



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 (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 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.

For patient or technical questions, please contact the Patient Support Center toll free at 888-713-1564, 7:30 am-4:30 pm PT, Monday-Friday.



Edwards

Table of Contents

Replacement Heart Valve Product Description (Stented Tissue)

Carpentier-Edwards aortic and mitral porcine bioprostheses Models 2625, 6625	4
Carpentier-Edwards S.A.V. aortic and mitral bioprostheses Models 2650, 6650	4
Carpentier-Edwards Duraflex low pressure porcine bioprostheses Model 6625LP	4
Carpentier-Edwards Duraflex low pressure porcine bioprostheses with extended sewing ring Model 6625-ESR-LP	4
Carpentier-Edwards bioprosthetic valved conduit Model 4300	4
Carpentier-Edwards PERIMOUNT RSR pericardial aortic bioprostheses Models 2800, 2800TFX	5
Carpentier-Edwards PERIMOUNT pericardial aortic bioprostheses Models 2900, 2900TFX	5
Carpentier-Edwards PERIMOUNT Magna pericardial aortic bioprostheses Models 3000, 3000TFX	5
Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprostheses Model 3300TFX	6
Carpentier-Edwards PERIMOUNT pericardial mitral bioprostheses Model 6900	7
Carpentier-Edwards PERIMOUNT Plus pericardial mitral bioprostheses Model 6900P	7
Carpentier-Edwards PERIMOUNT Theon mitral pericardial bioprostheses Model 6900PTFX	7
Carpentier-Edwards PERIMOUNT Magna Mitral pericardial bioprostheses Models 7000, 7000TFX	8
Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprostheses Model 7300TFX	8
EDWARDS INTUITY Aortic Valve, EDWARDS INTUITY Elite aortic valve Models 8300A, 8300ACA, 8300AB, 8300ACB	9
INSPIRIS RESILIA aortic valve Model 11500A	10
KONECT RESILIA aortic valved conduit (AVC) Model 11060A	11
MITRIS RESILIA mitral valve Model 11400M	12
Carpentier-Cribier aortic bioprostheses (Exclusively for Clinical Investigations/ Investigational Device/ To Be Used by Qualified Investigators only) Model PHV1-23	13
Cribier-Edwards aortic bioprostheses (Exclusively for Clinical Investigations/ Investigational Device/ To Be Used by Qualified Investigators only) Models 9000, 9000PHV, 9000MIS	13
Edwards SAPIEN transcatheter heart valve Model 9000TFX	14
Edwards SAPIEN XT transcatheter heart valve (THV) Model 9300TFX	15
Edwards SAPIEN 3 transcatheter heart valve (THV) Model 9600TFX	16
Edwards SAPIEN 3 Ultra transcatheter heart valve (THV) Model 9750TFX	16
Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve (THV) Model 9755RSL	16
CardiAQ-Edwards transcatheter mitral valve (TMV) Model TMV3040B	17
Edwards EVOQUE Transcatheter Mitral Valve (TMV) Model 9850TMV48	18
Edwards EVOQUE Transcatheter Tricuspid Valve Models 9850EV44, 9850EV48, 9850EV52, 9850EV56	19

Transcatheter Valve Repair Product Description

Edwards PASCAL Precision Transcatheter Valve Repair System Models 20000IS, 20000ISM	20
--	----

Replacement Heart Valve Product Description (Stented Tissue)

Edwards CENTERA transcatheter heart valve Model 9551S	21
Edwards Alterra adaptive presten in conjunction with Edwards SAPIEN 3 transcatheter heart valve Models 29AP4045, 9600TFX	22,23
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve Models 9770DDS, 9780DDS, 9680DSC with 9680TFX29M	24
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve Models 9770DDS, 9780DDS, 9680DSC with 9680TFX29M	25
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve Models 9880DDS with 9880TFX29M	26
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve Models 9880DDS with 9880TFX29M	27
Edwards SAPIEN Future transcatheter heart valve (THV) Model 14000RSL	28



