

Subject: Magnetic Resonance Imaging (MRI) Information on Sorin Group Heart Valve Prostheses and Annuloplasty Devices

To whom it may concern

This letter summarizes the required MRI information for all Sorin Group Heart Valve Prostheses and Annuloplasty Devices.

Due to the different materials that constitute each product, some of them are classified as “MR Safe” and others as “MR Conditional”, according to the requirements of the ASTM F2503-08 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 | <ul style="list-style-type: none"> ▪ Freedom Solo ▪ Solo Smart ▪ Pericarbon Freedom Stentless ▪ Carbomedics Annuloflex ▪ Covering ▪ Covering Miniband | MR Safe  |
| Table 2a | <ul style="list-style-type: none"> ▪ Carbomedics Prosthetic Heart Valve (CPHV) ▪ Carbomedics Annuloflo | MR Conditional  |
| Table 2b | <ul style="list-style-type: none"> ▪ Carbomedics Carbo-Seal ▪ Carbomedics Carbo-Seal Valsalva | |
| Table 2c | <ul style="list-style-type: none"> ▪ Perceval S | |
| Table 2d | <ul style="list-style-type: none"> ▪ Soprano Armonia ▪ Pericarbon More ▪ Bicarbon | |
| Table 2e | <ul style="list-style-type: none"> ▪ Mitroflow Aortic Pericardial Heart Valve | |
| Table 2f | <ul style="list-style-type: none"> ▪ Mitroflow Valsalva Conduit | |
| Table 2g | <ul style="list-style-type: none"> ▪ Memo 3D | |

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Cod. Fisc. 10556980158 - Part. IVA 02109510368

ISO CODE IT02109510368

Registro Nazionale Produttori AEE N. IT08020000000823

Table 1: MR Safe products

|  <i>MR Safe: the following devices pose no known hazards in all MR environments</i> | | |
|---|-------------------------------------|-------------------------|
| Product Type | Product Name | REF* |
| Biological Valve | <i>Freedom Solo</i> | ARTXXSG |
| | <i>Pericarbon Freedom Stentless</i> | PFXX |
| | <i>Solo Smart</i> | ARTXXSMT |
| Annuloplasty Device | <i>Carbomedics Annuloflex</i> | AF-8XX |
| | <i>Sovering</i> | SAXXM SBXXM SBXXT |
| | <i>Sovering Miniband</i> | SMNXX |

*XX indicates different sizes available

Table 2a: MR Conditional products –
Carbomedics Prosthetic Heart Valve 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 | <p>A patient with this device can be scanned safely immediately after placement under the following conditions:</p> <p>Static Magnetic Field</p> <ul style="list-style-type: none"> • Static magnetic field of 3-Tesla or less • Maximum spatial gradient magnetic field of 720-Gauss/cm or less <p>MRI-Related Heating</p> |
| Annuloplasty Device | Carbomedics Annuloflo | AR-7XX | <p>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).</p> <p>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:</p> <p>Highest temperature change +1.6°C</p> <p>Artifact Information</p> <p>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.</p> |

*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-0XX | <p>A patient with this device can be scanned safely immediately after placement under the following conditions:</p> <p>Static Magnetic Field</p> <ul style="list-style-type: none"> • Static magnetic field of 3-Tesla or less • Maximum spatial gradient magnetic field of 720-Gauss/cm or less <p>MRI-Related Heating</p> <p>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).</p> <p>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:</p> <p>Highest temperature change +1.6°C</p> <p>Artifact Information</p> <p>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.</p> <p>The conduit lumen is not obscured by artifact.</p> |
| | Carbomedics CarboSeal Valsalva | CP-0XX | |

*XX indicates different sizes available

Table 2c: MR Conditional products – Perceval S

|  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 S | PVSXX | <p>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:</p> <p>Static Magnetic Field</p> <ul style="list-style-type: none"> • Static magnetic field of 3-Tesla or less • Maximum spatial gradient magnetic field of 720-Gauss/cm or less <p>MRI-Related Heating</p> <p>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:</p> <p><i>Highest temperature change +1.8°C</i></p> <p>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</p> <p>+1.8°C.</p> <p>Artifact Information</p> <p>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.</p> |

*XX indicates different sizes available

Table 2d: MR Conditional products –
Soprano Armonia, 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 | <i>Soprano Armonia</i> | ARTXXSOP | <p>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:</p> <p>Static Magnetic Field</p> <ul style="list-style-type: none"> • Static magnetic field of 3-Tesla or less • Maximum spatial gradient magnetic field of 720-Gauss/cm or less <p>MRI-Related Heating</p> <p>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:</p> <p><i>Highest temperature change +1.6°C</i></p> <p>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</p> <p>+1.6°C.</p> <p>Artifact Information</p> <p>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.</p> |
| | <i>Pericarbon More</i> | PSXX PNXX | |
| Mechanical Valve | <i>Bicarbon</i> | ARTXXLN MTRXXLS ARTXXLNF MTRXXLSF ARTXXLFA MTRXXLFM ARTXXLNS MTRXXLSS ARTXXLSA ARTXXLOV ARTXXLNFJ ARTXXLNSJ MTRXXLSSJ | |

*XX indicates different sizes available

Table 2e: MR Conditional products –
Mitroflow Aortic Pericardial Heart Valve

|  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 | <i>Mitroflow</i> | 12AXX LXAXX DLAXX | <p>Magnetic Resonance Imaging (MRI)</p> <p>Non-clinical testing has demonstrated that the Mitroflow valve is MR Conditional. It can be scanned safely under the following conditions:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>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.</p> |

*XX indicates different sizes available

Table 2f: MR Conditional products – 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 | <i>Mitroflow Valsalva Conduit</i> | MVC0XX | <p>Magnetic Resonance Imaging (MRI)</p> <p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p><u>Artifacts information</u></p> <p>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.</p> <p>Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.</p> |

*XX indicates different sizes available

Table 2g: MR Conditional products – Memo 3D

| |
|---|
|  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 | <i>Memo 3D</i> | SMDXX | <p>Non-clinical testing demonstrated that the MEMO 3D, semirigid annuloplasty ring is MR Conditional. A patient with this implant can be scanned safely immediately after placement under the following conditions:</p> <ul style="list-style-type: none"> • 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. <p>In non-clinical testing, the MEMO 3D, semirigid annuloplasty ring 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 system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).</p> <p>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 MEMO 3D, semirigid annuloplasty ring. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.</p> |

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