

TUBE-MR CONDITIONAL

Non-clinical testing performed in the worst case product has demonstrated that Tube Malleable Penile prosthesis implants are MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,800 G/cm [128 T/m]
- Maximum force product of 231 T²/m
- Theoretically estimated maximum whole body averaged [WBA] specific absorption rate [SAR] of 2 W/kg [Normal Operating Mode]

Under the scan conditions defined above, the Tube Malleable Penile prosthesis implants are expected to produce a maximum temperature rise of less than 1.5°C [2 W/kg, 1.5 Tesla] RF-related temperature increase with a background temperature increase of $\approx 1.3^{\circ}\text{C}$ [2 W/kg, 1.5 Tesla] 0.6°C [2 W/kg, 3 Tesla] RF-related temperature increase with a background temperature increase of $\approx 0.6^{\circ}\text{C}$ [2 W/kg, 3 Tesla] after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 3.74 mm from the Tube Malleable Penile prosthesis implants when imaged with a spin echo pulse sequence and a 3 Tesla MR system.