

MR SAFETY INFORMATION FOR SAM MEDICAL PRODUCTS



SAM SPLINT PRODUCT FAMILY

Non-clinical testing has demonstrated the SAM Splint is MR Conditional. A patient with this device securely attached 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 10,000 gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning in the Normal Operating Mode of operation

Under the scan conditions defined above, the SAM Splint is expected to produce a maximum temperature rise of less than 2.0° C (3.6° F) in a 1.5 T and 2.5° C (4.5° F) in 3.0 T.

The SAM Splint will not present an additional risk or hazard to a patient in the 3.0 T MRI environment with regard to translational attraction or migration.

In non-clinical testing, the image artifact caused by the device extends approximately 10 mm relative to the size and shape of the SAM Splint in a 3.0 T MRI system.

SAM PELVIC SLING PRODUCT FAMILY SAM JUNCTIONAL TOURNIQUET (WHEN USED AS A PELVIC SLING ONLY)

Non-clinical testing has demonstrated the SAM Pelvic Sling is MR Conditional. A patient with this device securely attached can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T or less

The SAM Pelvic Sling is used externally on the body and is composed primarily of fabric and has minimal metallic components. The metallic components are isolated and insulated from the patient during its intended use so testing to evaluate MRI-related heating was deemed to be unnecessary.

Testing to assess MR safety was performed with the SAM Pelvic Sling firmly attached to a simulated patient and indicated that the product did not move or migrate during exposure to the 3.0 T MR system. As such, a Pelvic Sling will not present a hazard or risk to a patient undergoing an MRI procedure using an MR system operating at 3.0 T or less while the device is securely attached to a patient.

CAUTION

Check that the SAM Pelvic Sling is securely attached to the patient prior to entering the MR system room.

The SAM Sling should not be removed from the patient while in the MR system room.

Due to the presence of metal springs in the buckle of the SAM Pelvic Sling, MR images may be affected by artifacts if the imaging area of interest is located near the buckle.

MR safety testing performed by Shellock R&D Services, Inc. in compliance with the following standards:

ASTM F2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment

ASTM F2119, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

ASTM F2182, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

ASTM F2213, Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment