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Subject: Magnetic Resonance Imaging (MRI) Safety Information

To Whom It May Concern:

Thank you for your question about MRI safety. If you are a patient or patient advocate, it will be helpful to bring this document with you to your medical appointment. If you are unable to print this document, the same information is also available on the St. Jude Medical Web site. Just provide the link underlined below to your doctor.

http://health.sjm.com/heart-valve-answers/daily-life/~/media/SJM%20Health/HVA/PDF/Checklist_Questions%20PDFs/MRI_Safety_Information_2.ashx

For Medical Professionals:
Nonclinical testing has demonstrated that St. Jude Medical heart valves and repair devices may be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient of 525 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning

In nonclinical testing, St. Jude Medical heart valves and repair devices produced a temperature rise of less than or equal to 0.5˚C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a 3 Tesla Signa model (GE) MR scanner. MR image quality may be compromised if the area of interest is the exact same area or relatively close to the position of the device. This information applies to the models listed below, as well as earlier models that are no longer manufactured.

Mechanical Valves	Tissue Valves	Annuloplasty Rings
xxA-101 or xxM-101*	B100-xxA-00 or B100-xxM-00*	AFR-xx*
xxAEC-102 or xxMEC-102*	B10SP-xx*	TAB-xx*
xxAECJ-502 or xxMECJ-502*	B10-xxA-00 or B10-xxM-00*	TARP-xx*
xxAEHPJ-505 or xxMEHPJ-505*	BSP100-xx*	
xxAETJ-504 or xxMETJ-504*	E100-xxA-00 or E100-xxM-00*	
xxAFHPJ-505*	ESP100-xx-00*	
xxAGFN-756*	TF-xxA*	
xxAGN-751*		
xxAHP-105 or xxMHP-105*		
xxAHPJ-505 or xxMHPJ-505*		
xxAJ-501 or xxMJ-501*		
xxAT-103 or xxMT-103*		
xxATJ-503 or xxMTJ-503*		
xxCAVGJ-514-00*		
xxMET-104*		
xxVAVGJ-515*		

* “xx” denotes different sizes available

If you have further questions about MRI safety, please contact St. Jude Medical Customer Service at (800) 544-1664. Thank you.