

**SAFETY OF ST. JUDE MEDICAL® VALVES AND ANNULOPLASTY RINGS DURING MRI**

This information is intended to address safety and effects of Magnetic Resonance Imaging (MRI) on St. Jude Medical® valve and repair products. **All SJM heart valves and annuloplasty rings are MRI safe (3- Tesla or less).** This includes the models listed below as well as others not appearing on this list, some of which are no longer available. Please note: “xx” denotes different sizes available (e.g. 23A-101):

**Mechanical Valves:**

xxA-101 or xxM-101  
 xxAEC-102 or xxMEC-102  
 xxAT-103 or xxMT-103  
 xxAET-104 or xxMET-104  
 xxAHP-105 or xxMHP-105  
 xxATK-106 or xxMTK-106  
 xxAJ-501 or xxMJ-501\*  
 xxAHPJ-505 or xxMHPJ-505\*  
 xxAGN-751\*  
 xxAGFN-756\*  
 xxAK-101 or xxMK-101  
 xxATJ-503 or xxMTJ-503\*  
 xxAETJ-504 or xxMETJ-504\*  
 xxAFHPJ-505\*  
 xxAHPJ-505 or xxMHPJ-505\*  
 xxAEHPJ-505 or xxMEHPJ-505\*  
 xxCAVGJ-514\*  
 xxCAVGJ-514-00\*  
 xxCAVG-404  
 xxAECJ-502 or xxMECJ-502\*

**Tissue Valves:**

B10-xxA or B10-xxM\*  
 B10-xxA-00 or B10-xxM-00\*  
 B30-xxA or B30-xxM  
 EL-xxA or EL-xxM  
 EL-xxA-IDE or EL-xxM-IDE\*  
 ESP-xx\*  
 SPA-101-xx  
 SPA-201-xx  
 ROOT-xx or ROOT-xx-IDE  
 ROOT-SC-xx or ROOT-SC-xx-IDE

**Annuloplasty Rings:**

SARP-xx  
 TARP-xx  
 TAB-xx

Some of these devices listed above may not be commercially available in ALL geographies pending regulatory review and approval.

All SJM heart valves and annuloplasty rings either do not contain metal components or have been determined to be MR-safe by testing performed by an independent source. That is, these devices, when present in a patient undergoing an MRI procedure at 3-Tesla or less will not create an additional hazard or risk to the patient under the conditions used for testing. MRI procedures must be performed according to the following guidelines:

A patient with one of the above devices may safely undergo an MRI procedure using an MR system with a static magnetic field of 3-Tesla or less. These models do not exhibit substantial magnetic field interactions with respect to translational attraction (tested at a maximum spatial gradient, 5.25- Tesla/meter) and showed no torque during exposure to a 3- Tesla MR system. Therefore, there is no additional risk to a patient with one of the above models with respect to movement or dislodgment using an MR system with a static magnetic field of 3- Tesla or less.

MRI procedures must not exceed exposures to radiofrequency (RF) fields greater than a whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes at 3- Tesla in a patient with the above models.

\*Models with asterisks listed above contain metal components in the sewing cuff, which are visible on x-ray. Although there may be slight distortions of images surrounding these devices, these distortions do not affect the scanning images of other areas of the body, nor do they interfere with the function of the device. As with the other models listed above, these models are MRI safe under the conditions described.

Note: If you have additional medical questions after reading this information, please contact the patient’s following physician. If it is necessary to verify the patient having MRI has a SJM heart valve or annuloplasty ring, please call the SJM Patient Device Tracking Department toll free at 1-800-344-5833 (JUDE). Thank you.

Web site link: <http://www.sjm.com/resources/faq.aspx?section=Mechanical%20Valves#219>

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