95078

Cochlear™ Baha® Attract System

Security control information

English

This person is implanted with a hearing implant system from Cochlear. The system consists of a titanium implant with a magnet implanted under the skin, and an external sound processor (1) and SP Magnet (2). The system may activate airport security metal detectors.

MRI card

621701-02

DEC13. Printed in Sweden.

MRI Safety Information

MR

*The Baha sound processor and SP Magnet **must be removed** before entering a room where an MRI scanner is located.*

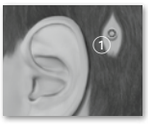
Non-clinical testing has demonstrated that the BIM400 Implant Magnet, in combination with BI300 Implant, is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions. Scanning under other conditions may result in severe patient injury or device malfunction.

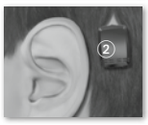
- Static magnetic field of 1.5 Tesla only
- Maximum spatial gradient field of 26600 Gauss/cm (266 T/m)
- Maximum switched gradient slew rate per axis of 200 mT/m/ms
- Maximum switched gradient amplitude per axis of 45 mT/m
- Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)
- Baha sound processor and SP Magnet must be removed before patient enters a room containing an MRI scanner

Additional instructions essential to safe use in the MR environment:

- Under the scan conditions defined above, the BIM400 Implant Magnet is expected to produce a maximum temperature rise of 4.5°C after 30 minutes of continuous scanning.
- In non-clinical testing with the implant magnet in place, the image artifact caused by the device extends approximately 11.5 cm (4.5 in.) from the BIM400 Implant Magnet when imaged with a gradient echo pulse sequence and a 1.5 Tesla MRI system.

English





Cochlear™ Baha® Connect System

Security control and MRI information

This person is implanted with a hearing implant system from Cochlear. The system consists of titanium implant(s) and abutment(s) penetrating the skin (1) and a sound processor (2). The sound processor can be removed before passing through a metal detector unit. If you require any additional information, contact your local Cochlear office, see www.cochlear.com for contact details.

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

MR

Information for MR professionals

As long as the sound processor is removed for the MRI procedure, this person may be safely scanned with MRI without any risk. The resulting artefacts are minor. If you require any additional information, contact your local Cochlear office, see www.cochlear.com for contact details.

Cochlear™ Vistafix® prostheses

Patients fitted with facial or auricular prostheses can also undergo an MRI, as long as the prosthesis and the bar construction, any fixation magnets, magnabutments or magnacaps attached to the implants are removed for the procedure. This will eliminate the risk of implant loss and minimise the artefacts.

Patient identification

Name: _____

Phone: _____

Hospital: _____

Clinican: _____

This patient has the following System:

- ☐ Cochlear Baha Connect System
- ☐ Cochlear Baha Attract System
- ☐ Cochlear Vistafix System

Cochlear®