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Subject: Magnetic Resonance Imaging (MRI) Safety Information

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 doctor's appointment. If you are unable to print this document, it is also available on the St. Jude Medical Website. Just provide this link to your doctor. It includes the same information as below.

<http://health.sjm.com/mri-info-sjm.aspx>

If you have further questions about MRI safety, please contact St. Jude Medical Customer Service at 1-8554STJUDE or 1-855-477-5833. Thank you.

MECHANICAL HEART VALVES

St. Jude Medical™ Regent™ Mechanical Heart Valve

Models	
xxAGN-751	xxAGN-756

xx denotes different sizes available (e.g. 19 AGN-751).

Non-clinical testing has demonstrated that these St. Jude Medical™ mechanical heart valves are MR-Conditional. Patients can be safely scanned, immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m).
- Normal Operating Mode: Maximum whole-body averaged specific absorption rate (SAR) of:
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF heating

In non-clinical testing with body coil excitation, the St. Jude Medical™ Regent™ mechanical heart valves produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 3.1 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5T RF heating

In non-clinical testing with body coil excitation, the St. Jude Medical™ Regent™, mechanical heart valves, produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 1.0 W/kg for 15 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another heating field strength.

MR Artifacts

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact follows the approximate contour of the device and extends radially up to 0.7 cm from the implant at 3.0T in spin echo imaging and 0.8 cm at 1.5T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

MECHANICAL HEART VALVES

St. Jude Medical™ Standard and Masters Series Mechanical Heart Valves and Valved Grafts

Models				
xxA-101	xxM-101	xxAJ-501	xxMJ-501	xxAVG-201
xxAEC-102	xxMEC-102	xxAECJ-502	xxMECJ-502	xxPVG-201
xxAT-103	xxMT-103	xxATJ-503	xxMTJ-503	xxSAVG-301
xxAET-104	xxMET-104	xxAETJ-504	xxMETJ-504	xxCAVG-404
xxAHP-105	xxMHP-105	xxAHPJ-505	xxMHPJ-505	xxCAVGJ-514
		xxAEHPJ-505	xxMEHPJ-505	xxCAVGJ-514 00
		xxAFHPJ-505		xxVAVGJ-515

xx denotes different sizes available (e.g. 19A-101).

Non-clinical testing has demonstrated that these St. Jude Medical™ mechanical heart valves and valved grafts are MR-Conditional. Patients can be safely scanned, immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m).
- Normal Operating Mode: Maximum whole-body averaged specific absorption rate (SAR) of:
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF heating

In non-clinical testing with body coil excitation, the St. Jude Medical™ mechanical heart valves and valved grafts produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 3.4 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5 RF heating

In non-clinical testing with body coil excitation, St. Jude Medical™ mechanical heart valves and valved grafts produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 2.0°C.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another heating field strength.

MR Artifacts

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact follows the approximate contour of the device and extends radially up to 1.4 cm from the implant at 3.0T and 1.1cm at 1.5T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

TISSUE VALVES

St. Jude Medical™ Biocor™ and Epic™ Heart Valves

Models			
B10-xxA	B100-xxA	EL-xxA	E100-xxA
B10-xxA-00	B100-xxA-00	EL-xxM	E100-xxA-00
B10-xxM-	B100-xxM	ESP-xx	E100-xxM
B10-xxM-00	B100-xxM-00		E100-xxM-00
B10SP-xx	BSP100-xx		ESP100-xx
B30-xxA			ESP100-xx-00

xx denotes different sizes available (e.g. B10-19A).

Non-clinical testing has demonstrated that the Biocor™ and Epic™ heart valve devices are MR-Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m).
- Normal Operating Mode: Maximum whole-body averaged specific absorption rate (SAR) of:
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF heating

In non-clinical testing with body coil excitation, the Biocor™ and Epic™ heart valve devices produced a differential temperature rise of less than or equal to 2.0°C when exposed to a whole-body specific absorption rate (SAR) of 2.8 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 2.0°C.

1.5T RF heating

In non-clinical testing with body coil excitation, the Biocor™ and Epic™ heart valve devices produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of scanning in a 1.5- Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifacts

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact follows the approximate contour of the device and extends radially up to 0.3 cm from the implant at 3.0T and 0.2 cm at 1.5T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

TISSUE VALVES
Trifecta™ Heart Valve

Models
TF-xxA

xx denotes different sizes available (e.g. TF-19A).

Non-clinical testing has demonstrated that the Trifecta™ heart valve devices are MR-Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m).
- Normal Operating Mode: Maximum whole-body averaged specific absorption rate (SAR) of:
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF heating

In non-clinical testing with body coil excitation, the Trifecta™ heart valve device produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 3.4 W/kg for 15 minutes of scanning in a 3.0- Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5T RF heating

In non-clinical testing with body coil excitation, the Trifecta™ heart valve device produced a differential temperature rise of less than or equal to 2.0°C when exposed to a whole-body specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than or equal to 2.0°C.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifacts

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact follows the approximate contour of the device and extends radially up to 0.3 cm from the implant at 3.0T and 0.2 cm at 1.5T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

ANNULOPLASTY RINGS

St. Jude Medical™ Rigid Saddle Ring

Models
RSAR-xx

xx denotes different sizes available (e.g. RSAR-24).

Non-clinical testing has demonstrated that the SJM™ Rigid Saddle Rings are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m).
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
 - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T RF heating

In non-clinical testing with body coil excitation, the SJM™ Rigid Saddle Rings produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning in a 3.0-Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5T RF heating

In non-clinical testing with body coil excitation, the SJM™ Rigid Saddle Rings produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 1.3 W/kg for 15 minutes of scanning in a 1.5-Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 2.0°C.

Caution: The RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

MR Artifacts

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact follows the approximate contour of the device and extended radially up to 0.9 cm from the implant at 3.0T in gradient echo imaging and 0.7cm from the implant at 1.5T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

The following products are labeled as MR Safe and not MR Conditional per ASTM F2503.

St. Jude Medical™ Seguin Annuloplasty Ring	St. Jude Medical™ Attune Flexible Adjustable Annuloplasty Ring	St. Jude Medical™ Tailor Annuloplasty Ring	St. Jude Medical™ Tailor Annuloplasty Band
SARP-xx	AFR-xx	TARP-xx	TAB-xx

xx denotes different sizes available (e.g. SARP-24).