

Resolution[®] Clip Device

Date Placed: _____

Anatomical Location: _____

Magnetic Resonance (MR) Information

Non-clinical testing has demonstrated the Resolution[®] Clip is MR Conditional according to ASTM F2503. A patient with this clip(s) can be safely scanned under the following conditions:

Static Magnetic Field

Static magnetic field of 1.5 and 3 Tesla with:

- Spatial gradient field of 2500 Gauss/cm (value extrapolated) and less
- Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg in Normal Operating Mode for a maximum scan time of 15 minutes of continuous scanning at 1.5T and at 3T.



MR Conditional
per ASTM F2503

MR Related Heating

In non-clinical testing, the “Resolution Clips” produced a temperature rise of less than 1.4 °C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15 min. of continuous MR scanning with body coil in a 1.5 Tesla Intera™, Philips Medical Systems (software: release 12.6.1.3, 2010-12-02) MR Scanner.

In non-clinical testing, the “Resolution Clips” produced a temperature rise of less than 4.0 °C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15 min. of continuous MR scanning with body coil in a 3 Tesla Magnetom Trio™, Siemens Medical Systems (software: Numaris/4, syngo MRA30) MR Scanner.

Image Artifacts

MR image quality may be compromised if the area of interest is within approximately 80 mm of the clip(s) as found in non-clinical testing using a spin echo and gradient echo pulse sequence in a 3T MR system (Philips Medical Systems, Best, The Netherlands, Achieva, software 2.6.3.7 2010-11-24). Therefore, it may be necessary to optimize MR Imaging parameters in the presence of this implant.

Boston Scientific recommends that the patient register the MR conditions disclosed in this DFU with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

The logo for Boston Scientific, featuring the words "Boston" and "Scientific" stacked vertically in a serif font. The "B" in "Boston" is significantly larger than the other letters.