

Cochlear™ Baha® Connect System

Radiographer's

Instructions

MRI for Baha Connect System

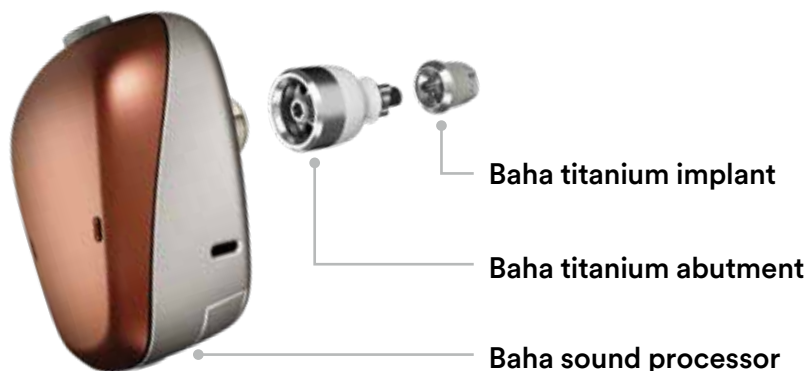
The Cochlear Baha Connect System is a bone conduction implant system. The system includes an osseointegrated titanium implant and a titanium abutment that protrudes through the skin. A Baha sound processor is worn on the head (see figure).

Cochlear Baha implants offer patients a high level of MRI compatibility. These guidelines are intended for radiologists performing MRI scans on a patient with the Cochlear Baha Connect System. Please read this information carefully. For more information, contact Cochlear.

Baha sound processor

As long as the Baha sound processor (see figure) is removed for the MRI procedure, a patient fitted with the Baha system may be exposed to an MRI examination. When undergoing an MRI, the following conditions apply.

Components of Baha system



MRI Safety Information

The sound processor must be removed before entering a room where an MRI scanner is located.



Non-clinical testing has demonstrated that the Implant and Abutment [BI300, BIA400 & BIA300] is MR Conditional at 1.5 and 3.0 Tesla. It can be scanned safely under the following conditions. Scanning under other conditions may result in severe patient injury or device malfunction.

- Static magnetic field of 1.5 Tesla and 3 Tesla only
- Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m)
- Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2 W/kg or maximum head averaged SAR of 3.2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the implant and abutment are expected to produce a maximum temperature rise of 1.1 °C after 15 minutes of continuous scanning.

In non-clinical testing with the implant and abutment in place, the image artefact caused by the device extends approximately 1.8 cm from the implant and abutment when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system. The artefact is reduced to 1.2 cm from the implant when the abutment is removed.

Note:

MR System manufacturers may claim that scanning patients with implanted devices is generally contraindicated. This is a general precautionary claim due to the fact that MR System manufacturers are unable to ensure safety for all types of implantable devices. Cochlear has performed specific testing for the above implants and established the necessary SAR safety limits as outlined. Recently available MR Systems are able to monitor SAR levels. The MR System manufacturer should be able to provide advice on how to maintain SAR levels with their system.

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