Edwards

(Table of Contents continued on next page)

Table of Contents (continued)

Replacement Heart Valve Product Description

Carpentier-Edwards BioPhysio valve (Exclusively for Clinical Investigations / Investigational Device / To Be Used by Qualified Investigators only) Model 3100TFX	29
---	----

Replacement Heart Valve Product Description (Stentless Tissue)

Edwards Prima aortic stentless bioprosthesis Model 2500	29
Edwards Prima Plus aortic stentless bioprosthesis Model 2500P	29

Replacement Heart Valve Product Description (Bileaflet Mechanical)

Edwards MIRA mechanical aortic and mitral valves Models 3600, 3600f, 3600u, 9600	29
Edwards-Duromedics bileaflet aortic and mitral prostheses Models 3160, 3160R, 9120, 9120R	30
Edwards TEKNA bileaflet aortic and mitral valves Models 3200, 9200	30

Replacement Heart Valve Product Description (Ball and Cage Mechanical)

Starr-Edwards aortic and mitral prostheses Models 1000, 1200, 2300, 2310, 2400, 6000, 6120, 6300, 6310, 6320, 6400	30
Starr-Edwards aortic and mitral prostheses Models Pre-1000, Pre-6000, 1260, 2320, 6520 (plastic disk)	30

Valve Repair Product Description

Carpentier-Edwards Classic annuloplasty mitral and tricuspid rings Models 4400, 4500	31
Carpentier-Edwards Classic annuloplasty mitral and tricuspid rings with Duraflo treatment Models 4425, 4525	31
Edwards MC3 Tricuspid annuloplasty ring Model 4900	31
Carpentier-McCarthy-Adams IMR ETlogix mitral annuloplasty ring Model 4100	31
GeoForm mitral annuloplasty ring Model 4200	31
Carpentier-Edwards Physio mitral annuloplasty ring Model 4450	31
Carpentier-Edwards Physio mitral annuloplasty ring with Duraflo treatment Model 4475	31
Carpentier-Edwards Physio II mitral annuloplasty ring Model 5200	32
Physio Flex annuloplasty ring Model 5300	32
Carpentier-Edwards Physio Tricuspid annuloplasty ring Model 6200	33
Edwards Myxo ETlogix mitral annuloplasty ring Model 5100	33
Cosgrove-Edwards mitral and tricuspid annuloplasty bands Model 4600	33
Cosgrove-Edwards mitral and tricuspid annuloplasty bands with Duraflo treatment Model 4625	33

Pericardial Patches

Equine Pericardial Patch Model XAG	33
Bovine Pericardial Patch Model 4700	33



Product Information:

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards aortic and mitral porcine bioprostheses	2625, 6625	12, 21, 22
Carpentier-Edwards S.A.V. aortic and mitral bioprostheses	2650, 6650	12, 21, 22
Carpentier-Edwards Duraflex low pressure porcine bioprosthetic	6625LP	12, 21, 22
Carpentier-Edwards Duraflex low pressure porcine bioprosthetic 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.
- Maximum spatial gradient field of 3000 gauss/cm or less.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2W/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 device when imaged with a gradient echo pulse sequence and approximately as far as 14 mm from the device when imaged with a spin echo pulse sequence and 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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT RSR pericardial aortic bioprostheses	2800, 2800TFX	18, 20, 21, 22
Carpentier-Edwards PERIMOUNT pericardial aortic bioprostheses	2900, 2900TFX	
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 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 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 and 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 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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprostheses	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:

- Static magnetic field of 3 tesla or less.
- Maximum 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 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 bioprostheses 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 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



Edwards

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 these 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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT Magna Mitral pericardial bioprostheses	7000, 7000TFX	20, 21, 22
Carpentier-Edwards PERIMOUNT Magna Mitral Ease pericardial bioprostheses	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.
- 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 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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
EDWARDS INTUITY Aortic Valve, EDWARDS INTUITY Elite aortic valve	8300A, 8300ACA, 8300AB, 8300ACB	14



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 magnetic gradient field of 2670 gauss/cm or less.
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR 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 0.8 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by these devices extends approximately as far as 40 mm from the bioprostheses when imaged with a gradient echo pulse sequence and approximately as far as 40 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

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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
INSPIRIS RESILIA aortic valve	11500A	23



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 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 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.

