

# MRI Safety Guidelines for Commonly Used Otologic Implants in the United States

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## ABSTRACT

**Objective:** To review information on MRI safety for commonly used otologic implants including cochlear implants, middle ear implantable hearing devices, osseointegrated cochlear stimulators, and middle ear prosthetic devices.

**Data Sources:** Manufacturing companies and the National Library of Medicine's online database

**Review Methods:** A literature review of the National Library of Medicine's online database was performed with focus on MRI safety of routinely used implanted hearing devices. Manufacturing companies were contacted for latest MRI safety guidelines and for devices with no information on MRI safety in the literature.

**Results:** The Baha system and Ponto Pro osseointegrated implants' abutment and fixture, middle ear ossicular reconstruction prosthetic devices, and all stapes prosthetic devices except for the 1987 McGee prosthesis are safe to use in standard MRI fields. Cochlear implants with removable magnets such as the newer Cochlear Americas Implants and the HiResolution Bionic Ear System's HiRes 90K can be used in standard MRI fields upon removal of the magnet. The newer MED-EL cochlear implants can be used in low MRI magnetic fields up to 0.2T. All other cochlear implants, middle ear implantable hearing devices, and the Sophono device are not approved for MRI use.

**Conclusion:** MRI safety status of otologic implants depends on their magnetic potential. Knowledge of the MRI safety guidelines for the commonly used otologic implants is important. United States guidelines on MRI safety and compatibility are not always the same as in Europe and other parts of the world.

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## INTRODUCTION

Magnetic Resonance Imaging (MRI) is an important medical diagnostic tool that is restricted in patients with certain implanted devices. MRI magnetic fields have the potential to demagnetize or damage electronic components and lead to hardware malfunction. Mechanical force from the effect of the magnetic field or induced current and heat can potentially lead to patient injury.

Implanted otologic devices with strong magnetic property may be hazardous when exposed to MRI magnetic fields. Magnetic susceptibility ranges from -1 for superconductors to 10<sup>6</sup> for ferromagnetic materials. Ferromagnetic materials are very strongly attracted to magnetic fields and include material made of grade 400 stainless steel. Paramagnetic materials include titanium, palladium, gold, platinum, and grade 300 series stainless steel. Paramagnetic materials have some attraction to magnetic fields, but if secured in position in the form of an implant, may be safe to use in standard MRI fields. Human tissue magnetic susceptibility is very low in the range of 10<sup>-6</sup>.

We hope to provide a source that answers the question of MRI safety of commonly used otologic implants in the United States based on current information available in the literature. This source and its recommendations will be based on exposure to 1.5 Tesla (T) MRI magnetic strength or less. The routine closed and open MRIs are at 1.5 T and 0.3 T magnetic strengths, respectively.

## METHODS

A literature review of the National Library of Medicine's online database was performed with focus on MRI safety of routinely used implanted hearing devices. The search was restricted to the more commonly used otologic implants including stapes and metallic middle ear prosthesis, cochlear implants, osseointegrated cochlear stimulators and middle ear hearing aid implants. Manufacturing companies were contacted for devices with little or no literature available on MRI compatibility.

## RESULTS

**Stapes Prosthesis and Metallic Middle Ear Ossicular Chain Reconstruction Implants:** All devices are safe for use in a 1.5T magnetic field or less with the exception of the 1987 McGee stainless steel prosthesis.

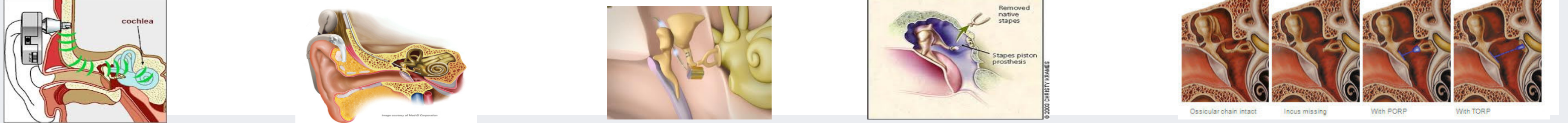
**Osseointegrated Cochlear Stimulator:** The Baha and Ponto System by Oticon Medical's abutment and fixture are MRI safe. The Sophono Alpha 1 is contraindicated for MRI use as it involves an implanted magnet which ultimately osseointegrates into the skull.

