ASTM F2503.

A Patient with this device can be safely scanned under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla
- Spatial gradient field of 4000 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg in Normal Operating Mode for a maximum scan time
- 15min of continuous scanning at 1.5-Tesla and 3-Tesla

TR-ROCC-KP-01 (A/0)

MR Safety Information



In non-clinical testing, the DuraClip produced a temperature rise of less than 1.5°C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15min of continuous MR scanning with body coil in a 1.5 Tesla MR Scanner.

In non-clinical testing, the DuraClip produced a temperature rise of less than 1.4°C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15min of continuous MR scanning with body coil in a 3 Tesla MR Scanner.

In non-clinical testing, the DuraClip produced a temperature rise of less than 1.5°C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15min of continuous MR scanning.

MR image quality may be compromised if the area of interest is within approximately 25 mm from the DuraClip as found in non-clinical testing using a *gradient echo* or *spin echo* sequence in a 3.0 T MRI system.