

MEMO

May 19, 2010

To: Whom it May Concern

From: Pam Simons, Vice President, Regulatory and Clinical Affairs

Re: AMPLATZER® Implantable Devices 1

Through non-clinical testing, AMPLATZER devices have been shown to be MR Conditional². A patient with an implanted AMPLATZER device can be scanned under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 720 Gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of 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 for the presence of this implant.

¹ This MRI information pertains to the AMPLATZER® Septal Occluder, AMPLATZER® Multifenestrated Septal Occluder – "Cribriform," AMPLATZER® Duct Occluder, AMPLATZER® Muscular VSD Occluder and AMPLATZER® Vascular Plug devices.

² Indications, contraindications, warnings, precautions and instructions for use can be found in the Instructions For Use available by request or online at www.amplatzer.com/products.