MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the proGAV is MR Conditional. A patient with the proGAV valve can be scanned safely under the following conditions:

- static magnetic field of 1.5 and 3 Tesla
- spatial gradient field of 4.3 T/m (430 Gauss/cm)
- maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg for 15 minutes of scanning

In non-clinical testing, the proGAV produces a temperature rise of less than 0.2 °C at a maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg, as assessed by calorimetry for 15 minutes of scanning in 1.5 Tesla Vision Sonata of Siemens Healthcare (Erlangen, Germany), software version Numaris/4 MR A30 and 3 Tesla Trio of Siemens Healthcare (Erlangen, Germany), software version Numaris/4 MR B15.

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 valve is MR Conditional (ASTM F2503-08). The proGAV valve 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 MRI Safety Information, including artifact information, Warnings and Precautions see product IFU SOP-AIC-5000585.