



**June 24, 2020**

**MRI Safety information for the following NuMED Balloon Catheters:**

- Tyshak
- Tyshak II
- Tyshak Mini
- Tyshak NuCLEUS
- Z-MED
- Z-MED II
- COEfficient
- PTS
- BIB PTA
- Z5 Atrioseptostomy
- Mini Ghost
- Multi-Track Angiographic
- NuCLEUS

**MRI Safety Information**

Non-clinical testing has demonstrated that NuMED's Balloon Catheter Systems are MR Conditional. The following labeling is specific to NuMED's catheters and does not apply to guidewires or other accessory devices used in combination with NuMED's Balloon Catheter Systems. Users should consult the instructions for use and MRI safety information of other accessory devices used with NuMED's catheters. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 1,900 G/cm (19 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Operating Mode).

**RF heating**

Under the scan conditions defined above, NuMED's Balloon Catheter Systems are expected to produce a maximum temperature rise of less than 5.7<sup>0</sup>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.

**MR Artifact**

In non-clinical testing, the image artifact caused by the catheter extend radially approximately 3 mm from the catheter when imaged in a 3 T MRI system.