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NuMED has the following statement regarding the MRI safety of our CP Stents.

## **MRI Conditional - MRI Safety Information**

Nonclinical testing and modeling have demonstrated that the CP Stent is 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 T and 3 T
- Maximum spatial gradient magnetic field of 2500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (Normal Operating Mode)

Based on nonclinical testing and modeling, under the scan conditions defined above, the CP Stent is expected to produce a maximum in vivo temperature rise of less than 2°C after 15 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. In nonclinical testing, the image artifact caused by the device extends approximately 3 mm from the CP Stent when imaged with a spin echo pulse sequence and 6 mm when imaged with a gradient echo pulse sequence and a 3 T MRI System. The lumen of the device was obscured.

The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters.