

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

Declaration on MRI Compatibility (Discovery elbow system)

MR Test performed on LimaCorporate Discovery Elbow 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 Discovery Elbow 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 Discovery Elbow System.

The Discovery Elbow 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 8,600 G/cm (86 T/m)
 - Maximum force product of 156,000,000 G²/cm (156 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 Discovery Elbow System is expected to produce a maximum temperature rise of less than:

- 14.7°C (2 W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of $\approx 1.4^{\circ}\text{C}$ (2 W/kg, 1.5 Tesla)
- 6.0°C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of $\approx 1.0^{\circ}\text{C}$ (2 W/kg, 3 Tesla)

after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 70.7 mm from the Discovery Elbow System when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

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

Best regards,

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Regulatory Manager

