proGAV 2.0

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing demonstrated that the proGAV 2.0 valve is MR Conditional. A patient with the proGAV 2.0 valve can be safely scanned immediately after implantation in an MR system meeting the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 1,400-Gauss/cm (14.0 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode)
- Do not take the *proGAV 2.0* tools into the MR environment. They are MR Unsafe.

Under the scan conditions defined above, the *proGAV 2.0* valve is expected to produce a maximum temperature rise of +3°C after 15 minutes of continuous scanning.

COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

MRI examinations with field strengths of up to 3.0 tesla and CT examinations can be carried without endangering or impairing the functionality of the shunt. The *proGAV 2.0* is MR Conditional (ASTM F2503-13). The setting of the *proGAV 2.0* will not change when subjected to an MRI of 1.5 T or 3.0 T. All components are visible via X-ray. The provided catheters are MRI Safe. Reservoirs, deflectors and connectors are MR Conditional.

For additional proGAV 2.0 MRI Safety Information, including artifact information, Warnings and Precautions see product IFU SOP-AIC-5001399.