Dear Imaging Center:

This letter is in response to your inquiry concerning the safety of performing magnetic resonance (MR) procedures in patients who have been implanted with Edwards Lifesciences LLC (formerly Baxter Healthcare Corporation) heart valve therapy products.

MR Information:
MR procedures have been performed on numerous occasions on patients with Edwards' implantable products without reported problems. The products listed below are made from non-ferromagnetic or weakly ferromagnetic materials. For the weakly ferromagnetic products, the *in vivo* forces are greater than those pertaining to the magnetic field interactions (i.e., the forces associated with translational attraction and torque are less than those associated with gravitational forces). Thus, these products are considered safe for patients undergoing MRI procedures using MR systems operating with static magnetic fields as described below.

Product Information:

Replacement Heart Valve Product Description (Stented Tissue)	**Models**	**Reference**
Carpentier-Edwards aortic and mitral bioprostheses	2625, 6625	1
Carpentier-Edwards S.A.V. aortic bioprosthesis	2650	1
Carpentier-Edwards Duraflex low pressure porcine mitral bioprosthesis	6625LP	1
Carpentier-Edwards Duraflex low pressure porcine mitral bioprosthesis with extended sewing ring	6625-ESR-LP	1
Carpentier-Edwards PERIMOUNT Plus mitral pericardial bioprosthesis	6900P	1
Carpentier-Edwards PERIMOUNT Theon mitral pericardial bioprosthesis	6900PTFX	1
Carpentier-Edwards bioprosthetic valved conduit	4300	1

Testing of these devices in a magnetic field of 1.5, 3.0, and 8.0 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures.

The valve wireform stent, and orifice-stiffening band when present, are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT pericardial aortic bioprostheses	2700, 2700TFX	12
Carpentier-Edwards PERIMOUNT RSR pericardial aortic bioprostheses	2800, 2800TFX	13

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards PERIMOUNT pericardial aortic bioprostheses, models 2700, 2700TFX, and Carpentier-Edwards PERIMOUNT RSR pericardial aortic bioprostheses, models 2800 and 2800TFX are MR Conditional. A patient with the valve can be scanned safely, immediately after placement of this valve under the following conditions:

- Static magnetic field of 3 tesla or less.
- Spatial gradient field of less than 3000 gauss/cm.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg in the normal operating mode for 15 minutes of MR scanning per sequence

Based on worst-case non-clinical testing according to ASTM F2182-11a using a test valve that produced a temperature rise greater than that of the models 2700, 2700TFX PERIMOUNT pericardial aortic bioprostheses, and the models 2800 and 2800TFX PERIMOUNT RSR pericardial aortic bioprostheses, the valve was determined to produce a maximum temperature rise of 2.3 °C at a whole-phantom-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a GE Signa 64 MHz (1.5 T) RF coil. The maximum temperature rise was 2.1 °C at a whole-phantom-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a GE Signa HDx 3T MR system with Software version 15\LX\MR, Software release 15.0.M4.0910.a.

Image artifact was measured non-clinically in a GE Signa 3T HDx MR system according to ASTM F2119-07(2013) using the spin echo and gradient echo sequences specified therein. The spin echo images exhibited light and dark artifacts that extended as far as 8.5 mm from the implant, and partially to fully obscured the lumen. The gradient echo images exhibited opaque dark or light and dark triangular shaped artifacts that extended as far as 27.5 mm from the implant and totally obscured the lumen. Reduction in artifact may be possible with sequences designed for reduction of metal artifact.

The valve wireform stent, and orifice-stiffening band when present, are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT Magna mitral pericardial bioprosthesis	7000/7000TFX	1

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards PERIMOUNT Magna mitral pericardial bioprosthesis is MR Conditional. A patient with the PERIMOUNT Magna mitral bioprosthesis can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less.
- Maximum spatial gradient field of 720 gauss/cm.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.

In non-clinical testing, the PERIMOUNT Magna mitral bioprosthesis produced a temperature rise of less than or equal to 0.5 °C at a maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PERIMOUNT Magna mitral bioprosthesis. Optimization of MR imaging parameters is recommended.

The valve wireform stent and orifice-stiffening band are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis	7200TFX	1

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis is MR Conditional. A patient with the PERIMOUNT Magna Mitral Ease bioprosthesis can be scanned safely immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less.
- Maximum spatial gradient field of 720 gauss/cm.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.

In non-clinical testing, the PERIMOUNT Magna Mitral Ease bioprosthesis produced a temperature rise of less than or equal to 0.5 °C at a maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PERIMOUNT Magna Mitral Ease bioprosthesis. Optimization of MR imaging parameters is recommended.

