



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, CardioVascular Group) 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, weakly ferromagnetic materials or paramagnetic materials. For all 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 magnetic resonance imaging (MRI) procedures using MR systems operating under the conditions described in the following pages.

Product Information:

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards aortic and mitral bioprostheses	2625, 6625	12, 21, 22
Carpentier-Edwards S.A.V. aortic bioprosthesis	2650	12, 21, 22
Carpentier-Edwards Duraflex low pressure porcine mitral bioprosthesis	6625LP	12, 21, 22
Carpentier-Edwards Duraflex low pressure porcine mitral bioprosthesis with extended sewing ring	6625-ESR-LP	12, 21, 22
Carpentier-Edwards bioprosthetic valved conduit	4300	12, 21, 22



MR Conditional

Non-clinical testing has demonstrated that these devices are MR Conditional. A patient with these devices can be scanned safely immediately after placement of the implant under the following conditions:

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

Under the scan conditions defined above these devices are expected to produce a maximum temperature rise of 3 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by these devices extends approximately as far as 30 mm from the devices when imaged with a gradient echo pulse sequence and approximately as far as 14 mm from the devices when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of these devices. Optimization of MR imaging parameters is recommended.

The valve wireform stent is 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	18, 20, 21, 22, 23
Carpentier-Edwards PERIMOUNT RSR pericardial aortic bioprostheses	2800, 2800TFX	
Carpentier-Edwards PERIMOUNT Magna pericardial aortic bioprostheses	3000, 3000TFX	



MR Conditional

Non-clinical testing has demonstrated that these devices are MR Conditional. A patient with these valves 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 for 15 minutes of continuous scanning per sequence in the normal operating mode

Under the scan conditions defined above these devices are expected to produce a maximum temperature rise of 2.3 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by these devices extends approximately as far as 27.5 mm from the bioprostheses when imaged with a gradient echo pulse sequence and approximately as far as 8.5 mm from the valves when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the bioprostheses. 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 Ease pericardial aortic bioprosthesis		3300TFX	20, 21, 22																
 MR Conditional Non-clinical testing has demonstrated that this device is MR Conditional. A patient with this valve can be scanned safely, immediately after placement of this implant under the following conditions: <ul style="list-style-type: none"> • 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 for 15 minutes of continuous scanning per sequence in the normal operating mode <p>Under the scan conditions defined above this device is expected to produce a maximum temperature rise of 2.3 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately as far as 25.5 mm from the bioprosthesis when imaged with a gradient echo pulse sequence and approximately as far as 12.5 mm from the valve when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the bioprosthesis. Optimization of MR imaging parameters is recommended.</p> <p>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:</p> <table border="1"> <thead> <tr> <th>Cobalt</th> <th>Chromium</th> <th>Nickel</th> <th>Molybdenum</th> <th>Manganese</th> <th>Carbon</th> <th>Beryllium</th> <th>Iron</th> </tr> </thead> <tbody> <tr> <td>40%</td> <td>20%</td> <td>15%</td> <td>7%</td> <td>2%</td> <td>< 0.10%</td> <td>< 0.10%</td> <td>Bal</td> </tr> </tbody> </table>				Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron	40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal
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 mitral bioprosthesis	6900	20, 21, 22
Carpentier-Edwards PERIMOUNT Plus pericardial mitral bioprosthesis	6900P	
Carpentier-Edwards PERIMOUNT Theon mitral pericardial bioprosthesis	6900PTFX	



MR Conditional

Non-clinical testing has demonstrated that these devices are MR Conditional. A patient with these valves can be scanned safely, immediately after placement of these implants 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 for 15 minutes of continuous scanning per sequence in the normal operating mode

Under the scan conditions defined above these devices are expected to produce a maximum temperature rise of 2.3 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately as far as 33 mm from the bioprostheses when imaged with a gradient echo pulse sequence and approximately as far as 12.5 mm from the valves when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of these bioprostheses. 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 pericardial bioprostheses	7000, 7000TFX	20, 21, 22
Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprostheses	7200TFX, 7300TFX	



MR Conditional

Non-clinical testing has demonstrated that these devices are MR Conditional. A patient with these valves can be scanned safely immediately after placement of these implants under the following conditions:

