Prosan International B.V.
IJsselburcht 3
6825BS Arnhem
The Netherlands

Arnhem, 17 February 2020

Non-clinical testing according to ASTM standards has demonstrated that Flexi-T intrauterine devices are 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 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 12,700 G/cm (127 *Tim)*
- 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 Flexi-T intrauterine device is expected to produce a maximum temperature rise of less than:

- 1.7°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of::::: 1.4 ° C (2 W /kg , 1.5 Tesla)
- 1.2°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of::::: 0.8°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 1.99 mm from the Flexi-T intrauterine device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested and no clinically significant displacement or torque was measured.

C. van der Zaal,
QARA Officer,
Prosan International B.V.