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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
KONECT RESILIA aortic valved conduit (AVC)	11060A	20, 21, 22, 25



MR Conditional

Non-clinical testing has demonstrated that the KONECT RESILIA AVC, Model 11060A, is MR Conditional. A patient with the Model 11060A AVC 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 3000 gauss/cm (30 T/m).
- Maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg in the normal operating mode.

Under the scan conditions defined above, KONECT RESILIA AVC Model 11060A is expected to produce a maximum *in vivo* temperature rise of less than 2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact extends approximately 12.5 mm from the Model 11060A valve when imaged with a spin echo pulse sequence, and 25.5 mm from the device when imaged with a gradient echo pulse sequence and a 3 tesla MRI system. The artifact obscures the device lumen.

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



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
MITRIS RESILIA mitral valve	11400M	26



MR Conditional

Non-clinical testing demonstrated that the Model 11400M 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 1.5T and 3.0T only.
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m) or less.
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg per 15 minutes of scanning (i.e. per pulse sequence).
- Normal mode operation of the MR system for both SAR and gradients.

Under the scan conditions above, the Model 11400M valve is expected to produce a maximum temperature rise of 2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Model 11400M valve when imaged with a gradient echo pulse sequence and a 3.0 tesla MRI system. Optimization of MR imaging parameters is recommended.

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

Component	Cobalt	Chromium	Nickel	Carbon	Iron	Niobium	Titanium	Copper
Wireform	<0.05%	<0.01%	54.5 - 57.0%	<0.04%	<0.05%	<0.025%	Bal	<0.01%
<hr/>								
Component	Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
Band	40%	20%	15%	7%	2%	<0.10%	<0.10%	Bal



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference																				
Cribier aortic bioprosthesis (Exclusively for Clinical Investigations/ Investigational Device/ To Be Used by Qualified Investigators only)	PHV1-23	N/A																				
Cribier-Edwards aortic bioprosthesis (Exclusively for Clinical Investigations/ Investigational Device/ To Be Used by Qualified Investigators only)	9000, 9000PHV, 9000MIS	N/A																				
<p>Non-clinical testing has demonstrated that the Cribier-Edwards aortic bioprosthesis 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 composition (wt. percent) of the stainless steel material meets the chemical composition requirements of ASTM F138-08 Standard for surgical implants which is as follows:</p>																						
<table border="1"><thead><tr><th>Chromium</th><th>Nickel</th><th>Molybdenum</th><th>Manganese</th><th>Silicon</th><th>Copper</th><th>Carbon</th><th>Phosphorus</th><th>Sulfur</th><th>Iron</th></tr></thead><tbody><tr><td>17.00 to 19.00%</td><td>13.00 to 15.00%</td><td>2.25 to 3.00%</td><td>2.00% max</td><td>0.75% max</td><td>0.50% max</td><td>0.030% max</td><td>0.025% max</td><td>0.010% max</td><td>Bal</td></tr></tbody></table>			Chromium	Nickel	Molybdenum	Manganese	Silicon	Copper	Carbon	Phosphorus	Sulfur	Iron	17.00 to 19.00%	13.00 to 15.00%	2.25 to 3.00%	2.00% max	0.75% max	0.50% max	0.030% max	0.025% max	0.010% max	Bal
Chromium	Nickel	Molybdenum	Manganese	Silicon	Copper	Carbon	Phosphorus	Sulfur	Iron													
17.00 to 19.00%	13.00 to 15.00%	2.25 to 3.00%	2.00% max	0.75% max	0.50% max	0.030% max	0.025% max	0.010% max	Bal													



Edwards

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



MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN THV (implant) is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 tesla (T) or 3.0 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 device was determined to produce a temperature rise of less than 1.1 °C above background for a WB-SAR of 2 W/kg for 15 minutes of MR scanning in a 1.5 T and 3.0 T cylindrical bore whole body MR systems.

