proGAV

MRI SAFETY INFORMATION

MR Conditional

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.