The valve wireform stent and orifice-stiffening band are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis	7300TFX	1

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprosthesis is MR Conditional. A patient with the PERIMOUNT Magna Mitral Ease bioprosthesis can be scanned safely immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less.
- Maximum spatial gradient field of 720 gauss/cm.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.

In non-clinical testing, the PERIMOUNT Magna Mitral Ease bioprosthesis produced a temperature rise of less than or equal to 0.5 °C at a maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PERIMOUNT Magna Mitral Ease bioprosthesis. Optimization of MR imaging parameters is recommended.

The valve wireform stent and orifice-stiffening band are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT Magna pericardial aortic bioprostheses	3000, 3000TFX	1

The device has been shown not to have magnetic interactions at up to 8 tesla. It is also safe with respect to RF heating at 1.2 W/kg for up to 15 minutes. Artifacts have been determined at 1.5 tesla.

The valve wireform stent and orifice-stiffening band are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprosthesis	3300TFX	1

MR Conditional

Non-clinical testing has demonstrated that the PERIMOUNT Magna Ease aortic bioprosthesis is MR Conditional. A patient with the PERIMOUNT Magna Ease aortic bioprosthesis can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less.
- Maximum spatial gradient field of 720 gauss/cm .
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3W/kg for 15 minutes of scanning.

In non-clinical testing, the PERIMOUNT Magna Ease aortic bioprosthesis produced a temperature rise of less than or equal to 0.4 ºC at a maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PERIMOUNT Magna Ease aortic bioprosthesis. Optimization of MR imaging parameters is recommended.

The valve wireform stent and orifice-stiffening band are composed of a corrosion-resistant cobalt-chromium spring alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Cribier-Edwards aortic bioprosthesis (PHV) (Caution: Investigational device. Limited by Federal law to investigational use.)	9000, 9000PHV	N/A

Non-clinical testing has demonstrated that the Cribier-Edwards aortic bioprosthesis (PHV) is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 tesla or less.
- Spatial gradient field of 720 gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.

In non-clinical testing, the device produced a maximum temperature increase of 0.5 °C at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MRI.

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 device.

The valve's stent frame is composed of stainless steel material. The nominal composition (wt. percent) of the stainless steel material used is as follows:

Chromium	Nickel	Molybdenum	Manganese	Silicon	Copper	Carbon	Phosphorus	Sulfur	Iron
17.3%	14.4%	2.53%	1.74%	0.54%	0.093%	0.026%	0.017%	0.001%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Edwards SAPIEN transcatheter heart valve	9000TFX	N/A

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN transcatheter heart valve is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3 Tesla.
- Spatial gradient field of 2500 gauss/cm or less.
- Maximum whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning
- Normal mode operation, as defined in IEC 60601-2-33 Ed. 3.0, of the MR system.

In non-clinical testing and analysis, the implant was determined to produce a temperature rise of less than 1.1 °C above background for a whole body SAR of 2W/kg for 15 minutes of MR scanning in a 1.5 T and 3.0 T cylindrical whole body MR system.
The image artifact extended as far as 15 mm from the device for spin echo images and 40 mm for gradient images when scanned in non-clinical testing in a 3 T GE Signa HDx MR system. The artifact obscures the device lumen in gradient echo images. The implant has not been evaluated in MR systems other than 1.5 or 3.0 T.

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 device.

The valve's stent frame is composed of stainless steel material. The nominal composition (wt. percent) of the stainless steel material used is as follows:

Chromium	Nickel	Molybdenum	Manganese	Silicon	Copper	Carbon	Phosphorus	Sulfur	Iron
17.3%	14.4%	2.53%	1.74%	0.54%	0.093%	0.026%	0.017%	0.001%	Bal

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Edwards SAPIEN XT transcatheter heart valve (THV)	9300TFX	N/A

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN XT transcatheter heart valve is MR Conditional. A patient with this device can be scanned safely, immediately after placement of this device under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla
- Maximum spatial gradient field of 2500 gauss/cm (25 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SAPIEN XT transcatheter heart valve is expected to produce a maximum temperature rise of 2.6º C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends as far as 14.5 mm from the implant for spin echo images and 30 mm for gradient echo images when scanned in a 3.0 T MRI system. The artifact obscures the device lumen in gradient echo images. The implant has not been evaluated in MR systems other than 1.5 or 3.0 T.

For valve-in-surgical valve implantation or in the presence of other implants, please refer to the MRI safety information for the surgical valve or other devices prior to MR imaging.

