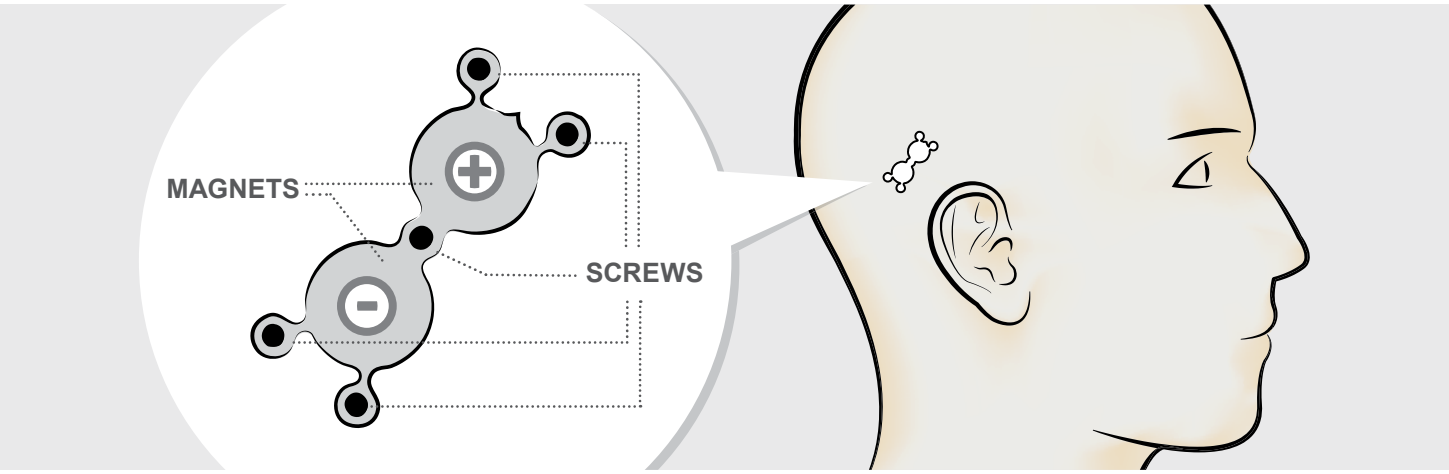
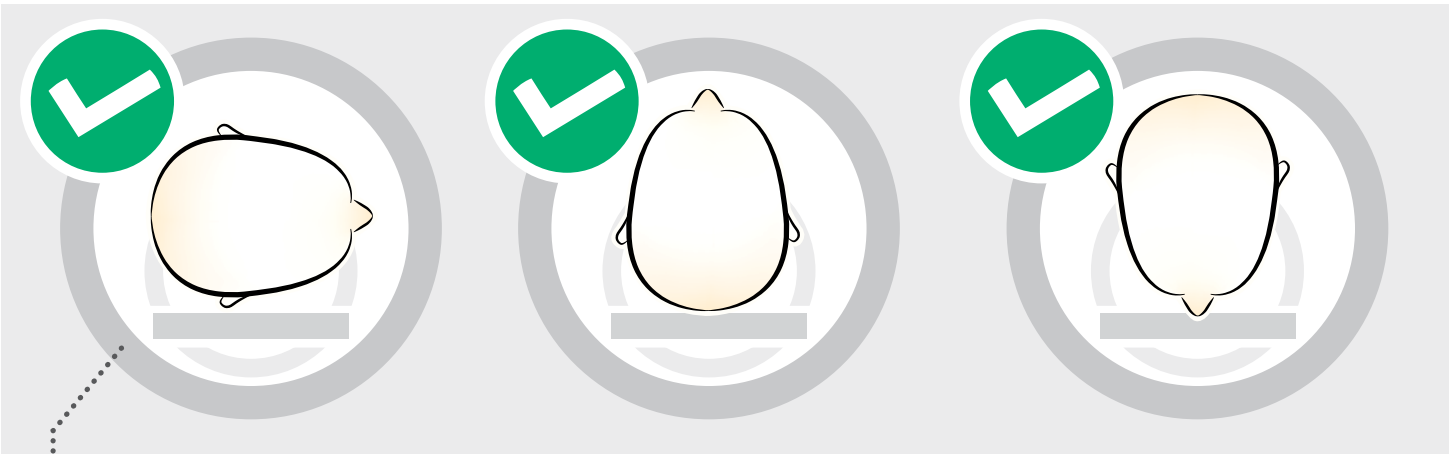
MRI TECHNOLOGIST'S GUIDE
MEDTRONIC MAGNETIC IMPLANT PRECAUTIONS

The Medtronic Magnetic Implant is a magnetic device implanted in the bone.