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 3T GE Signa-HDx MR system. The implant has not been evaluated in MR systems other than 1.5 or 3.0 T.

The valve's stent frame is composed of stainless steel material. The composition (wt. percent) of the stainless steel material meets the chemical composition requirements of ASTM F138-08 Standard for surgical implants which is as follows:

Chromium	Nickel	Molybdenum	Manganese	Silicon	Copper	Carbon	Phosphorus	Sulfur	Iron
17.00 to 19.00%	13.00 to 15.00%	2.25 to 3.00%	2.00% max	0.75% max	0.50% max	0.030% max	0.025% max	0.010% max	Bal



Edwards

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



MR Conditional

Non-clinical testing has demonstrated that the SAPIEN XT THV (implant) is MR Conditional. It can be scanned safely, immediately after placement of this device under the following conditions:

- Static magnetic field of 1.5 tesla (T) or 3.0 tesla (T).
- Spatial gradient field of 2500 gauss/cm or less.
- Maximum whole body averaged specific absorption rate (WB-SAR) of 2.0 W/kg for 15 minutes of scanning.
- Normal mode operation, as defined in IEC 60601-2-33, Ed. 2.0, of the MR system.

In non-clinical testing and computer analysis using anatomically correct models of the human anatomy, the implant was determined to produce an estimated *in vivo* temperature rise of less than 2.3 °C for a WB-SAR of 2.0 W/kg for 15 minutes of MR scanning in a 1.5 T whole body coil from a GE Signa MR System. The estimated *in vivo* temperature rise was less than 2.6 °C for a WB-SAR of 2.0 W/kg in a 3.0 T GE Signa HDxt 3T (software version 14LX\MR) whole body cylindrical bore MR system. These calculations may overestimate the true *in vivo* temperature rise, since the cooling effects of blood are not considered.

The image artifact extends as far as 14.5 mm from the implant for spin echo images and 30 mm for gradient echo images when scanned in non-clinical testing using a 3.0 T GE Signa HDx MR system (software version 14LX\MR).

The implant has not been evaluated in MR systems other than 1.5 T or 3.0 T.

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. 1.0 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	Balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards SAPIEN 3 transcatheter heart valve (THV)	9600TFX	N/A
Edwards SAPIEN 3 Ultra transcatheter heart valve (THV)	9750TFX	N/A
Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve (THV)	9755RSL	N/A



MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA 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 (T) or 3.0 tesla (T).
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode) .

Under the scan conditions defined above, the transcatheter heart valve is expected to produce a maximum temperature rise of 1.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 9.0 mm from the implant for spin echo images and 23 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 T 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. 1.0 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	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%

CAUTION: Not available for commercial use. To be used only by qualified investigators, or physicians with valid approval for compassionate use or other expanded access.



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Edwards EVOQUE Transcatheter Mitral Valve (TMV)	9850TMV48	N/A



MR Conditional

Non-clinical testing has demonstrated that the Edwards 9850TMV48 valve is 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 3.0 tesla or less
- Spatial magnetic gradient field of less than 3000 gauss/cm
- Maximum MR system-reported, whole body averaged SAR of 2.0 W/kg
- Normal operating mode of the MR system for both gradients and SAR

Based on worst-case non-clinical testing and calculated SAR in the patient during MRI, the 9850TMV48 valve was determined to produce a temperature rise of less than 3 °C at a maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg, for 15 minutes of MR scanning at 1.5 T and a rise of less than 4 °C at a background local specific absorption rate (SAR) of 2.0 W/kg, for 15 minutes of MR scanning at 3.0 T.

