Kind attention to:
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Villanova di San Daniele, February 21, 2020

Declaration on MRI Compatibility (Physica Knee System)

MR Test performed on LimaCorporate Physica Knee 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 IFU of the Physica Knee System 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 Physica Knee System.
The Physica Knee 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 3,880 G/cm (38.80 T/m)
  - Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of: 2 W/kg at 1.5T (Normal Operating Mode); 1.6 W/kg at 3T (Normal Operating Mode).

Under the scan conditions defined above, the Physica Knee System is expected to produce a maximum temperature rise of less than 6.0°C after 15 minutes of continuous scanning.
Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

In non-clinical testing, the image artifact caused by the device extends approximately 5.5 cm from the Physica Knee System when imaged with a gradient echo pulse sequence in a 1.5 T MR system and approximately 7.9 cm from the Physica Knee System when imaged with a spin echo pulse sequence in a 3 T MR system.

Given the above conclusion on MRI compatibility of the Physica Knee System, the IFU of the system will be updated accordingly.

Best regards,

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