LimaCorporate
Orthopaedic motion

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

Declaration on MRI Compatibility (Hip Implant System)

Villanova di San Daniele, September 21, 2020

MR Test performed on LimaCorporate Hip Implant System (for total and partial hip replacement)

The present declaration covers, but it is not limited to, the following implantable medical devices manufactured by Limacorporate:

- Revision femoral system;
- Femoral heads (Biolox Delta, CoCrMo, AISI);
- SL Femoral stem;
- Bipolar Heads (AISI);
- Modulus Femoral system;
- Modulus-R femoral system;
- Acetabular Cup Delta TT, Delta Revision TT, Delt One-TT, Delta Multihole TT
- Hemispheric modules
- Spacers
- Delta liners (Biolox Delta, LimaVit, UHMWPE X-Lima)
- Delta Dual Mobility
- Bone Screws;

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 IFU of the Hip implant system report 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 Hip Implant System (for both total and partial hip replacement).
The Hip Implant 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 1,700 G/cm (17 T/m)
  - Maximum force product of 31,000,000 G2/cm (31 T2/m)
  - Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

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Under the scan conditions defined above, the Hip Implant System is expected to produce a maximum temperature rise of less than:

- 9.0°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of ≈1.3°C (2 W/kg, 1.5 Tesla)
- 5.9°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ≈1.1°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 >153.8 mm from the Hip Implant System when imaged with a gradient and spin echo pulse sequence and a 3 Tesla MR system.
Given the above conclusion on MRI compatibility of the Hip Implant System, the IFU of the system will be updated accordingly.

Best regards,

Roberto Gabetta
Regulatory Manager