Image artifact was measured non-clinically in a GE Signa 3T Discovery 750 MR system according to ASTM F2119-07 using the spin echo and gradient echo sequences specified therein. The spin echo images had artifacts that extended as far as 4 mm from the implant. The gradient echo images had artifacts that extended as far as 5.85 mm from the valve. The lumen of the valve was partially to fully obscured.

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

Nickel	55.8 wt.-%
Titanium	Balance
Nitrogen plus Oxygen	<0.04 wt.-%
Carbon	<0.04 wt.-%

CAUTION: Not available for commercial use. To be used only by qualified investigators, or physicians with valid approval for compassionate use or other expanded access.



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Edwards EVOQUE Transcatheter Tricuspid Valve	9850EV44 9850EV48 9850EV52 9850EV56*	N/A



MR Conditional

Non-clinical testing has demonstrated the Edwards EVOQUE valve, Model 9850EV, is MR Conditional. A patient with the valve can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3 T only
- Maximum spatial gradient magnetic field of 3000 gauss/cm (30.0 T/m) or less
- Maximum MR system-reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg
- Normal operating mode of the MR system for both gradients and SAR

Under the scan conditions defined above, the EVOQUE valve is expected to produce a maximum temperature rise of 4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the EVOQUE valve extends approximately 0.8 cm from the device when imaged with a gradient echo or spin echo pulse sequence and a 3 T MRI system.

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

Nickel	55.8 wt.-%
Titanium	Balance
Nitrogen plus Oxygen	<0.04 wt.-%
Carbon	<0.04 wt.-%

***CAUTION: Model 9850EV56 is not available for commercial use. To be used only by qualified investigators, or physicians with valid approval for compassionate use or other expanded access.**



Transcatheter Valve Repair Product Description	Models	Reference
Edwards PASCAL Precision Transcatheter Valve Repair System	20000IS	N/A
Edwards PASCAL Precision Transcatheter Valve Repair System	20000ISM	N/A



MR Conditional

Non-clinical testing demonstrated that the PASCAL and PASCAL Ace implants are MR Conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan condition defined above, the implant is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device in a worst-case multiple implant configuration extends up to 15 mm from the implant when imaged in the worst-case gradient echo pulse sequence in a 3.0 T MRI system.

The PASCAL (Model 20000IS) and PASCAL Ace (Model 20000ISM) implants are primarily composed of Nitinol spacer, paddles and clasps (in accordance with ASTM F2063). The nominal composition (wt. percent) of the materials are as follows:

Nickel	54.5 to 57.0%
Carbon	Max 0.040%
Cobalt	Max 0.050%
Copper	Max 0.010%
Chromium	Max 0.010%
Hydrogen	Max 0.005%
Iron	Max 0.050%
Niobium	Max 0.025%
Nitrogen + Oxygen	Max 0.040%
Titanium	Balance

The 20000IS implant also comprises a titanium nut and bolt. The 20000ISM implant comprises a titanium nut, bolt, proximal plate and distal plate (in accordance with ASTM F136). The nominal composition (wt. percent) of the materials are as follows:

Nitrogen	Max 0.05%
Carbon	Max 0.08%
Hydrogen	Max 0.012%
Iron	Max 0.25%
Oxygen	Max 0.13%
Aluminum	5.5-06.50%
Vanadium	3.5-4.5%
Titanium	Balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards CENTERA transcatheter heart valve	9551S	24



MR Conditional

The Edwards CENTERA THV has been determined to be MR Conditional. A patient with this device can be immediately scanned safely in an MR system meeting the following conditions:

- Static magnetic fields of 1.5 tesla (T) or 3.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m).
- Maximum MR System reported, whole-body-averaged specific absorption rate (WB-SAR) of 2.0 W/kg (Normal Operating Mode).

Based on worst-case non-clinical testing and calculated SAR in the patient during MRI, the CENTERA valve was determined to produce a temperature rise of less than 2.0 °C at a maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of MR scanning at 1.5 T, and a temperature rise of 2.0 °C at a SAR of 2 W/kg for 15 minutes of MR scanning at 3.0 T.