The frame of the implant is composed of MP35N alloy with the chemical constituents listed below:

Carbon	max. 0.025 wt.-%
Silicon	max. 0.15 wt.-%
Manganese	max. 0.15 wt.-%
Phosphorus	max. 0.015 wt.-%
Sulfur	max. 0.010 wt.-%
Chromium	19.0 – 21.0 wt.-%
Nickel	33.0 – 37.0 wt.-%
Iron	max. 0.1 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	balance

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Edwards SAPIEN 3 transcatheter heart valve (THV)	9600TFX	N/A

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 transcatheter heart valve is MR Conditional. A patient with this device can be scanned safely, immediately after placement of this device under the following conditions:

- Static magnetic field of 1.5 tesla or 3 tesla.
- Maximum spatial gradient field of 2500 gauss/cm (25 T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SAPIEN 3 transcatheter heart valve is expected to produce a maximum temperature rise of 3.0 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 14.5 mm from the implant for spin echo images and 30 mm for gradient echo images when scanned in a 3.0 T MRI system. The artifact obscures the device lumen in gradient echo images. The implant has not been evaluated in MR systems other than 1.5 or 3.0T.

For valve-in- valve implantation or in the presence of other implants, please refer to the MRI safety information for the surgical valve or other devices prior to MR imaging.*

The frame of the implant is composed of MP35N alloy with the chemical constituents listed below:

Carbon	max. 0.025 wt.-%
Silicon	max. 0.15 wt.-%
Manganese	max. 0.15 wt.-%
Phosphorus	max. 0.015 wt.-%
Sulfur	max. 0.010 wt.-%
Chromium	19.0 – 21.0 wt.-%
Nickel	33.0 – 37.0 wt.-%
Iron	max. 0.1 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	balance

***INVESTIGATIONAL DEVICES. CAUTION: The Edwards SAPIEN 3 transcatheter heart valve is an investigational device when used in valve-in- valve implantation. Limited by Federal (USA) law to investigational use only. These devices are not available for marketing or commercial sale in the United States for valve-in- valve implantation. See instructions for use for full information, including indications, contraindications, warnings, precautions and adverse events.**

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
CardiAQ-Edwards transcatheter mitral valve (TMV)	TMV3040B	N/A

MR Conditional

Non-clinical testing has demonstrated that the TMV is MR Conditional. A patient with this device can be scanned safely in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla only
- Maximum spatial gradient field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg

Under the scan conditions defined above, the TMV is expected to produce a maximum temperature rise of 1.8°C in a 1.5 Tesla system and 2.4°C in a 3.0 Tesla system after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the TMV when imaged with a gradient echo and spin echo pulse sequence and a 3.0 Tesla MRI system. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the TMV. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

The frame of the implant is composed of Nitinol alloy with the chemical constituents listed below in accordance with ASTM F2063-12.

Nickel	54.5 to 57%
Titanium	Balance
Nitrogen plus Oxygen	0.05%
Carbon	<0.05%

Replacement Heart Valve Product Description (Stentless Tissue)	Model
Edwards Prima aortic stentless bioprosthesis Edwards Prima Plus aortic stentless bioprosthesis	2500 2500P
These valves are made of porcine aortic valves and there are no metallic components. Therefore there are no MRI issues for these implants.	

Replacement Heart Valve Product Description (Ball and Cage Mechanical)	Models	Reference
Starr-Edwards aortic and mitral prostheses	1000, 1200, 2300, 2310, 2400, 6000, 6120, 6300, 6310, 6320, 6400	2, 3
Testing of these devices in a static magnetic field up to 1.5 tesla show that they are safe during MR procedures performed at 1.5 tesla or less though they are weakly ferromagnetic.		
Starr-Edwards prostheses	Pre-1000, Pre-6000, 1260, 2320, 6520 (plastic disk)	2, 4, 5
Testing of these devices in a static magnetic field up to 2.35 tesla show that they are safe during MR procedures performed at 2.35 tesla or less though they are weakly ferromagnetic.		
Valve cages are comprised of Stellite 21. Additionally, the hollow balls of the metallic ball valves (Models 2300, 2310, 2320, 2400, 6300, 6310, 6320 and 6400) are also composed of Stellite 21. The nominal composition (wt. percent) of Stellite 21 is as follows:		

Cobalt	Carbon	Manganese	Silicon	Chromium	Nickel	Molybdenum	Iron
61.5%	<0.35%	< 1.0	1.0%	28.5%	<1.0%	6%	0.75%

