Subject: **On-X Prosthetic Heart Valve MRI Information**
Date: **March 2010**

MR Conditional

The **On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33*** was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania.

Non-clinical testing demonstrated that the On-X Conform-X Mitral Heart Valve Prosthesis; Size 25-33 is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
-Static magnetic field of 3-Tesla or less
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating
In non-clinical testing, the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6˚C

Therefore, the MRI-related heating experiments for the On-X Conform-X Mitral Heart Valve Prosthesis; Size 25-33 at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6˚C.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the On-X Conform-X Mitral Heart Valve Prosthesis; Size 25-33. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,090-mm^2	686-mm^2	1,478-mm^2	1,014-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

***The MRI findings apply to this specific largest heart valve prosthesis and all other smaller sizes which are made from similar materials.**

For further information go to www.MRIsafety.com.