Image artifact was measured non-clinically in a GE Signa 3T HDx MR system according to ASTM F2119-07 using the spin echo and gradient echo sequences specified therein. The spin echo images had artifacts that extended as far as 4 mm from the implant and partially to fully obscured the lumen. The gradient echo images had artifacts that extended as far as 5 mm from the valve.

The THV has not been evaluated in MR systems other than 1.5 T or 3.0 T. The delivery system has not been evaluated for MR compatibility and is considered MR unsafe.

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% - 57.0%
Cobalt	Max. 0.05%
Iron	Max. 0.05%
Carbon	Max. 0.04%
Niobium	Max 0.025%
Copper	Max 0.01%
Chromium	Max 0.01%
Oxygen	Max 0.04%
Oxygen + Nitrogen	Max. 0.05%
Hydrogen	Max 0.005%
Titanium	Balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards Alterra adaptive presten in conjunction with Edwards SAPIEN 3 transcatheter heart valve	29AP4045, 9600TFX	N/A



MR Conditional

Non-clinical testing has demonstrated that the Edwards Alterra Adaptive Presten, alone or with a deployed SAPIEN 3 transcatheter heart valve, is MR Conditional. A patient with this device can be scanned safely immediately after placement of this device in an MR system meeting the following conditions:

- Static magnetic fields of 1.5 tesla (T) or 3.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m) or less.
- Maximum MR System reported, whole-body-averaged specific absorption rate (WB-SAR) of 2.0 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Edwards Alterra presten is expected to produce a maximum temperature rise of 4.0 °C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 6.6 mm for gradient echo images when scanned using 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 T or 3.0 T.

The frame of the valve 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. 1.0 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	balance

(continues on next page)



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards Alterra adaptive presten in conjunction with Edwards SAPIEN 3 transcatheter heart valve	29AP4045, 9600TFX	N/A

(continued from previous page)

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

Nickel	54.5% - 57.0%
Cobalt	Max. 0.05%
Iron	Max. 0.05%
Carbon	Max. 0.05%
Niobium	Max 0.025%
Copper	Max 0.01%
Chromium	Max 0.01%
Oxygen	Max 0.04%
Oxygen + Nitrogen	Max. 0.05%
Hydrogen	Max 0.005%
Titanium	Balance

CAUTION: Not available for commercial use. To be used only by qualified investigators, or physicians with valid approval for compassionate use or other expanded access.



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve	9770DDS/9780DDS/9680DSC with 9680TFX29M	N/A



MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN M3 dock implant, with a deployed SAPIEN M3 valve, is MR Conditional. A patient can be scanned safely immediately after placement of these devices under the following conditions:

- Static magnetic field of 1.5 tesla (T) or 3.0 T only.
- Maximum spatial gradient field of 3,000 gauss/cm (30 T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (WB-SAR) of 2.0 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Edwards SAPIEN M3 implants are expected to produce a maximum temperature rise of 2 °C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the implant when imaged with spin echo pulse sequence and a 3.0 T MR system. The lumen of the valve inside the dock was partially to fully obscured in spin and echo gradient images.

Reduction in artifact may be possible with sequences designed for reduction of metal artifact.

The frame of the valve 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. 1.0 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve	9770DDS/9780DDS/9680DSC with 9680TFX29M	N/A

(continued from previous page)

The braid of the dock is composed of Nitinol alloy with the chemical constituents listed below in accordance with ASTM F2063-12:

Nickel	54.5% - 57.0%
Cobalt	max. 0.05%
Iron	max. 0.05%
Carbon	max. 0.05%
Niobium	max. 0.025%
Copper	max. 0.01%
Chromium	max. 0.01%
Oxygen	max. 0.04%
Oxygen + Nitrogen	max. 0.05%
Hydrogen	max. 0.005%
Titanium	Balance

CAUTION: Not available for commercial use. To be used only by qualified investigators, or physicians with valid approval for compassionate use or other expanded access.



