

MRI Safety/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.

If the patient needs to undergo MRI (Magnetic Resonance Imaging) the sound processor must be disconnected since it is MR Unsafe. The implant and abutment can remain in place.

FOLD

Safety information for MR professionals

If the patient needs to undergo MRI (Magnetic Resonance Imaging) the sound processor must be disconnected since it is MR Unsafe. The implant and abutment can remain in place.

Non-clinical testing has demonstrated that the Ponto Implant System is MR Conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg in the first level controlled mode.

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Under the scan conditions defined above, the Ponto Implant System is expected to produce a maximum temperature rise of 3.2°C after 15 minutes of continuous scanning.

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 to compensate for the presence of this implant.

In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the Ponto Implant System when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.



The Ponto implant and abutment are MR Conditional. The sound processor is MR Unsafe.

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MRI Safety/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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