

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](#).