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve	9880DDS with 9880TFX29M	N/A



MR Conditional

Non-clinical testing has demonstrated that the SAPIEN M3 dock, with a deployed SAPIEN M3 valve, is MR Conditional. A patient can be scanned safely immediately after placement of this valve under the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3.0 T.
- Spatial magnetic gradient field of 4,000 Gauss/cm (40 T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (WB-SAR) of 2.0 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the dock and valve are expected to produce a temperature rise of 2 °C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 1.1 cm from the dock and valve when imaged with a gradient echo pulse sequence and a 3.0 T MR system. The lumen of the valve inside the dock was partially to fully obscured in spin and gradient echo images.

The frame of the valve 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. 1.0 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
SAPIEN M3 dock in conjunction with the SAPIEN M3 valve	9880DDS with 9880TFX29M	N/A

(continued from previous page)

The braid of the dock is composed of Nitinol alloy with the chemical constituents listed below in accordance with ASTM F2063-12:

Nickel	54.5% - 57.0%
Cobalt	max. 0.05%
Iron	max. 0.05%
Carbon	max. 0.05%
Niobium	max. 0.025%
Copper	max. 0.01%
Chromium	max. 0.01%
Oxygen	max. 0.04%
Oxygen + Nitrogen	max. 0.05%
Hydrogen	max. 0.005%
Titanium	Balance



Edwards

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards SAPIEN Future transcatheter heart valve (THV)	14000RSL	N/A



MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN Future transcatheter heart valves are 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 (T) or 3.0 T.
- 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 2.0 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the SAPIEN Future 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.

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. 1.0 wt.-%
Molybdenum	9 – 10.5 wt.-%
Titanium	max. 1.0 wt.-%
Boron	max. 0.015 wt.-%
Cobalt	Balance

CAUTION: Not available for commercial use. To be used only by qualified investigators, or physicians with valid approval for compassionate use or other expanded access.



Edwards

Replacement Heart Valve Product Description	Model	Reference		
Carpentier-Edwards BioPhysio valve (Exclusively for Clinical Investigations / Investigational Device / To Be Used by Qualified Investigators only)	3100TFX	N/A		
The device has been shown not to have magnetic interactions at up to 3 tesla. It is also safe with respect to RF heating at 1.5 W/kg for up to 20 minutes. Artifacts have been determined at 1.5 tesla. Optimization of MR imaging parameters is recommended.				
The frame of the valve is composed of nitinol, an alloy with high flexibility characteristics. The composition (wt. percent) ranges for the nitinol is are follows:				
Nickel	Carbon	Oxygen	Iron	Titanium
55-57%	0.05% Max	0.05% Max	0.05% Max	42.85% Min

Replacement Heart Valve Product Description (Stentless Tissue)	Models
Edwards Prima aortic stentless bioprostheses	2500
Edwards Prima Plus aortic stentless bioprostheses	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 (Bileaflet Mechanical)	Models	Reference						
Edwards MIRA mechanical aortic and mitral valves	3600, 3600f, 3600u, 9600	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. 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 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%)	



Replacement Heart Valve Product Description (Bileaflet Mechanical)	Models	Reference				
Edwards-Duromedics bileaflet aortic and mitral prostheses	3160, 3160R, 9120, 9120R	2				
Edwards TEKNA bileaflet aortic and mitral valves	3200, 9200	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 (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 aortic and mitral 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%



Edwards

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		N/A
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		15		
GeoForm mitral annuloplasty ring					4200		16		
The device has been shown not to have magnetic interactions at 3 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		Reference		
Carpentier-Edwards Physio mitral annuloplasty ring					4450		1, 13		
Carpentier-Edwards Physio mitral annuloplasty ring with Duraflo treatment					4475		1, 13		
Testing of these devices indicates that MR procedures may be conducted safely with static magnetic fields of 1.5 tesla and 3.0 tesla. Ring cores have corrosion-resistant cobalt-chromium spring alloy bands separated by polyester film strips. Core is 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%	Bal		



