Non-clinical testing has demonstrated the Resolution™ Clip and Resolution 360™ Clip are 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 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.

All trademarks are the property of their respective owners.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Information for the use only in countries with applicable health authority product registrations.