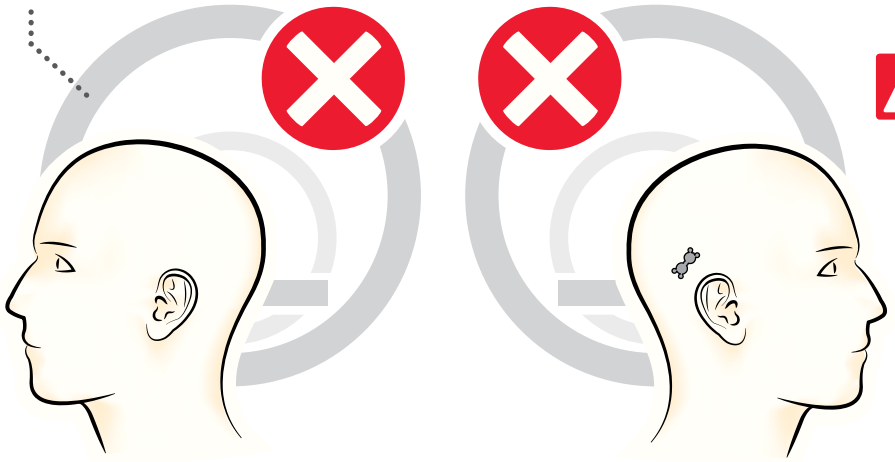


The Medtronic Magnetic Implant consists of two rare-earth magnets hermetically sealed in a titanium frame. The implant is typically located about 2 cm superior and posterior to the patient's ear.

The two magnets face outward from the side of the head, and are mounted with opposite polarity. The implant is secured to the skull bone with 5 titanium maxillofacial screws.



BORE/TUNNEL



To minimize demagnetization, avoid facing the side of the patient's head (ear) toward or away from the bore of the MRI system at any time. As much as possible, maintain 90° between the face of the magnetic implant and the static magnetic field of the MRI system.

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MRI Information

Non-clinical testing demonstrated the Medtronic Magnetic Implant is MR Conditional and can be scanned safely using MRI only under the following conditions:

- Remove all external components including the Alpha Sound Processor, Attract™ Magnetic Spacer, Headband or Softband before entering the MR environment
- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum whole-body averaged specific absorption rate (SAR) of 4 W/kg in the First Level Controlled Mode for a maximum scan time of 15 minutes of continuous scanning (per pulse sequence).

In non-clinical testing the Medtronic Magnetic Implant produced a maximum temperature rise less than 3.2°C during 15 minutes of continuous MR scanning in the First Level Controlled Mode at a maximum whole-body averaged SAR of 4 W/kg. The computed implant temperature increase in response to the worst-case, time-varying magnetic field (94.7 Tesla/sec) for the 15 minute possible exposure for a series of clinical MRI scans is less than 2.6°C.

Image Artifact

The maximum image artifact size extends approximately 5 cm relative to the size and shape of the implant when scanned in non-clinical testing using the Gradient echo (GRE) pulse sequence in a 3 Tesla/128MH, Excite, Software 14X.M5, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field MR system with a send receive RFcoil. Artifacts were less with the T1-weighted, spin echo pulse sequence.

Implant Function Following MR Scanning

In non-clinical testing, when positioned parallel to the patient table, the Medtronic Magnetic Implant maintained over 95% of its original magnetic strength after 10 insertions into the static magnetic field and a 10 minute imaging sequence in a 3 Tesla Siemens Tri Clinical MRI Scanner (MRC20587).[1,2]

To minimize demagnetization of the internal magnets, Medtronic recommends that the patient's head is positioned along the long axis of the MRI system and that the patient is instructed to avoid head movement while lying on the patient table. If the head is tilted at an angle to the long axis of the patient table during a scan, the internal magnets may be demagnetized and a stronger external magnet may be needed to keep the device in place.

Rx only. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications.

For further information, please call Medtronic ENT at 800.874.5797 or consult Medtronic's website at **www.medtronic.com/ent**.

Additional MRI safety information can be obtained by visiting www.MRISafety.com maintained by Frank G. Shellock, Ph.D., FACR, FISMRM.

References:

1. Internal Test Report: Evaluation of Magnetic Field Interactions, Heating and Artifacts for the Alpha 1 (M) Magnetic Implant. Frank G. Shellock. August 10, 2012.
2. Azadarmaki R, Tubbs R, Chen DA, Shellock FG. MRI information of commonly used otologic implants: Review and update. Otolaryngology–Head and Neck Surgery 2014, Vol. 150(4) 512–519

If you have any questions or need advice in order to ensure patient safety relative to the use of the Medtronic magnetic implant in an MR procedure, contact Medtronic at 800-874-5797.

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