

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,					
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 Con	ditional. A patient with	these valves					
 can be scanned safely, immediately after placement of this valve under Static magnetic field of 3 tesla or less 	er the following condition	ons:					
Spatial gradient field of less than 3000 gauss/cm							
 Maximum MR system-reported whole-body-averaged specific absorminutes of continuous scanning per sequence in the normal operation 	rption rate (SAR) of 2.0 ng mode	W/kg for 15					
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 ionows.	-					
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	3300TFX	19, 20, 21						
bioprosthesis								
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 minutes of continuous scanning per sequence in the normal operating 	on rate (SAR) of 2.0 M mode	W/kg for 15						
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 c spring alloy that is commonly used in implantable devices. The nominal of	orrosion-resistant col composition (wt. perc	oalt-chromium ent) is as follows:						

spring and	by that is con	intoniy u	seu in implantai	JIE UEVICES. II		omposition (wt. perc	ent) is as ioliows.
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 Condition be scanned safely, immediately after placement of these implants under	onal. A patient with the following condition	nese valves can ons:
 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 minutes of continuous scanning per sequence in the normal operating in 	on rate (SAR) of 2.0 mode	W/kg for 15
Under the scan conditions defined above these devices are expected to p of 2.3 °C after 15 minutes of continuous scanning. In non-clinical testing, device extends approximately as far as 33 mm from the bioprostheses w sequence and approximately as far as 12.5 mm from the valves when im in a 3 T MRI system. The lumen is partially to fully obscured under these compromised if the area of interest is in the same area or relatively close Optimization of MR imaging parameters is recommended.	produce a maximum the image artifact ca hen imaged with a gr aged with a spin ech conditions. MR ima to the position of the	temperature rise used by the radient echo pulse o pulse sequence uge quality may be ese bioprostheses.
The valve wireform stent and orifice-stiffening band are composed of a cospring alloy that is commonly used in implantable devices. The nominal of	orrosion-resistant col composition (wt. perc	oalt-chromium ent) is as follows:

spining and		in the target of t					
Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal



Replaceme	ent Heart Valv	e Produc	t Description (S	tented Tissue)	Mode	el R	eference	
Carpentier- bioprosthes	Edwards PER	IMOUNT N	Magna Mitral per	icardial	7000, 700	OTFX 1	9, 20, 21	
Carpentier- bioprosthes	Edwards PER	IMOUNT N	Magna Mitral Eas	se pericardial	7200TFX, 7	300TFX		
	IR Conditional							
Non-clinica can be scar	l testing has d nned safely im	emonstrate mediately	ed that these dev after placement	vices are MR Cond of these implants u	litional. A pati under the follo	ent with thes wing conditi	e valves ons:	
 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	



Replacemen	it Heart Valve	Product	Description (S	tented Tissue))	Μ	lodel	Reference	e
EDWARDS INTUITY Elite aortic valve						83	00AB	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 mag 	netic field of 3	tesla or l	ess.						
 Spatial gra 	dient field of le	ess than 2	2670 gauss/cm.						
Maximum I continuous	VR system-re scanning per	ported wh sequence	ole-body-average in the normal c	ged specific abs operating mode	sorption	rate (S	SAR) of 2.0 \	N/kg for 15 min	utes of
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.									
alloy that is commonly used in implantable devices. The nominal composition (wt. percent) is as follows:									
Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carb	oon	Ber	yllium	Iron
40%	20%	15%	7%	2%	< 0.1	0%	< 0	0.10%	Bal
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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



Replacen	nent Heart V	alve Pro	Model	Reference				
INSPIRIS	RESILIA ao	tic 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 m 	agnetic field	of 3 tesla	a or less.					
Spatial	gradient field	of less t	han 3000 gauss	s/cm.				
 Maximu minutes 	 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.								
Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron	
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal	



