LivaNova

Health innovation that matters

October 14th, 2019

Subject: **Magnetic Resonance Imaging (MRI) Information for LivaNova Heart Valve Prostheses and Annuloplasty Devices**
For Use in the Worldwide Markets with the exception of the USA

To whom it may concern:

This letter summarizes the currently approved MRI information for all LivaNova Heart Valve Prostheses and Annuloplasty Devices manufactured by Sorin Group Italia S.r.l. and LivaNova Canada Corp., and distributed worldwide, excluding the United States of America.

Due to the different materials that constitute each product, some of them are classified as "MR Safe" and others as "MR Conditional", in accordance with the requirements of the ASTM F2503 standard, *"Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"*.

The following tables provide detailed MRI information for each product.

Table #	Referenced products	MR Safety
Table 1	▪ Solo Smart ▪ Pericarbon Freedom Stentless ▪ Carbomedics Annuloflex ▪ Sovering ▪ Sovering Miniband	MR Safe 
Table 2a	▪ Carbomedics Prosthetic Heart Valve (CPHV) ▪ Carbomedics Annuloflo	MR Conditional 
Table 2b	▪ Carbomedics Carbo-Seal ▪ Carbomedics Carbo-Seal Valsalva	
Table 2c	▪ Perceval ▪ Perceval PLUS	
Table 2d	▪ Perceval (Canada and Australia)	
Table 2e	▪ Crown PRT Aortic Pericardial Heart Valve with PR Treatment	
Table 2f	▪ Crown PRT Aortic Pericardial Heart Valve with PR Treatment (Japan)	
Table 2g	▪ Mitroflow Aortic Pericardial Heart Valve – Model DL	
Table 2h	▪ Mitroflow Aortic Pericardial Heart Valve – Model 12 ▪ Mitroflow Aortic Pericardial Heart Valve – Model LX	
Table 2i	▪ Soprano Armonia ▪ Pericarbon More ▪ Bicarbon	
Table 2j	▪ Mitroflow Valsalva Conduit	
Table 2k	▪ Memo 3D ▪ Memo 3D ReChord	
Table 2l	▪ Memo 4D	

LivaNova

Health innovation that matters

Table 1: MR Safe Products –
Solo Smart, Pericarbon, Carbomedics Annuloflex, and Sovering

MR ***MR Safe: the following devices pose no known hazards in all MR environments***			
Product Type	**Product Name**	**REF***	**MRI Information**
Biological Valve	Solo Smart	ARTXXSMT	This device contains no metals and, therefore, poses no known hazards in all MR environments.
	Pericarbon Freedom Stentless	PFXX	
Annuloplasty Device	Carbomedics Annuloflex	AF-8XX	
	Sovering	SAXXM SBXXM SBXXT	
	Sovering Miniband	SMNXX	

* XX indicates different sizes available.

LivaNova

Health innovation that matters

Table 2a: MR Conditional Products –
Carbomedics Prosthetic Heart Valve (CPHV) and **Carbomedics Annuloflo**

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Mechanical Valve	Carbomedics Prosthetic Heart Valve (CPHV)	A5-0XX M7-0XX R5-0XX S5-0XX A1-0XX M2-0XX F7-0XX	A patient with this device can be scanned safely immediately after placement under the following conditions: **Static Magnetic Field** • Static magnetic field of 3 Tesla or less • Maximum spatial gradient magnetic field of 720 Gauss/cm or less **MRI-Related Heating** Whole body averaged specific absorption rate (SAR) of 2 W/kg in the Normal Operating Mode (the mode of operation of the MR EQUIPMENT in which none of the outputs have a value that cause physiological stress to PATIENTS) for 15 minutes (i.e., per pulse sequence). In non-clinical testing, the device produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C **Artifact Information** 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. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10 mm relative to the size and shape of the device using a 3 Tesla/128 MHz, MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) and the transmit body RF coil.
Annuloplasty Device	Carbomedics Annuloflo	AR-7XX	

***** XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2b: MR Conditional Products –
Carbomedics Carbo-Seal and **Carbomedics Carbo-Seal Valsalva**

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Ascending Aortic Prosthesis	Carbomedics CarboSeal	AP-0XX	A patient with this device can be scanned safely immediately after placement under the following conditions: **Static Magnetic Field** • Static magnetic field of 3 Tesla or less • Maximum spatial gradient magnetic field of 720 Gauss/cm or less **MRI-Related Heating** Whole body averaged specific absorption rate (SAR) of 2 W/kg in the Normal Operating Mode (the mode of operation of the MR EQUIPMENT in which none of the outputs have a value that cause physiological stress to PATIENTS) for 15 minutes (i.e., per pulse sequence). In non-clinical testing, the device produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C **Artifact Information** 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. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 10 mm relative to the size and shape of the device using a 3 Tesla/128 MHz, MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) and the transmit body RF coil. The conduit lumen is not obscured by artifact.
	Carbomedics CarboSeal Valsalva	CP-0XX	

* XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2c: MR Conditional Product –
Perceval†

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Biological Valve	Perceval	PVSXX	Non-clinical testing demonstrated that the Perceval S is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions: • Static magnetic field of 3 Tesla or less • Maximum spatial gradient magnetic field of 720 Gauss/cm or less. In non-clinical testing, the Perceval S produced a maximum temperature rise of 1.8°C during MRI performed in a 3 Tesla MR system for 15 min. The reported whole-body averaged SAR was 2.9 W/kg. 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 Perceval S.
	Perceval PLUS	PVF-X	Non-clinical testing demonstrated that the PERCEVAL PLUS is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions: - Static magnetic field of 3 Tesla or less - Maximum spatial gradient magnetic field of 720 Gauss/cm or less In non-clinical testing, the PERCEVAL PLUS produced a maximum temperature rise of 1.8°C during MRI performed in a 3 Tesla MR system for 15 min. The reported whole-body averaged SAR was 2.9 W/kg. 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 PERCEVAL PLUS.

† Refer to **Table 2d** for Perceval distributed in **Canada and Australia**.

***** XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2d: MR Conditional Product –
Perceval (Canada and Australia)

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Biological Valve	Perceval	PVSXX	Non-clinical testing demonstrated that the Perceval S is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions: • Static magnetic field of 1.5 Tesla or 3.0 Tesla only • Maximum spatial gradient magnetic field of 2500 Gauss/cm or less • Maximum whole-body averaged specific absorption rate (SAR) of 4 W/kg in the First Level Controlled Mode for the MR system ***MRI-Related Heating*** In non-clinical testing and modeling at 1.5 T, the device produced a maximum temperature rise less than 3.0°C during 15 minutes of continuous MR scanning in the First Level Controlled Mode at a maximum whole-body averaged SAR of 4.0 W/kg. In non-clinical testing and modeling at 3.0 T, the device produced a maximum temperature rise less than 2.7°C during 15 minutes of continuous MR scanning in the First Level Controlled Mode at a maximum whole-body averaged SAR of 4.0 W/kg. ***Artifact Information*** The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5 mm relative to the size and shape of the device Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

* XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2e: MR Conditional Product –
Crown PRT Aortic Pericardial Heart Valve with PR Treatment‡

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information†
Biological Valves	Crown PRT	CNAXX	Non-clinical testing demonstrated that the Crown PRT valve is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions: • Static magnetic field of 1.5 Tesla and 3 Tesla, only • Maximum spatial gradient magnetic 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 for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode of operation for the MR system. Under the scan conditions defined, the Crown PRT valve is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the Crown PRT valve extends approximately 3 mm from this implant when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

‡ Refer to **Table 2f** for Crown distributed in **Japan**.

***** XX indicates different sizes available.

† MRI information has been approved for use by the regulatory bodies, but the manufacturer has not yet implemented into the current labeling material. This will be included in the next IFU revision.

LivaNova
Health innovation that matters

Table 2f: MR Conditional Product –
Crown PRT Aortic Pericardial Heart Valve with PR Treatment (Japan)

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Biological Valves	Crown PRT	CNAXX	Non-clinical testing has proven that this product does not pose danger in certain MRI tests. MRI tests can be conducted safely under the following conditions: • Magnetic flux density of 3.0 Tesla or less • Spatial gradient field of 720 Gauss/cm or less • Maximum whole-body averaged SAR (Specific Absorption Rate) for 15 minutes scanning of 2.9 W/kg Increase in temperature was less than 1.6℃ at Maximum whole-body averaged SAR for 15 minutes scanning of 2.9W/kg in non-clinical testing. The quality of MR image may degrade if the area scanned is in the exact same area or relatively close to the position of the implanted product. For that reason, optimizing MR image parameters is required in order to making up for the degradation of the image quality due to the valve existence.

* XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2g: MR Conditional Products –
Mitroflow Aortic Pericardial Heart Valve – Model DL

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information†
Biological Valves	Model DL	DLAXX	Non-clinical testing demonstrated that the valve is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions: • Static magnetic field of 1.5 Tesla and 3 Tesla, only • Maximum spatial gradient magnetic 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 for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode of operation for the MR system. Under the scan conditions defined, the valve is expected to produce a maximum temperature rise of 1.5°C after 15 minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the valve extends approximately 3 mm from this implant when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

***** XX indicates different sizes available.

† MRI information has been assessed/approved for use by the regulatory bodies, but the manufacturer has not yet implemented into the current labeling material. This will be included in the next IFU revision.