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

Under the scan conditions defined above these devices are expected to produce a maximum temperature rise of 2.3 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately as far as 36 mm from the bioprostheses when imaged with a gradient echo pulse sequence and approximately as far as 11.5 mm from the valves when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of these bioprostheses. 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
EDWARDS INTUITY Elite aortic valve	8300AB	14



MR Conditional

Non-clinical testing has demonstrated that this device is MR Conditional. A patient with this valve 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 less than 2670 gauss/cm.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of continuous scanning per sequence in the normal operating mode

Under the scan conditions defined above this device is expected to produce a maximum temperature rise of 0.8°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately as far as 40 mm from the bioprosthesis when imaged with a gradient echo pulse sequence and approximately as far as 40 mm from the valve when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the 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

The expandable frame is composed of a stainless steel alloy that is commonly used in implantable devices. The nominal composition (wt. percent) of the stainless steel material used is as follows:

Chromium	Nickel	Molybdenum	Manganese	Silicon	Carbon	Phosphorus	Sulfur	Copper	Iron
18%	14%	2.6%	< 2.0%	< 0.75%	< 0.03%	< 0.025%	< 0.01%	< 0.5%	Bal




Replacement Heart Valve Product Description (Stented Tissue)				Model	Reference		
INSPIRIS RESILIA aortic valve				11500A	24		
 MR Conditional Non-clinical testing has demonstrated that this device is MR Conditional. A patient with this valve can be scanned safely, immediately after placement of this implant under the following conditions: <ul style="list-style-type: none"> • 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 for 15 minutes of continuous scanning per sequence in the normal operating mode <p>Under the scan conditions defined above this device is expected to produce a maximum temperature rise of 2.5 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately as far as 17 mm from the bioprosthesis when imaged with a gradient echo pulse sequence and approximately as far as 10 mm from the valve when imaged with a spin echo pulse sequence in a 3 T MRI system. The lumen is partially to fully obscured under these conditions. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the bioprosthesis. Optimization of MR imaging parameters is recommended.</p> <p>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:</p>							
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						
<p>Non-clinical testing has demonstrated that the Cribier-Edwards aortic bioprosthesis (PHV) is MR Conditional. It can be scanned safely under the following conditions:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>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. Optimization of MR imaging parameters is recommended.</p> <p>The valve's stent frame is composed of stainless steel material. The nominal composition (wt. percent) of the stainless steel material as follows:</p>									
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							
<p data-bbox="256 520 505 575">  MR Conditional </p> <p data-bbox="256 615 1382 674"> Non-clinical testing has demonstrated that the Edwards SAPIEN transcatheter heart valve is MR Conditional. It can be scanned safely under the following conditions: </p> <ul data-bbox="302 680 1430 835" style="list-style-type: none"> • 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. <p data-bbox="256 867 1438 953"> 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. </p> <p data-bbox="256 959 1438 1077"> 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. </p> <p data-bbox="256 1129 1484 1188"> 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. </p> <p data-bbox="256 1220 1484 1276"> 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: </p>									
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 2.6° 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 °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- 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
CardiaAQ-Edwards transcatheter mitral valve (TMV)	TMV3040B	N/A
<p data-bbox="253 449 505 506">  MR Conditional </p> <p data-bbox="245 541 1461 600">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:</p> <ul data-bbox="293 604 1455 699" style="list-style-type: none"> • 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 <p data-bbox="245 730 1498 789">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.</p> <p data-bbox="245 821 1498 972">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.</p> <p data-bbox="245 1003 1401 1062">The frame of the implant is composed of Nitinol alloy with the chemical constituents listed below in accordance with ASTM F2063-12.</p>		
Nickel	54.5 to 57%	
Titanium	Balance	
Nitrogen plus Oxygen	0.05%	
Carbon	<0.05%	



Replacement Heart Valve Product Description (Stentless Tissue)	Models
Edwards Prima aortic stentless bioprosthesis	2500
Edwards Prima Plus aortic stentless bioprosthesis	2500P
These valves are made of porcine aortic valves and there are no metallic components. Therefore there are no MRI issues for these implants, and they may be considered as MR safe.	

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 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. Optimization of MR imaging parameters is recommended.							
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 knit polyester cloth and there are no metallic components. Therefore, there are no MRI issues for these implants, and they may be considered as MR safe.	

