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May 6th, 2024

To Whom It May Concern

Re: MRI (Magnetic Resonance Imaging) compatibility of Silicone Foley Catheters with Temperature Sensor, manufactured by Well Lead Co. Ltd. and distributed by UNOQUIP GmbH under the brand UNOQUIP

The undersigned company Well Lead Medical Co. Ltd. declares that two components of the Silicone Foley Catheters with Temperature Sensor, namely the temperature sensor, for monitoring patient temperature, and the spring in the self-closing inflation valve, for inflation and deflation of the balloon, contain metal.

Non-clinical testing has demonstrated that the Silicone Foley Catheters with Temperature Sensor manufactured by Well Lead Co. Ltd. are MRI conditional.[1,2]

A patient with this device can be scanned in an MRI system under the following conditions:

- Static magnetic field of 1.5-tesla and 3-Tesla only
- Maximum spatial gradient magnetic field of 2,500-Gauss/cm (25-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the Silicone Foley Catheters with Temperature Sensor is expected to produce a maximum temperature rise of 2.6℃ after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the Silicone Foley Catheters with Temperature Sensor extends approximately 6 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Sincerely,
Well Lead Medical Co. Ltd.



1.Test report on Evaluation of Magnetic Field Interactions, Heating, and Artifacts for the Foley Catheter with Temperature Sensor (Well Lead Foley, 10Fr. UOT – OTS), Date 04/27/20. Data on file at Well Lead Co. Ltd.

2.Test report on Evaluation of Magnetic Field Interactions, Heating, and Artifacts for the Foley Catheter with Temperature Sensor (Well Lead Foley, 18Fr. UOT – OTS), Date 04/27/20. Data on file at Well Lead Co. Ltd.