Abbott

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 Abbott website. Just provide this link to your doctor. It includes the same information as below.

https://www.cardiovascular.abbott/us/en/hcp/resources/mri-ready-resources/structural-heart-mri-safety.html

MECHANICAL HEART VALVES

SJM Regent™ Mechanical Heart Valve

MODELS	
xxAGN-751	xxAGFN-756

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

Nonclinical testing has demonstrated that these Abbott 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 (1.5 T) or 3.0 T
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30 T/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 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

3.0 T RADIO FREQUENCY (RF) HEATING

In nonclinical testing with body coil excitation, the SJM Regent mechanical heart valves produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body SAR of 3.1 W/kg for 15 minutes of scanning in a 3.0 T magnetic resonance (MR) system (Siemens MAGNETOM Trio SYNGO‡ MR A35 4VA35A software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5 T RF HEATING

In nonclinical testing with body coil excitation, the SJM Regent mechanical heart valves produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body SAR of 1.0 W/kg for 15 minutes of scanning in a 1.5 T MR system (Siemens MAGNETOM Espree SYNGO‡ MR B19 software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an 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 that 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 as 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 3.0 T in spin echo imaging and 0.8 cm at 1.5 T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

MECHANICAL HEART VALVES

SJM™ 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).

Nonclinical testing has demonstrated that these Abbott 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 T or 3.0 T
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30 T/m)
- Normal Operating Mode: Maximum whole-body averaged SAR of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T

3.0 T RF HEATING

In nonclinical testing with body coil excitation, the Abbott 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 SAR of 3.4 W/kg for 15 minutes of scanning in a 3.0 T MR system (Siemens MAGNETOM Trio SYNGO‡ MR A35 4VA35A software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5 T RF HEATING

In nonclinical testing with body coil excitation, Abbott 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 SAR of 1.4 W/kg for 15 minutes of scanning in a 1.5 T MR system (Siemens MAGNETOM Espree SYNGO‡ MR B19 software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an 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 that 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 as 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 3.0 T and 1.1 cm at 1.5 T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

TISSUE VALVES

Biocor™ and Epic™ Stented Tissue 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).

Nonclinical testing has demonstrated that the Biocor™ and Epic™ stented tissue valve devices are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

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

3.0 T RF HEATING

In nonclinical testing with body coil excitation, the Biocor and Epic stented tissue valve devices produced a differential temperature rise of less than or equal to 2.0°C when exposed to a whole-body SAR of 2.8 W/kg for 15 minutes of scanning in a 3.0 T MR system (Siemens MAGNETOM Trio SYNGO‡ MR A35 4VA35A software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 2.0°C.

1.5 T RF HEATING

In nonclinical testing with body coil excitation, the Biocor and Epic stented tissue valve devices produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body SAR of 1.4 W/kg for 15 minutes of scanning in a 1.5 T MR system (Siemens MAGNETOM Espree SYNGO‡ MR B19 software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an 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 that 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 as 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 3.0 T and 0.2 cm at 1.5 T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

TISSUE VALVES

Trifecta™ Valve

MODEL
TF-xxA

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

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

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

3.0 T RF HEATING

In nonclinical testing with body coil excitation, the Trifecta valve device produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body SAR of 3.4 W/kg for 15 minutes of scanning in a 3.0 T MR system (Siemens MAGNETOM Trio SYNGO‡ MR A35 4VA35A software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5 T RF HEATING

In nonclinical testing with body coil excitation, the Trifecta valve device produced a differential temperature rise of less than or equal to 2.0°C when exposed to a whole-body SAR of 1.4 W/kg for 15 minutes of scanning in a 1.5 T MR system (Siemens MAGNETOM Espree SYNGO‡ MR B19 software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an 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 that 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 as 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 3.0 T and 0.2 cm at 1.5 T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

TISSUE VALVES

Trifecta™ Valve with Glide™ Technology (GT)

MODEL
TFGT-xxA

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

TRIFECTA™ GT VALVE

Nonclinical testing has demonstrated that the Trifecta™ GT Valve is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial field gradient of 3,000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole-body averaged SAR of 2.0 W/kg (Normal Operating Mode)

RF HEATING

Under the scan conditions defined above, the Trifecta GT Valve is expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

MR ARTIFACTS

In nonclinical testing, the image artifact extended radially 0.6 cm from the prosthetic valve when imaged with a gradient echo pulse sequence and a 3.0 T system.

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

ANNULOPLASTY RINGS

SJM™ Rigid Saddle Ring

MODEL
RSAR-xx

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

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

3.0 T RF HEATING

In nonclinical 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 SAR of 3.0 W/kg for 15 minutes of scanning in a 3.0 T MR system (Siemens MAGNETOM Trio SYNGO‡ MR A35 4VA35A software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

1.5 T RF HEATING

In nonclinical 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 SAR of 1.3 W/kg for 15 minutes of scanning in a 1.5 T MR system (Siemens MAGNETOM Espree SYNGO‡ MR B19 software, Erlangen, Germany). Scaling of the SAR and observed heating indicates that an 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 that 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 as 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 3.0 T in gradient echo imaging and 0.7 cm from the implant at 1.5 T 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.

SJM™ SÉGUIN SEMI-RIGID ANNULOPLASTY RING	ATTUNE™ FLEXIBLE ADJUSTABLE ANNULOPLASTY RING	SJM TAILOR™ FLEXIBLE ANNULOPLASTY RING	SJM TAILOR™ FLEXIBLE ANNULOPLASTY BAND
SARP-xx	AFR-xx	TARP-xx	TAB-xx

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

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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