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 indicates that MR procedures may be conducted safely with static fields of 1.5 tesla and 3.0 tesla. Rings have corrosion-resistant cobalt-chromium spring alloy bands separated by polyester film strips covered by silicone rubber and a knit polyester covering. The nominal composition (wt. percent) of the cobalt-chromium alloy 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: <ul style="list-style-type: none"> • 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							
<p>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:</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>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.</p> <p>The ring has a titanium alloy core. The nominal composition (wt. percent) of the titanium alloy is as follows:</p>							
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. Nyenhuis, J. MRI Heating Tests for Edwards Stented Porcine Valves, Edwards Report RD1954, 2013.
13. Shellock, F.G., Evaluation of Magnetic field Interactions, Heating, and Artifacts at 3-tesla for the Edwards Myxo ETlogix Annuloplasty Ring, Model 5100; Carpentier-Edwards Physio Annuloplasty ring, Model 4450; and Carpentier-Edwards Magna II Pericardial Aortic Valve, Model 3300/3300TFX, Edwards Report RD1837, 2012.
14. Zeng K, Interactions of the MRI Fields with the AQC 3500TFX Valve, Edwards Technical Summary 19300 Rev B, 2012.
15. Chang D, Technical Summary for MRI Testing of Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring, Model 4100, Edwards Technical Summary 14613, 2008.
16. Zollinger C, Technical Justification of MRI Properties of GeoForm Annuloplasty Ring Model 4200, Edwards Report RD1845, 2012.
17. Chang D, Technical Summary for MRI Testing Physio II Annuloplasty Ring, Model 5200, Edwards Technical Summary 13100, 2008
18. Schmidt, P, MR Safety Information for Model 2800, 2800TFX, 2900, and 2900TFX. Edwards Report RD1988, Rev. B, 2014.
19. Pesce, L, Engineering Technical Summary: Test Report Evaluation of MRI for CardiAQ Transcatheter Mitral Valve (TMV), Edwards Report ETS-2203-02, Rev. A, 2014
20. Nyenhuis, J. MRI Heating Tests for Edwards Stented Pericardial Valves, Edwards Report RD1953, Rev A, 2014
21. Nyenhuis, J. Measurement and Analysis of Artifacts in MRI at 3.0 T with Edwards' Bioprosthetic Replacement Heart Valves, Edwards Report RD1951, 2013



22. Nyenhuis, J. Measurement and Analysis of Force and Torque Interactions of the Electromagnetic Fields in MRI at 1.5 and 3.0 T with Edwards' Tissue Valves, Edwards Report RD1952, 2013
23. Schmidt, P, MR Safety Information for Model 2700 and 2700TFX. Edwards Report RD1995, Rev. B, 2014
24. Nyenhuis, J. Measurement and Analysis of Interactions of the Electromagnetic Fields in MRI at 1.5 and 3.0 T with INSPIRIS™ RESILIA™ Aortic Valve, Model 11500A, Edwards Report RD2155, Rev C, 2016

Edwards, Edwards Lifesciences, the stylized E logo, CardiAQ, CardiAQ-Edwards, Carpentier-Edwards, Carpentier-Edwards Classic, Carpentier-Edwards Physio, Carpentier-Edwards Physio II, Carpentier-Edwards S.A.V., Carpentier-McCarthy-Adams IMR ETlogix, Cosgrove-Edwards, Cribier-Edwards, dETlogix, Duraflex, Duraflo, Edwards-Duromedics, Edwards MC3, EDWARDS INTUITY, EDWARDS INTUITY Elite, Edwards MIRA, Edwards Prima, Edwards Prima Plus, Edwards SAPIEN, Edwards SAPIEN XT, Edwards SAPIEN 3, GeoForm, IMR ETlogix, INSPIRIS, INSPIRIS RESILIA, Magna, Magna Ease, Magna Mitral Ease, MC3 Tricuspid, PERI, PERIMOUNT, PERIMOUNT Magna, PERIMOUNT Plus, PERIMOUNT Theon, Physio Tricuspid, RESILIA, SAPIEN, SAPIEN XT, SAPIEN 3, S.A.V., Starr-Edwards, and TFX are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.