February 2025

Subject: Magnetic Resonance Imaging (MRI) Information for Corcym 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 Corcym Heart Valve Prostheses and Annuloplasty Devices manufactured by Corcym S.r.l. and Corcym 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)	MR Conditional 
Table 2b	▪ Carbomedics Carbo-Seal ▪ Carbomedics Carbo-Seal Valsalva	
Table 2c	▪ Perceval ▪ Perceval Plus	
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	
Table 2l	▪ Carbomedics Annuloflo	
Table 3	▪ All other codes of devices manufactured by companies merged into the current CORCYM holding.	See reference in the table

For MRI information on products not listed in the table above, please contact customer.qualityhv@corcym.com

Instructions for Use are available upon request through the manufacturer's website.

Table 1: MR Safe Products

Solo Smart and **Carbomedics Annuloflex**

MR Safe: the following device poses no known hazards in all MR environments

Product Type	Product Name	REF*	MRI Information
Biological Valve	Solo Smart	ART**XX**SMT	This device contains no metals and, therefore, poses no known hazards in all MR environments.
Annuloplasty Device	Carbomedics Annuloflex	AF-8**XX**	

*** XX** indicates different sizes available.

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	Carbomedics Standard Aortic	A5-0**XX**	Non-clinical testing has demonstrated that the Carbomedics Prosthetic Heart Valve is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions. Failure to follow these conditions may result in injury. Static Magnetic Field Strength (Bo): 1.5 T or 3.0 T Maximum Spatial Field Gradient: 40 T/m (4,000 gauss/cm) RF Excitation: Circularly Polarized (CP) RF Transmit Coil Type: There are no Transmit Coil restrictions RF Receive Coil Type: Any Operating Mode: Normal Operating Mode Maximum Gradient Slew Rate: 200 T/m/s per axis Maximum Whole-Body SAR: 2 W/kg (Normal Operating Mode) Maximum Head SAR: 3.2 W/kg (Normal Operating Mode) Scan Duration: 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) MR Image Artifact: The presence of this implant may produce an image artifact of 18 mm.
	Carbomedics Standard Mitral	M7-0**XX**	
	Carbomedics Reduced	R5-0**XX**	
	Carbomedics Top Hat	S5-0**XX**	
	Carbomedics Orbis Aortic	A1-0**XX**	
	Carbomedics Orbis Mitral	M2-0**XX**	
	Carbomedics Optiform	F7-0**XX**	

*** XX** indicates different sizes available.

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-0**XX**	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-0**XX**	

*** XX** indicates different sizes available.

Table 2c: MR Conditional Products

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	PVS**XX**	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.

*** XX** indicates different sizes available.

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 Plus	PVF-**XX**	Non-clinical testing has demonstrated the Perceval PLUS Valve System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions: • Static magnetic field of 3.0 T or less; • Maximum spatial field gradient of 9,100 G/cm (91 T/m); • Use of a circularly polarized (CP), whole-body transmit RF coil together with any combination of receive-only RF coils; • Maximum MR system-reported, whole-body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or less. Under the scan conditions defined above, the Perceval PLUS Valve System is expected to produce a maximum temperature rise of less than 1.6 ºC after 15 minutes of continuous scanning at 1.5 T and less than 1.5 ºC after 15 minutes of continuous scanning at 3 T. In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the Perceval PLUS Valve System imaged with a gradient echo pulse sequence and a 3 T MRI system.

*** XX** indicates different sizes available.

Table 2d: MR Conditional Products

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	CNA**XX**	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.

*** XX** indicates different sizes available.

Table 2e: MR Conditional Product

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	DLA**XX**	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.

***** **XX** indicates different sizes available.

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

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	

*** XX** indicates different sizes available.

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	MVC0**XX**	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.

Table 2h: MR Conditional Products

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	SMD**XX**	Non-clinical testing has demonstrated that the Memo 3D and Memo 3D ReChord 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 8,030 G/cm (80.3 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 3D System when imaged with a gradient echo pulse sequence and a 3T MRI system." MRI-related heating: Under the scan conditions defined above, the Memo 3D and Memo 3D ReChord Annuloplasty Ring System is expected to produce a maximum temperature rise of less than 2.4 °C after 15 minutes of continuous scanning
	Memo 3D ReChord	MRCS**XX**	

*** XX** indicates different sizes available.

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 8,030 G/cm (80.3 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.

Table 2I: 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
Annuloplasty Device	Carbomedics Annuloflo	AR-7**XX**	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.

* **XX** indicates different sizes available.

Table 3: List of historical reference and codes for devices manufactured by companies merged into the current CORCYM holding.

REF*	Product Name *	MRI Information see Table
CF4	CardioFix Circular Diameter 12	**1**
CF6	CardioFix Rectangular 6x8	**1**
500-0**XX**	Carbomedics Standard Aortic size **XX** (old denomination)	**2a**
700-0**XX**	Carbomedics Standard Mitral size **XX** (old denomination)	**2a**
R500-0**XX**	Carbomedics Reduced size **XX** (old denomination)	**2a**
S500-0**XX**	Carbomedics Top Hat size **XX** (old denomination)	**2a**

*** XX** indicates different sizes available.