proSA

MRI SAFETY INFORMATION

MR Conditional

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

- Static magnetic field of 1.5 and 3 Tesla only
- Spatial gradient field of 7.2 T/m (720 Gauss/cm)
- Maximum whole body averaged specific absorption rate (SAR) 4 W/kg for 15 minutes of scanning
- No local transmit coils should be placed over the implant.

In non-clinical testing, the proSA valve produced a temperature rise of less than 2.5°C at the maximum whole body average specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3.0 tesla MR-scanner Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field scanner.

COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

A patient with the proSA valve may undergo an MRI procedure using an MR system with a static magnetic field of 1.5 and 3.0 tesla only. MRI and CT examinations can be carried without endangering or impairing the functionality of the Shunt. The proSA valve will not change when subjected to an MRI of 1.5T or 3T. The proSA is MR Conditional (ASTM-F2503-08). All components are visible via X-ray. The provided catheters are MRI Safe. Reservoirs, deflectors and connectors are MR Conditional.

For additional proSA MRI Safety Information, including artifact information, Warnings and Precautions see product IFU SOP-AIC-5001094.