MRI/Security Control Information

This person has a titanium implant system from Oticon Medical that is surgically implanted into his/her skull. The system consists of an implant and an abutment and cannot be removed. The sound processor which attaches to the abutment can be removed before passing through a metal detector.

The sound processor MUST be removed if the patient needs to undergo Magnetic Resonance Imaging (MRI)! The implant and the abutment can remain in place.

FOLD

Information for MR professionals

Non-clinical testing has demonstrated that the Ponto implant system is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 6,000-Gauss/cm
- Maximum whole body averaged specific absorption rate of 4 W/kg for 15 minutes of scanning in the first level controlled mode

FOLD

In non-clinical testing, the Ponto implant system produced a temperature rise of less than 3.2°C at a maximum whole body average specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MRI scanning in a (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI scanner.

Image artifacts
MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. The maximum artifact size extends approximately 10 mm relative to the size and shape of the implant.

FOLD

MRI/Security Control Information

Name: .....

Surgery performed by clinic/hospital:

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For information about the Ponto System please visit www.oticonmedical.com

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