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July 9th, 2019

Subject: Magnetic Resonance Imaging (MRI) Information for LivaNova Heart Valve Prostheses and Annuloplasty Devices
For Use in the USA Market Only

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 in the United States of America (USA).

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 FDA recognized standard, ASTM F2503, *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 ▪ Carbomedics Annuloflex	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	
Table 2d	▪ Crown PRT Aortic Pericardial Heart Valve with PRT Treatment	
Table 2e	▪ Mitroflow Aortic Pericardial Heart Valve – Model DL	
Table 2f	▪ Mitroflow Aortic Pericardial Heart Valve – Model 12 ▪ Mitroflow Aortic Pericardial Heart Valve – Model LX	
Table 2g	▪ Mitroflow Valsalva Conduit	
Table 2h	▪ Memo 3D ▪ Memo 3D ReChord	
Table 2i	▪ Memo 4D	

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Table 1: MR Safe Products –
Solo Smart and **Carbomedics Annuloflex**

MR

MR Safe: the following device poses 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.
Annuloplasty Device	Carbomedics Annuloflex	AF-8XX	

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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	

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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	

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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 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 3.0oC 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 2.7oC 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.

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Table 2d: 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 has demonstrated that the Crown PRT valve 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 2,500-Gauss/cm or less • Maximum MR system reported, whole body average specific absorption rate (SAR) of 2W/kg (Normal Operating Mode) Under the scan conditions defined above, the Crown PRT valve is expected to produce a maximum temperature rise of less than 1.6°C after 15 minutes of continuous scanning. In non-clinical testing, the *image artifact* caused by the device extends no more than 10-mm from the Crown PRT valve when imaged with a *gradient echo* pulse sequence and a 3-Tesla MRI system. 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 Crown PRT valve. 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 Crown PRT valve using a 3-Tesla/128-MHz, MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) and the transmit body RF coil.

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Table 2e: 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 has demonstrated that the Mitroflow valve is MR Conditional. A patient with this device can be scanned safely under the following conditions: • Static magnetic field of 3-Tesla or less • Maximum spatial gradient magnetic field of 2,500-Gauss/cm • Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (Normal Operating Mode). Under the scan conditions defined above, the Mitroflow valve is expected to produce a maximum temperature rise of less than 1.6°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends no more than 10-mm from the Mitroflow valve when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

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† MRI information approved by FDA but not yet implemented in the labeling material. This will be included in the next IFU revision.

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Table 2f: 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	

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Table 2g: 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.

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Table 2h: 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	

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Table 2i: 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.

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