LimaCorporate
Orthopaedic motion

To: SPLOŠNA BOLNIŠNICA NOVO MESTO
ŠMIHELSKA CESTA 1
8000 NOVO MESTO
SLOVENIJA

Declaration on MRI Compatibility (SMR Shoulder System)

Villanova di San Daniele, September 23, 2020

MR Test performed on LimaCorporate SMR Shoulder System

There are inherent risks associated with the use of metallic implants in the MR environment, including component migration, heat induction and signal interference or distortion near the component(s).
Heat induction of metallic implants is a risk related to the component geometry and material, as well as the MR power, duration and pulse sequence.
Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.
Nowadays, the SMR Shoulder System IFU reports that its "*components have not been evaluated for safety and compatibility in the MR environment*".

LimaCorporate performed tests to evaluate displacement force, torque, heating and artifacts produced by the interaction between the MRI and the SMR Shoulder System.
The SMR Shoulder System has resulted to be **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 8,500 G/cm (85 T/m)
  - Maximum force product of 154,000,000 G2/cm (154 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 SMR Shoulder System is expected to produce a maximum temperature rise of less than:

- 6.0°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of: ≈0.4°C (2 W/kg, 1.5 Tesla, SMR anatomical shoulder system) after 5 minutes of continuous scanning; ≈0.2°C (2 W/kg, 1.5 Tesla, SMR reverse shoulder system) after 4.3 minutes of continuous scanning;
- 6.0°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of: ≈0.6°C (2 W/kg, 3 Tesla, SMR anatomical shoulder system) after 12 minutes of continuous scanning; ≈0.9°C (2 W/kg, 3 Tesla, SMR reverse shoulder system) after 12.5 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 98.9 mm (SMR anatomical shoulder system) / 72.9 mm (SMR reverse shoulder system) from the SMR Shoulder System when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.
Given the above conclusion on MRI compatibility of the SMR Shoulder System, the IFU of the system will be updated accordingly.

Best regards,

Roberto Gabetta
Regulatory Manager