**Middle Ear Implantable Hearing Devices:** These devices are contraindicated for MRI use. There are several studies in the literature looking at the effect of MRI on patients with Vibrant Soundbridge implants. There are reports of disturbing noise perception, pain, pressure at the receiver bed, subcutaneous movement of the implant receiver, and the need for repositioning of the FMT portion of the VSB in these patients.

**Cochlear Implants:** Overall these Implants are contraindicated for MRI use in the United States with some exceptions. Implants with removable magnets can be safely used when the magnet is removed. The newer MED-EL implants are approved in magnetic strengths up to 0.2T. There are studies that report no adverse events in patients who underwent MRI imaging with the application of a compression dressing over the device.

OTOLOGIC IMPLANT	MRI SAFETY at 1.5T or LESS
<b>Stapes Prosthesis</b>  <b>Total or Partial Ossicular Reconstruction Prosthesis</b>  <b>Osseointegrated Cochlear Stimulator</b> <ul style="list-style-type: none"> <li>Baha System</li> <li>Ponto System by Oticon Medical</li> <li>Sophono Alpha 1</li> </ul> <b>Middle Ear Implantable Hearing Devices</b> <ul style="list-style-type: none"> <li>Vibrant Soundbridge</li> <li>Esteem by Envoy</li> <li>Ototronix Maxum</li> </ul>	<b>All are MRI compatible except for the 1987 McGee stainless steel Prosthesis</b>  <b>MRI compatible</b>  <b>Sophono is not approved for MRI use. The abutment and fixture of the Baha system and Ponto System by Oticon Medical are MRI compatible</b>  <b>Not Approved for MRI use</b>
<b>Cochlear Implants with Removable Internal Magnets</b> <ul style="list-style-type: none"> <li>Nucleus 5 devices, Nucleus Freedom, Nucleus 24, and some Nucleus 22 implants</li> <li>HiResolution Bionic Ear System's HiRes 90K (Advanced Bionics)</li> </ul>	<b>All cochlear implants with removable internal magnets are MRI safe after removal of the internal magnet</b>
<b>Cochlear implants without Removable Internal Magnets</b> <ul style="list-style-type: none"> <li>Newer MED-EL implants: COMBI 40+, PULSAR, CONCERTO, and SONATA cochlear implants</li> <li>All other implants</li> </ul>	<b>The newer MED-EL cochlear implants are approved for MRI magnetic fields of 0.2T* or less. All other implants without removable magnets are not approved for MRI use**</b>

\*MRI machines with magnetic fields of 0.2T are not common in the United States  
 \*\* Although not in the United States, in parts of the world MRI imaging is approved with the application of compression devices



## DISCUSSION

Implants with strong magnetic capacity are associated with risks with MRI imaging. We suspect that the majority of physicians are unfamiliar with MRI safety status of otologic implants. The ideal implant would be both inherently and functionally safe with no artifact properties. There is a trend toward manufacturing non-ferromagnetic implants. There are some cochlear implants that are FDA approved for MRI use and the practicing physician should be aware of these exceptions. Although MRI at 1.5T fields is contraindicated in patients with cochlear implants with non-removable magnets, studies have shown no adverse events in patients who have used compression devices at the time of MRI imaging. A revision stapedectomy with an MRI-safe implant is recommended in patients with the mis-manufactured 1987 stapes prosthesis who absolutely need an MRI.

Patients are provided with MRI safety information cards for cochlear implants, osseointegrated cochlear stimulators, and middle ear implantable hearing devices. Regardless of the presence of an MRI safety card, it is imperative that the MRI facility contact the manufacturer of the device as there may be necessary precautions to take when performing an MRI. There are no safety cards given for stapes prosthesis and partial and total ossicular chain reconstruction implants.

As new information becomes available from studies and changes in FDA regulations, we suggest implementing a way for manufacturing companies to update patients. A national registry of patients with implanted devices should be considered. Websites that are available with MRI safety information on implantable devices should be cautiously used by medical professionals based on source reliability and accuracy.

With the current trend of magnetic resonance imaging, soon we will need updated reviews on MRI safety of otologic implants in stronger magnetic fields. In the meantime this review can serve as a simple reference for current MRI safety standards for otologic implants in the United States in fields up to 1.5T magnetic field strength.

## CONCLUSIONS

MRI safety status of otologic implants depends on their magnetic potential. Knowledge of the MRI safety guidelines for the commonly used otologic implants is important. United States guidelines on MRI safety and compatibility are not always the same as in Europe and other parts of the world. Prior to performing an MRI on patients with otologic implants their MRI safety cards should be reviewed and the manufacturing companies should be contacted.