Replacement Heart Valve Product Description (Bileaflet Mechanical)	Models	Reference
Edwards-Duromedics aortic and mitral bileaflet prostheses	3160, 9120	2
Testing of these devices in a static magnetic field up to 1.5 tesla show that they are safe during MR procedures performed at 1.5 tesla or less. Valve housings are composed of solid pyrolytic carbon and the leaflets are graphite substrate coated with pyrolytic carbon. The retainer rings in the sewing ring are commercially pure titanium grade II. The stiffener rings are Stellite 25. The nominal composition (wt. percent) for Stellite 25 is as follows:		

Cobalt	Chromium	Tungsten	Nickel	Iron	Manganese	Carbon
50%	20%	15%	10%	< 3%	1.5%	0.1%

The nominal composition (wt. percent) for commercially pure titanium grade II is as follows:

Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Titanium
< 0.03%	< 0.10%	< 0.012%	< 0.30%	< 0.25%	99%

Replacement Heart Valve Product Description (Bileaflet Mechanical)	Models	Reference
Edwards MIRA aortic and mitral mechanical valves (Caution: Investigational device. Limited by Federal law to investigational use.)	3600, 3600f, 3600u, 9600	1

Testing of these devices in a magnetic field of 1.5, 3.0, and 8.0 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures. Valve housing is composed of ASTM B348 Grade 5 Ti-6Al-4V titanium alloy coated with turbostatic carbon. Leaflets are composed of graphite substrate coated with pyrolytic carbon. The nominal composition for Ti-6Al-4V titanium alloy is as follows:

Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Aluminum	Vanadium	Titanium
< 0.03%	< 0.10%	< 0.0125%	< 0.40%	< 0.20%	5.5 to 6.75%	3.5 to 4.5%	Balance (~90%)

Valve Repair Product Description	Models	Reference
Carpentier-Edwards Classic annuloplasty mitral and tricuspid rings	4400, 4500	1
Carpentier-Edwards Classic annuloplasty mitral and tricuspid rings with Duraflo treatment	4425, 4525	1
Edwards MC3 Tricuspid annuloplasty ring	4900	1

Testing of these devices in a magnetic field of 1.5, 3.0, and 8.0 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures. Rings have titanium alloy cores. The nominal composition (wt. percent) of the titanium alloy is as follows:

Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Aluminum	Vanadium	Titanium
< 0.05%	< 0.08%	< 0.012%	< 0.25%	< 0.13%	6%	4%	89%

Exceptions:

Carpentier-Edwards annuloplasty rings, Models 4400 and 4500, marketed from 1980 to 1983, were made of stainless steel. Therefore we are unable to advise on the safety of MR procedures for patients with these particular annuloplasty rings. These older rings were labeled with lot numbers (not serial numbers) that had the following format: 1C005 (i.e., where the first character was numeric, the second character was a letter from A to L and the last three or four characters were numeric).

Valve Repair Product Description	Models	Reference
Carpentier-McCarthy-Adams IMR ETlogix mitral annuloplasty ring	4100	1
GeoForm mitral annuloplasty ring	4200	1

The device has been shown not to have magnetic interactions at up to 8 tesla. It is also safe with respect to RF heating at 1.2 W/kg for up to 15 minutes. Artifacts have been determined at 1.5 tesla.

Rings have titanium alloy cores. The nominal composition (wt. percent) of the titanium alloy is as follows:

Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Aluminum	Vanadium	Titanium
< 0.05%	< 0.08%	< 0.012%	< 0.25%	< 0.13%	6%	4%	89%

Valve Repair Product Description	Models
Cosgrove-Edwards annuloplasty mitral and tricuspid band	4600
Cosgrove-Edwards annuloplasty mitral and tricuspid band with Duraflo treatment	4625
These bands are composed of a silicone rubber strip impregnated with barium sulfate covered with a woven polyester cloth and there are no metallic components. Therefore, there are no MRI issues for these implants.	

Valve Repair Product Description	Models	Reference
Carpentier-Edwards Physio mitral annuloplasty ring	4450	1
Carpentier-Edwards Physio mitral annuloplasty ring with Duraflo Treatment	4475	1

Testing of these devices in a magnetic field of 1.5, 3.0, and 8.0 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures. Rings have metallic bands separated by polyester film strips covered by silicone rubber and a woven polyester covering. The nominal composition (wt. percent) of the metal is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	16.0%

Valve Repair Product Description	Model	Reference
Carpentier-Edwards Physio II mitral annuloplasty ring	5200	1

MR Conditional

Non-clinical testing has demonstrated that the Carpentier-Edwards Physio II annuloplasty ring, model 5200, is MR Conditional. A patient with this annuloplasty ring can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less
- Spatial gradient field of 720 gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In non-clinical testing, the Carpentier-Edwards Physio II annuloplasty ring produced a temperature rise of less than or equal to 1.8 °C at a maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR System.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Optimization of MR imaging parameters is recommended.