Replacer	nent Heart V	alve Pro	duct Descripti	ion (Stented T	ïssue)	Model	Reference
KONECT	RESILIA ao	rtic valve	d conduit			11060A	19, 20, 21, 26
MR	MR Conditio	nal					I
Non-clinic 11060A, i after place	cal testing ha s MR Condit ement of this	s demon ional. A p implant,	strated that the patient with the under the follow	KONECT RES Model 11060A wing conditions	SILIA aortic v AVC can be s:	alved conduit (scanned safel	AVC), Model y immediately
 Static n 	nagnetic field	of 3 tesl	a or less				
 Spatial 	gradient field	l of less t	han 3000 gaus	s/cm (30 T/m)			
 Maximu normal 	im MR syster operating mo	m-reporte ode	ed whole-body-a	averaged spec	ific absorptic	on rate (SAR) o	f 2.0 W/kg in the
Under the a maximu	e scan condit ım in vivo ten	ions defir nperature	ned above, KON e rise of less tha	NECT RESILIA an 2 °C after 15	AVC Model 5 minutes of	11060A is exp continuous sca	ected to produce nning.
n non-clii when ima gradient e	nical testing, ged with a sp echo pulse se	the imag bin echo equence	e artifact exten pulse sequence and a 3 tesla M	ds approximate e, and 25.5 mm RI system. The	ely 12.5 mm n from the de e artifact obs	from the Model evice when imag cures the devic	11060A valve ged with a ce lumen.
The valve	wireform ste	ent and o	rifice-stiffening	band are comp	osed of a co	orrosion-resista	nt cobalt-
chromium percent) i	n spring alloy s as follows:	that is co	ommonly used i	n implantable o	devices. The	nominal comp	osition (wt.
Cobalt	Chromium	Nickel	Molybdenum	Manganese	Carbon	Beryllium	Iron
40%	20%	15%	7%	2%	< 0.10%	< 0.10%	Bal



Replacemer	nt Heart V	alve Produ	ct Descrip	otion	(Stented	Tissue)		Mod	el	Refe	rence
MITRIS RESILIA mitral valve11400M27							27				
	MR Conditional										
Non-clinical t	esting de	monstrated t	that the Mo	odel [·]	11400M va	lve is MR (Cor	nditional. /	A patie	nt with	this
device can b	e safely s	canned in ar	n MR syste	em m	eeting the	following c	ono	ditions:			
Static mag	netic field	of 1.5T and	3.0T only								
Maximum	spatial gra	adient field o	f 3000 gau	uss/c	m (30 T/m)) or less					
 Maximum 15 minutes 	MR syste s of scann	m-reported, [,] ing (i.e. per	whole-bod pulse sequ	ly-ave uence	eraged spe e)	cific absor	ptic	on rate (S	AR) of	2.0 W/ł	kg per
Normal mo	de opera	tion of the M	R system	for b	oth SAR ar	nd gradient	s.				
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:						n the em. nat is on- I					
Component	Cobalt	Chromium	Nicke		Carbon	Iron	Ν	liobium Titanium Copp		Copper	
Wireform	<0.05%	<0.01%	55.8%	0	<0.04%	<0.05%	<	0.025%	Ba		<0.01%
			NP 1 7						-		
Component	Cobalt	Chromium		Mol		Manganes	se		Bei	ryllium	Iron
Dallu	4070	2070	1370		1 70	∠ 70		< 0.10%		J. 1070	Dai



Replacement Heart Valve Product Description (Stented Tissue)	Models	Reference			
Cribier-Edwards aortic bioprosthesis (PHV)(Caution: Investigational	9000, 9000PHV,	N/A			
device. Limited by Federal law to investigational use.)					
Non-clinical testing has demonstrated that the Cribier-Edwards aortic	bioprosthesis (PHV) i	s 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 scanning. 	⁵ 3.0 W/kg for 15 minu	ites of			
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 r the stainless steel material as follows:	nominal composition (wt. percent) of			

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 trans 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. 	scatheter heart valve i	is MR			
 Maximum whole-body-averaged specific absorption rate (WB of scanning 	-SAR) of 2 W/kg for 1	5 minutes			
 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 to the position of the device.	e exact same area or r	elatively close			
The valve's stent frame is composed of stainless steel material. The r the stainless steel material used is as follows:	nominal composition (wt. percent) of			
Chromium Nickel Molybdenum Manganese Silicon Copper (Carbon Phosphorus	Sulfur Iron			