Edwards

Valve Repair Product Description	Model	Reference
Carpentier-Edwards Physio II mitral annuloplasty ring	5200	17



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%	Bal

Valve Repair Product Description	Model	Reference
Physio Flex annuloplasty ring	5300	27



MR Conditional

Non-clinical testing demonstrated that the Physio Flex annuloplasty ring, model 5300, is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3.0T only
- Maximum MR spatial gradient field of 3000 gauss/cm (30 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 above, the Physio Flex annuloplasty ring, model 5300 is expected to produce a maximum temperature rise of 2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 6 mm from the Physio Flex annuloplasty ring when imaged with a gradient echo pulse sequence and a 3.0 tesla MRI system. Optimization of MR imaging parameters is recommended.

The Physio Flex annuloplasty rings have nitinol cores. The nominal composition (wt. percent) of the nitinol is as follows:

Nickel	Carbon	Cobalt	Copper	Chromium	Hydrogen	Iron	Niobium	Nitrogen + Oxygen	Titanium
55.8%	<0.04%	<0.05%	<0.01%	<0.01%	<0.005%	<0.05%	<0.025%	<0.04%	Bal



Edwards

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
Edwards Myxo ETlogix mitral annuloplasty ring	5100	13



MR Conditional

Non-clinical testing has demonstrated that the Myxo ETlogix annuloplasty ring, model 5100, is MR Conditional. A patient with the Myxo ETlogix 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 Myxo ETlogix 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%

Valve Repair Product Description	Models
Cosgrove-Edwards mitral and tricuspid annuloplasty bands	4600
Cosgrove-Edwards mitral and tricuspid annuloplasty bands 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.	

Pericardial Patches	Models
Equine Pericardial Patch	XAG
Bovine Pericardial Patch	4700
These patches are constructed from equine or bovine pericardial tissue and there are no metallic components. Therefore, there are no MRI issues for this implant, and they may be considered as MR Safe.	



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. 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
24. Ravi, S. CENTERA 9550C MR Compatibility Report, Edwards Report DOC-0022336, Rev. A, 2015
25. Schmidt, P, MR Safety Information for the Model 11060A, KONECT RESILIA Aortic Valved Conduit. Edwards Report RD2273, 2016
26. Nyenhuis, J. Measurement and Analysis of MRI Interactions with the Edwards Model 11400M Heart Valve, Edwards Report RD2626, 2020
27. Nyenhuis, J. Measurement and Analysis of Interactions of the Electromagnetic Fields in MRI at 1.5 and 3.0 T with the Physio Flex Annuloplasty Ring, Model 5300. Edwards Report RD2550, 2019

Edwards, Edwards Lifesciences, the stylized E logo, Alterra, BioPhysio, 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, CENTERA, Cosgrove-Edwards, Cribier-Edwards, Duraflo, Edwards CENTERA, Edwards EVOQUE, EDWARDS INTUITY, EDWARDS INTUITY Elite, Edwards-Duromedics, Edwards MC3, Edwards MIRA, Edwards Prima, Edwards Prima Plus, Edwards SAPIEN, Edwards SAPIEN M3, Edwards SAPIEN XT, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, Edwards TEKNA, EVOQUE, GeoForm, IMR ETlogix, INSPIRIS, INSPIRIS RESILIA, KONECT, KONECT RESILIA, Magna, Magna Ease, Magna Mitral Ease, MC3 Tricuspid, MITRIS, MITRIS RESILIA, Myxo ETlogix, PASCAL, PASCAL Ace, PASCAL Precision, PERI, PERIMOUNT, PERIMOUNT Magna, PERIMOUNT Plus, PERIMOUNT Theon, Physio, Physio Flex, Physio Tricuspid, RESILIA, SAPIEN, SAPIEN M3, SAPIEN XT, SAPIEN 3, SAPIEN 3 Ultra, S.A.V., and Starr-Edwards are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.