Rings have metal alloy bands separated by polyester film strips covered by silicone rubber and a woven polyester covering. The nominal composition (wt. percent) of the metal alloy is as follows:

Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	<0.10%	<0.10%	16%

Valve Repair Product Description	Model	Reference
Carpentier-Edwards Physio Tricuspid annuloplasty ring	6200	11

Testing of these devices in a magnetic field of 3.0 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures. Rings have titanium alloy cores. The nominal composition (wt. percent) of the titanium alloy is as follows:

Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Aluminum	Vanadium	Titanium
< 0.05%	< 0.08%	< 0.012%	< 0.25%	< 0.13%	6%	4%	89%

Valve Repair Product Description	Model	Reference
dETlogix mitral annuloplasty ring	5100	1

MR Conditional

Non-clinical testing has demonstrated that the dETlogix annuloplasty ring, model 5100, is MR Conditional. A patient with the dETlogix annuloplasty ring can be scanned safely, immediately after placement of this implant under the following conditions:

- Static magnetic field of 3 tesla or less
- Spatial gradient field of 720 gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning

In non-clinical testing, the dETlogix annuloplasty ring produced a temperature rise of less than or equal to 0.6 °C at a maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a 3 tesla MR System.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Optimization of MR imaging parameters is recommended.

The ring has a titanium alloy core. The nominal composition (wt. percent) of the titanium alloy is as follows:

Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Aluminum	Vanadium	Titanium
< 0.05%	< 0.08%	< 0.012%	< 0.25%	< 0.13%	6%	4%	89%

Bovine Pericardial Patch	Model
Bovine Pericardial Patch	4700

These patches are constructed from bovine pericardial tissue and there are no metallic components. Therefore there are no MRI issues for this implant.

Contact us in the USA at 800-424-3278 or outside the USA at 949-250-2500 if you have any questions.

Sincerely,
Technical Support

References:

1. Shellock FG, Prosthetic heart valves and annuloplasty rings: assessment of magnetic field interactions, heating, and artifacts at 1.5-Tesla. *Journal of Cardiovascular Magnetic Resonance* 2001; 3(4):317-324.
2. Shellock, F.G., *Pocket Guide to MR Procedures and Metallic Objects: Update 2000*, Lippincott Williams & Wilkins, Philadelphia, PA, 2000.
3. Shellock, F.G., Crues, J.V. High-field-strength MR imaging and metallic biomedical implants: an ex-vivo evaluation of deflection forces. *Am J Roentgenol* 1988; 151:389-392.
4. Soulen, R.L., et al, Magnetic Resonance Imaging of Prosthetic Heart Valves, *Radiology* 1985; 154:705-707.
5. Hassler M., Le Bas J.F., Wolf J.E., et al. Effects of magnetic fields used in MRI on 15 prosthetic heart valves. *J Radiol* 1986; 67:661-666.
6. Ahmed, S., Shellock, F.G. Magnetic resonance imaging safety: implications for cardiovascular patients. *Journal of Cardiovascular Magnetic Resonance* 2001; 3(3):171-182.
7. Randall, P.A., et al, Magnetic Resonance Imaging of Prosthetic Cardiac Valves In Vitro and In Vivo, *Am J Cardiology* 1988; 62:973-976.
8. Shellock, F.G., MR Imaging of Metallic Implants and Materials: A Compilation of the Literature, *Am J Roentgenol* 1988; 151:811-814.
9. Shellock, F.G. *Magnetic Resonance Procedures: Health Effects and Safety*, CRC Press, Boca Raton, FL, 2001.
10. http://www.MRIsafety.com - This website was developed and is maintained by Frank G. Shellock, Ph.D.
11. Nyenhuis, J. Measurement and analysis of interactions of the electromagnetic fields in MRI at 1.5 and 3.0T with the Edwards Physio Tricuspid Ring, Model 6200. *Purdue University School of Electrical and Computer Engineering* November, 2010.
12. Schmidt, P, MR Safety Information for Model 2700 and 2700TFX. Edwards Report RD1995, Rev. B, 2014.
13. Schmidt, P, MR Safety Information for Model 2800, 2800TFX, 2900, and 2900TFX. Edwards Report RD1988, Rev. B, 2014.
14. Pesce, L, Engineering Technical Summary: Test Report Evaluation of MRI for CardiAQ Transcatheter Mitral Valve (TMV), Edwards Report ETS-2203-02, Rev. A, 2014

Edwards Lifesciences LLC
One Edwards Way · Irvine, CA USA · 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com