Edwards

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, 20, 21
Carpentier-Edwards S.A.V. aortic bioprosthesis	2650	12, 20, 21
Carpentier-Edwards Duraflex low pressure porcine mitral bioprosthesis	6625LP	12, 20, 21
Carpentier-Edwards Duraflex low pressure porcine mitral bioprosthesis with extended sewing ring	6625-ESR-LP	12, 20, 21
Carpentier-Edwards bioprosthetic valved conduit	4300	12, 20, 21

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, 19, 20, 21, 22
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	19, 20, 21

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 2.3 °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.

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

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

Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference
Carpentier-Edwards PERIMOUNT pericardial mitral bioprosthesis	6900	19, 20, 21
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	19, 20, 21
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	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

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
KONECT RESILIA aortic valved conduit	11060A	19, 20, 21, 26

MR Conditional

Non-clinical testing has demonstrated that the KONECT RESILIA aortic valved conduit (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

Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
MITRIS RESILIA mitral valve	11400M	27

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%	55.8%	<0.04%	<0.05%	<0.025%	Bal	<0.01%

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

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

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

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

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

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

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

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

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

MR Conditional

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

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

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

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

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

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

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

MR Conditional

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

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

Under the scan conditions defined above, the SAPIEN XT transcatheter heart valve is expected to produce a maximum temperature rise of 2.6 °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. 1.0 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) Edwards SAPIEN 3 Ultra transcatheter heart valve (THV)	9600TFX 9750TFX	N/A

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 transcatheter heart valve and the Edwards SAPIEN 3 Ultra transcatheter heart valve 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 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 Edwards SAPIEN 3 transcatheter heart valve and the Edwards SAPIEN 3 Ultra transcatheter heart valve are 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. 1.0 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
CardiAQ-Edwards transcatheter mitral valve (TMV)	TMV3040B, 9650TMV	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 1.7 °C in a 1.5 tesla system and 1.8 °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 57.0 wt.-%
Titanium	Balance
Nitrogen plus Oxygen	0.05 wt.-%
Carbon	<0.05 wt.-%

***INVESTIGATIONAL DEVICES. CAUTION: The CardiAQ-Edwards transcatheter mitral valve is an investigational device. Limited by Federal (USA) law to investigational use only. Exclusively for clinical investigations. To be used by qualified investigators only. See instructions for use for full information, including indications, contraindications, warnings, precautions and adverse events.**

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

MR Conditional

Non-clinical testing has demonstrated that the Edwards 9850TMV 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 9850TMV 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.-%

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Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards CENTERA transcatheter heart valve	9551S	25

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).

Under the scan conditions defined above, the CENTERA valve is expected to produce a maximum temperature rise of less than 2.0 °C after 15 minutes of continuous scanning.

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 echosequences 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. 0.05%
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

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Replacement Heart Valve Product Description (Stented Tissue)	Model	Reference
Edwards Alterra adaptive prestent 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 Prestent, 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 prestent 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)

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

(continued from previous page)

The frame of the prestent 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

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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 or 3.0 tesla 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 (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Edwards SAPIEN M3 implant is 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 tesla MRI 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.

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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:

• 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
Physio Flex annuloplasty ring	5300	24

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	Iron	Niobium	Nitrogen + Oxygen	Titanium
55.8%	<0.04%	<0.05%	<0.01%	<0.01%	<0.05%	<0.025%	<0.04%	Bal

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

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

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

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

MR Conditional

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

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

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

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

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

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

Bovine Pericardial Patch	Model
Bovine Pericardial Patch	4700
These patches are constructed from bovine pericardial tissue and there are no metallic components. Therefore this device is MR Safe.	

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

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