Bardex® Latex-Free Temperature-Sensing 400-Series Foley Catheter MRI Safety Instructions

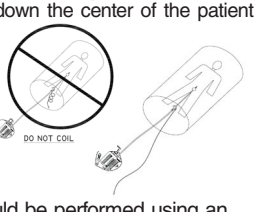
MR

Warning: This product should never be connected to the temperature monitor or connected to a cable during an MRI procedure. Failure to follow this guideline may result in serious injury to the patient. Refer to Instructions for Use! It is important to closely follow these specific conditions that have been determined to permit the examination to be conducted safely. Any deviation may result in a serious injury to the patient.

Non-clinical testing demonstrated that these Foley catheters with temperature sensors are MR Conditional. A patient with one of these devices can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less with regard to magnetic field interactions.
- Spatial gradient magnetic field of 720-Gauss/cm or less with regard to magnetic field interactions.
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3.5-W/kg at 1.5- or 3-W/kg at 3-Tesla for 15 minutes of scanning.

Special Instructions: The position of the wire of the Foley Catheter with Temperature Sensor has an important effect on the amount of heating that may develop during an MRI procedure. Accordingly, the Foley catheter with temperature sensor must be positioned in a straight configuration down the center of the patient table (i.e., down the center of the MR system without any loop) to prevent possible excessive heating associated with an MRI procedure.



Importantly, the MRI procedure should be performed using an MR system operating at a static magnetic field strength of 1.5-Tesla or 3-Tesla, ONLY. the safe use of an MR system operating at lower or higher field strength for a patient with a Foley catheter with temperature sensor has not been determined.

Additional safety instructions include the following:

1. The Foley catheter with temperature sensor should not be connected to the temperature monitoring equipment during the MRI procedure.
2. If the Foley catheter with temperature sensor has a removable catheter connector cable, it should be disconnected prior to the MRI procedure.
3. Remove all electrically conductive material from the bore of the MR system that is not required for the procedure (i.e., unused surface coils, cables, etc.).
4. Keep electrically conductive material that must remain in the bore of the MR system from directly contacting the patient by placing thermal and/or electrical insulation (including air) between the conductive material and the patient.
5. Position the Foley catheter with a temperature sensor in a straight configuration down the center of the patient table to prevent cross points and conductive coils or loops.
6. The wire and connector of the Foley catheter with temperature sensor should not be in contact with the patient during the MRI procedure. Position the device, accordingly.
7. MR Imaging should be performed using an MR system with static magnetic strength of 1.5-Tesla or 3-Tesla, ONLY.
8. At 1.5-Tesla, the MR system whole body averaged SAR should not exceed 3.5- W/kg for 15-min. of scanning.
9. At 3-Tesla, the MR system reported whole body averaged SAR should not exceed 3-W/kg for 15-min of scanning.

BARD

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