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 Pro	oduct Description (Stented Tissue)	Models	Reference		
Edwards SAPIEN XT transcath	eter heart valve (THV)	9300TFX	N/A		
MR Conditional Non-clinical testing has demons Conditional. A patient with this of under the following conditions: • Static magnetic field of • Maximum spatial gradie • Maximum MR system r (Normal Operating Mod	strated that the Edwards SAPIEN XT tr device can be scanned safely, immedia 1.5 tesla or 3 tesla ent field of 2500 gauss/cm (25 T/m) or l eported, whole body averaged specific le)	anscatheter heart valv ately after placement o ess absorption rate (SAR	ve is MR of this device R) of 2 W/kg		
Under the scan conditions defin produce a maximum temperatu testing, the image artifact cause images and 30 mm for gradient the device lumen in gradient ec 1.5 or 3.0 T. For valve-in-surgical valve implainformation for the surgical valve	ned above, the SAPIEN XT transcatheter re rise of 2.6 °C after 15 minutes of cor ed by the device extends as far as 14.5 echo images when scanned in a 3.0 T sho images. The implant has not been e antation or in the presence of other imple e or other devices prior to MR imaging.	er heart valve is expentinuous scanning. In mm from the implant MRI system. The art evaluated in MR system olants, please refer to	cted to non-clinical for spin echo ifact obscures ems other than the MRI safety		
The frame of the implant is com	posed of MP35N alloy with the chemic	al 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 Pro	oduct Description (Stented Tissue)	Models	Reference		
Edwards SAPIEN 3 transcathet	er heart valve (THV)	9600TFX	N/A		
Edwards SAPIEN 3 Oltra transc	catheter heart valve (THV)	97501FX			
MR Conditional					
Non-clinical testing has demons Edwards SAPIEN 3 Ultra transc scanned safely, immediately af	strated that the Edwards SAPIEN 3 trans catheter heart valve are MR Conditiona ter placement of this device under the f	nscatheter heart valve I. A patient with this d following conditions:	and the evice can be		
 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 for spin echo images and 30 mi artifact obscures the device lum systems other than 1.5 or 3.0 T	e artifact caused by the device extends m for gradient echo images when scan nen in gradient echo images. The impla	s as far as 14.5 mm fro ned in a 3.0 T MRI sy int has not been evalu	om the implant stem. The lated in MR		
For valve-in-valve implantation information for the surgical valv	or in the presence of other implants, pl e or other devices prior to MR imaging	ease refer to the MRI	safety		
The frame of the implant is com	posed of MP35N alloy with the chemic	al constituents listed l	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 Pro	oduct Description (Stented Tissue)	Models	Reference			
CardiAQ-Edwards transcathete	r mitral valve (TMV)	TMV3040B, 9650TMV	N/A			
MR Conditional						
Non-clinical testing has demons scanned safely in an MR syster • Static magnetic field of • Maximum spatial gradie • Maximum MR system r	strated that the TMV is MR Conditional m meeting the following conditions: 1.5 tesla or 3.0 tesla only ent field of 4,000 gauss/cm (40 T/m) or eported, whole body averaged specific	. A patient with this de less absorption rate (SAR	evice can be ?) of 2 W/kg			
Under the scan conditions defir 1.7 °C in a 1.5 tesla system and	ned above, the TMV is expected to prod d 1.8 °C in a 3.0 tesla system after 15 r	duce a maximum temp minutes of continuous	perature rise of 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%					

*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.

