MRI Compatibility Statement for Rigi10™ Malleable Penile Prosthesis

MRI Compatibility

Magnetic Resonance Imaging (MRI) studies on Rigi10™ malleable penile prosthesis conducted under the standards described in the guidance for Industry and Food and Drug Administration Staff titled “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment” concluded that MRI procedures carried-out following the below provided conditions will not produce additional risks to patients.¹

A detailed description of evidence demonstrating Rigi10™ malleable penile prosthesis’ “MR conditional” status is presented in the following statements.

MRI Safety Information

Non-clinical testing has demonstrated the Rigi10™ malleable penile prosthesis is MR Conditional.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg for 15 minutes of scanning (i.e. per pulse sequence) (Normal Operating Mode)

Under the scan conditions defined above, the Rigi10™ malleable penile prosthesis is expected to produce a maximum temperature rise of less than or equal to 1.6°C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the Rigi10™ malleable penile prosthesis extends approximately 55 mm from the device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.