LivaNova
Health innovation that matters

Table 2h: MR Conditional Products –
Mitroflow Aortic Pericardial Heart Valve – Model 12
Mitroflow Aortic Pericardial Heart Valve – Model LX

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Biological Valves	Model 12	12AXX	Non-clinical testing has demonstrated that the Mitroflow valve is MR Conditional. It can be scanned safely under the following conditions: • Static magnetic field of 3.0 Tesla or less • Spatial gradient field of 525 Gauss/cm or less • Maximum whole-body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning. In non-clinical testing, the Mitroflow valve produced a temperature rise of less than 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5 Tesla, Model Signa MR, GE Medical System, Milwaukee, WI, MR scanner. 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 Mitroflow valve. Therefore, it may be necessary to optimize MR imaging parameters to compensate for the presence of this implant.
	Model LX	LXAXX	

* XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2i: MR Conditional Products –
Soprano Amonia, **Pericarbon More** and **Bicarbon**

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Biological Valve	Soprano Armonia	ARTXXSOP	Non-clinical testing demonstrated that the device is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions: **Static Magnetic Field** • Static magnetic field of 3 Tesla or less • Maximum spatial gradient magnetic field of 720 Gauss/cm or less **MRI-Related Heating** In non-clinical testing, the device produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C Therefore, the MRI-related heating experiments for the device at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C. **Artifact Information** MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.
	Pericarbon More	PSXX PNXX	
Mechanical Valve	Bicarbon	ARTXXLN MTRXXLS ARTXXLNF MTRXXLSF ARTXXLFA MTRXXLFM ARTXXLNS MTRXXLSS ARTXXLSA ARTXXLOV ARTXXLNFJ ARTXXLNSJ MTRXXLSSJ	

***** XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2j: MR Conditional Product –
Mitroflow Valsalva Conduit

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Graft Conduit	Mitroflow Valsalva Conduit	MVC0XX	Non-clinical testing has demonstrated that the MITROFLOW VALSALVA CONDUIT assembled with the Mitroflow valve is MR Conditional. It can be scanned safely under the following conditions: • Static magnetic field of 3.0 Tesla or less • Maximum spatial gradient magnetic field of 720 Gauss/cm or less • Maximum whole-body-averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning. In non-clinical testing, the MRI-related heating experiment for the MITROFLOW VALSALVA CONDUIT assembled with the Mitroflow valve at 3 Tesla, using a transmit/receive RF body coil at an MR system (Exite, General Electric Healthcare, Milwaukee, WI) reported whole body averaged SAR of 2.9 W/kg, indicated that the greatest amount of heating occurred was equal to 1.7°C, value not considered to be physiologically consequential for a human subject. **Artifacts information** The artifacts for The MITROFLOW VALSALVA CONDUIT assembled with the Mitroflow Valve may presents problems if the MR imaging area of interest is in or near the area of were the device is located. The maximum artefact size extends approximately 10 mm using a 3 Tesla/128 Mhz, MR system (Exite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) and the transmit body RF coil. The lumen is not obscured by artefact. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

* XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2k: MR Conditional Product –
Memo 3D and **Memo 3D ReChord**

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Annuloplasty Device	Memo 3D	SMDXX	Non-clinical testing demonstrated that these devices are MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions: • Static magnetic field of 3 Tesla or less; • Spatial gradient magnetic 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, these devices produced a temperature rise of 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 scanner, Model Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of these devices. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.
	Memo 3D ReChord	MRCSXX	

* XX indicates different sizes available.

LivaNova
Health innovation that matters

Table 2l: MR Conditional Product –
Memo 4D

MR Conditional: Has been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use.

Product Type	Product Name	REF*	MRI Information
Annuloplasty Device	Memo 4D	4DM-XX	Non-clinical testing has demonstrated that the Memo 4D Annuloplasty Ring is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions: static magnetic field of 1.5 Tesla or 3 Tesla; maximum spatial field gradient of 4,000 G/cm (40 T/m) or less. transmit quadrature-driven coil (circularly polarized); maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 4 W/kg (First-level Operating Mode). Artifact Information: in non-clinical testing, the image artifact caused by the device extends 12 mm from the Memo 4D System when imaged with a gradient echo pulse sequence and a 3 T MRI system." MRI-related heating: Under the scan conditions defined above, the Memo 4D Annuloplasty Ring System is expected to produce a maximum temperature rise of less than 2.4 °C after 15 minutes of continuous scanning.

* XX indicates different sizes available.