<0.05 wt.-%

Carbon



Replacement Heart Valve Pro	oduct Description (Stented Tissue)	Models	Reference
Edwards EVOQUE Transcathet	er Mitral Valve (TMV)	9850TMV	N/A
MR Conditional			
Non-clinical testing has demons the valve can be scanned safely	trated that the Edwards 9850TMV valve , immediately after placement of this va	e is MR Conditional. alve under the follow	A patient with ing conditions:
 Static magnetic field of 3.0 t Spatial magnetic gradient field Maximum MR system-report Normal operating mode of the system 	esla or less eld of less than 3000 gauss/cm ted, whole body averaged SAR of 2.0 V he MR system for both gradients and S	N/kg AR	
Based on worst-case non-clinica valve was determined to produc whole-body-averaged specific a and a rise of less than 4 °C at a minutes of MR scanning at 3.0	al testing and calculated SAR in the pat e a temperature rise of less than 3 °C a bsorption rate (SAR) of 2.0 W/kg, for 1 background local specific absorption ra f.	ient during MRI, the at a maximum MR sy 5 minutes of MR sca ate (SAR) of 2.0 W/k	9850TMV /stem reported, nning at 1.5 T g, for 15
Image artifact was measured no ASTM F2119-07 using the spin images had artifacts that extend artifacts that extended as far as obscured.	on-clinically in a GE Signa 3T Discovery echo and gradient echo sequences spe led as far as 4 mm from the implant. Th 5.85 mm from the valve. The lumen of	750 MR system acceptified therein. The same gradient echo imathe the valve was partia	cording to pin echo ages had Ily to fully
The frame of the implant is com accordance with ASTM F2063-1	posed of Nitinol alloy with the chemical 2.	constituents listed b	elow in
Nickel	55.8 wt%		
The shows	Delevee		

NICKEI	55.8 WL-%
Titanium	Balance
Nitrogen plus Oxygen	<0.04 wt%
Carbon	<0.04 wt%

*INVESTIGATIONAL DEVICES. CAUTION: The Edwards EVOQUE 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 (St	ented 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 CENTE temperature rise of less than 2.0 °C after 15 minutes of	RA valve is expe of continuous sca	ected to produce a ma anning.	ıximum		
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 othe been evaluated for MR compatibility and is considered The frame of the implant is composed of Nitinol alloy v	r than 1.5 T or 3 d MR unsafe. with the chemica	0 T. The delivery sys	tem has not elow in		
accordance with ASTM F2063-12:	E4 E0/ E7 00/				
	54.5% - 57.0%				
	Max. 0.05%				
	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 Refe								
Edwards Alterra adaptive prestent in conjunction with 29AP4045, N/								
Edwards SAPIEN 3 transcatheter heart valve 9600TFX								
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 defin maximum temperature rise of 4.	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 frame of the valve implant i	s composed of MP35N alloy with the c	hemical constituents l	isted 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 Pro	Model	Reference						
Edwards Alterra adaptive preste	29AP4045,	N/A						
Edwards SAPIEN 3 transcatheter heart valve 9600TFX								
(continued from previous page)								
The frame of the prestent impla in accordance with ASTM F206	nt is composed of Nitinol alloy with the 3-12:	chemical constituents	s listed below					
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	9770DDS/9780DDS/9680DSC	N/A					
SAPIEN M3 valve	with 9680TFX29M						
MR Conditional Non-clinical testing has demonstrated that the Edwards SAI SAPIEN M3 valve, is MR Conditional. A patient can be scar 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 (i • Maximum MR system reported, whole body average (Normal Operating Mode)	PIEN M3 Dock implant, with a dep nned safely immediately after plac 30 T/m) or less ed specific absorption rate (SAR)	oloyed cement of of 2 W/kg					
Under the scan conditions defined above, the Edwards SAF maximum temperature rise of 2 °C or less after 15 minutes	PIEN M3 implant is expected to pr of continuous scanning.	oduce a					
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 desig	ned for reduction of metal artifact						
CAUTION: investigational device. Limited by Federal (USA) law to inv investigators only. See instructions for use for full information, inclue precautions and adverse events.	estigational use only. To be used by q ding indications, contraindications, wa	ualified rnings,					



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.				

Replacemer (Ball and Ca	nt Heart Valve age Mechanic	e Product Desc cal)		Models		Refe	erence	
Starr-Edward	1000, 12 2400, 60	200, 2300, 2 00, 6120, 6	310, 300,	2	2, 3			
	<u> </u>			6310	, 6320, 640	0		-
Testing of th	ese devices ir	n a static magne	etic field up to	1.5 tesla shov	w that they a	are safe	during N	/IR
procedures performed at 1.5 tesla or less though they are weakly ferromagnetic.								
Starr-Edward	Pre-1000,	Pre-1000, Pre-6000, 1260, 2, 4, 5			4, 5			
2320, 6520 (plastic disk)								
Testing of th	ese devices ir	n a static magne	tic field up to	2.35 tesla sho	ow that they	are safe	e during	MR
procedures	performed at 2	2.35 tesla or les	s though they	are weakly fe	rromagnetic	C.		
Valve cages	are comprise	d of Stellite 21.	Additionally, t	ne hollow ball	s of the me	allic bal	l valves	(Models
2300, 2310,	2320, 2400, 6	300, 6310, 632	0 and 6400) a	re also comp	osed of Stel	lite 21. 7	The nom	inal
composition (wt. percent) of Stellite 21 is as follows:								
Cobalt	Carbon	Manganese	Silicon	Chromium	Nickel	Molybo	lenum	Iron
61.5%	<0.35%	< 1.0	1.0%	28.5%	<1.0%	69	%	0.75%

