

To whom it may concern,

June 29th, 2016

RE: Visicoil compatibility with MRI

Visicoil™ consists of a helically wound coil of commercially pure gold (99.95%). The components and construction of Visicoil are non-ferromagnetic and to our knowledge, contain no materials that would react negatively with MRI equipment. We have received no reports of any MRI related problems. However, delivery devices such as the needles used for implant, have not been evaluated and therefore are not suitable for MRI Guided placement.

MRI Safety Information



MR Conditional

Non-clinical testing demonstrated that the Visicoil Gold based product is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the Visicoil Gold based product is expected to produce a maximum temperature rise of 2.4 °C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the Visicoil Gold based product extends approximately 2 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

MRI Safety Testing was performed by:

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Visicoil is a flexible linear fiducial marker indicated for use to radiographically mark soft tissue for future therapeutic use. Visicoil is a trademark of RadioMed Corporation.



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