Rigicon®
Innovative Urological Solutions

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).

[1] Shellock R&D Services, Inc. "Evaluation of Magnetic Field Interactions, Heating, and Artifacts for the Rigi10 Malleable Penile Implant", 09/23/2018.

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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.

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