Replacement Heart Valve Product Description							Mode	els	Refere	nce
(Blieaflet Mechanical)										
Edwards-Duromedics aortic and mitral bileaflet prostheses						31	160, 9	9120	2	
Testing of these devices in a static magnetic field up to 1.5 tesla show that they are safe during MR										
procedures per	procedures performed at 1.5 tesla or less. Valve housings are composed of solid pyrolytic carbon and the									
leaflets are dra	leaflets are graphite substrate coated with pyrolytic carbon. The retainer rings in the sewing ring are									
commercially p	ure titanium ar	ade II. Th	ne stiffe	ener rina	s are St	ellite 25. T	he no	ominal comp	osition (wt	
percent) for Ste	ellite 25 is as fo	llows:								-
Cobalt	Chromium	Tungs	sten	Nic	kel	Iron		Manganese	e Ca	rbon
50%	20%	15%	%	10)%	< 3%		1.5%	0.	1%
The nominal co	The nominal composition (wt. percent) for commercially pure titanium grade II is as follows:									
Nitrogen	Carbon		Hydrogen Iron			ron	on Oxygen		Titan	ium
< 0.03%	< 0.10%)	< 0.01	2%	< (.30%		< 0.25%	999	%



Replacemer (Bileaflet M	Replacement Heart Valve Product Description Bileaflet Mechanical)				Models		Reference	
Edwards MI	RA aortic and	nical valves	3600, 3600f, 3600u, 9600			1		
	instigational use	by rederal						
law to investigational use.)								
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-6AI-4V titanium alloy coated with turbostatic carbon. Leaflets are composed of graphite substrate coated with pyrolytic carbon. The nominal composition for Ti-6AI-4V titanium alloy is as follows:								
Nitrogen	Carbon	Hydrogen	Iron	Oxygen	Aluminum	Vanadiu	ım 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						els	Reference	
Carpentier-Edwards Classic annuloplasty mitral and tricuspid rings						4500	1	
Carpentier-Edwards Classic annuloplasty mitral and tricuspid rings with Duraflo treatment						4525	1	
Edwards MC3 Tricuspid annuloplasty ring					490	0	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						
< 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 Repai	ir Product De	Mode	els R	eference			
Carpentier-M	IcCarthy-Ada	410	0	1			
GeoForm mitral annuloplasty ring						0	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.							
kings have manium alloy cores. The nominal composition (wt. percent) of the titanium alloy is as follow							as ioliows.
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 Repa	ir Product De	Model	s Re	ference				
Carpentier-E	dwards Physi	4450		1				
Carpentier-Edwards Physio mitral annuloplasty ring with Duraflo							1	
Treatment								
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 corros	ion-resistant col	balt-chromium s	spring alloy ba	ands separate	ed by	
polyester filn	n strips covere	ed by silicor	e rubber and a	knit polyester co	overing. The	nominal com	position	
(wt. percent)	of the cobalt-	chromium a	alloy is as follows	S:				
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:

perfecter cevening. The hermital compectation (Wa percent) of the metal and j is de feneries.								
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 Repai	r Product De	scription	Model	Reference			
Carpentier-E	dwards Physi	io Tricuspid ar	6200	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:							and ores. The
Nitrogen Carbon Hydrogen Iron Oxygen Aluminum Vanadium Tita							Titanium
< 0.05%	< 0.08%	< 0.012%	< 0.25%	< 0.13%	6%	4%	89%



Valve Repair Product Description	Model	Reference					
	WOUEI	Reference					
dETlogix mitral annuloplasty ring	5100	1					
MR Conditional	lasty ring, mod	el 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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