

#### Purpose:

In March 2010, the US Food and Drug Administration (FDA) approved the first fully implantable hearing device, Esteem Implantable Hearing System (Envoy Medical Corporation, St Paul, MN), for use in patients with moderate to severe hearing loss. With the FDA approval, MRI scanning of patients with these devices is expected to become part of routine clinical practice. The purpose of this work was to investigate interactions between the Esteem system and MRI environment, at 1.5T and 3T, and provide the characterization of the device within the framework of standards established by American Society for Testing and Materials (ASTM).

#### Methods:

All tests were performed on the clinical 1.5T and 3T MRI Scanners (Signa Excite, GE Healthcare, Milwaukee, WI, running 14.0 M5 software) using the body coil to transmit RF power. The following characteristics were tested: magnetically-induced displacement force, RF-induced heating near the implant, and MR image artifact. The Esteem® hearing implant consists of three main components: the driver, sensor and sound processor (weight 1.4g, 1.3g and 22.3g, respectively). Characteristics of all components were tested individually.

#### Results:

The screening test using the handheld magnet did not show any attraction when any of the device components (sound processor, driver and sensor) were tested. Deflection angles for each component were all measured to be less than 45 degrees (12.3 degrees or less at 3T, 5.3 degrees or less at 1.5T) indicating that the deflection force was significantly weaker than the force on the implant due to gravity. No significant RF-induced heating of the implant was observed during MRI scanning at both field strengths. Artifact analysis conducted showed that appreciable artifacts were present and are a consideration for MR imaging near this implant.

#### Conclusions:

The device was found to be safe for clinical MRI scanning using 1.5T and 3T MRI systems evaluated.