

To Whom It May Concern:

DeRoyal Foley Catheters with Temperature Sensors have been tested for safe use in magnetic resonance environments at 1.5 and 3.0 Tesla according to ASTM International F2052, “Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.”

The testing at 1.5 Tesla and 3.0 Tesla was completed in 2014 and 2010 respectively. The results demonstrate that the catheters are “MR Conditional,” according to ASTM International F2503, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.” This designation means the device has demonstrated safety in an MR environment with defined conditions. These conditions are defined in the attached pages.

Please consult the Instructions for Use and the attached guidelines prior to using the device.



Additional instructions for use in MR environments based on testing performed in 2004 according to ASTM F2052-02, Standard Test Method for Measurement of Magnetically Induced Displacement force on Passive Implants in the Magnetic Resonance Environment

MR system: 1.5 Tesla



Important Note: To safely perform magnetic resonance imaging (MRI) in a patient, it is important to closely follow highly specific conditions and guidelines that have been determined to permit the examination to be conducted safely. Any deviation from these conditions and guidelines may result in a serious injury to the patient or damage to this device.

Important Note: *Magnetic Resonance Imaging (MRI) safety testing conducted on the Foley Catheters with Temperature Sensors was based on the fact that these devices are not intended for use to monitor temperature during MRI or in the MRI environment. Furthermore, these devices should not be connected to a cable or otherwise attached to a temperature recording device in the MRI environment. Failure to follow these instructions may result in serious injury to the patient or damage to the device.*

Magnetic resonance imaging (MRI) procedures must be performed according to the following conditions and guidelines:

Static Magnetic Field

Testing of magnetic field interactions (translational attraction and torque) in association with a shielded 1.5-Tesla MR system demonstrated that this device does not exhibit substantial translational attraction (maximum spatial gradient for the 1.5-Tesla MR system used to assess translational attraction, 2.4 Tesla/meter) or torque. (The evaluation of translational attraction was conducted according to ASTM F-2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment.) Therefore, in consideration of the intended *in vivo* use of this device, there is no additional risk to a patient with this device with respect to movement or dislodgment using a 1.5-Tesla MR system.

Accordingly, a patient with this device may safely undergo an MRI procedure using an MR system operating at a static magnetic field of 1.5-Tesla or lower, with special attention to closely following additional conditions and guidelines (see below).

Gradient Magnetic Fields

An MRI procedure conducted on a patient with this device may use conventional pulse sequences including spin echo, fast spin echo, gradient echo, and fast gradient echo pulse sequences at 1.5-Tesla or lower. Unconventional or non-standard MRI techniques have not been assessed for this device and, therefore, must be avoided.

In general, pulse sequences such as echo planar, magnetization transfer contrast, and other techniques or procedures that exceed gradient magnetic fields of 20-Tesla/sec. must not be used for an MRI procedure in a patient with this device.

Radiofrequency (RF) Fields: MRI-related heating was assessed for this device according to F 2182-02 Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging. Based on this information, MRI

procedures must not exceed exposures to radiofrequency (RF) fields greater than a whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20- minutes in a patient with this device.



Important Note: MRI-related heating was tested for *only* one configuration of the Foley Catheter with Temperature Sensor: straight configuration without coils or loops for the catheter and the temperature connector component. The Foley catheter and temperature connector component were directed down the center of the MR system bore, without touching an RF coil or other similar device.

Therefore, to ensure patient safety and to prevent excessive heating during an MRI procedure, this device should be placed in a straight configuration, directed down the center of the MR system, without touching an RF coil or other similar device. MRI- related heating for other configurations or positions of this device are unknown.

MRI Settings and Device Positioning

- Disconnect the device from cable or other temperature recording device before entering the MRI environment.
- Direct the device in a straight configuration down the center of the MR system, without touching an RF coil or similar device.
- Do not use MR systems operating at static magnetic field strengths higher than
 - 1.5-Tesla.
- Select MRI parameters so that they do not exceed a whole body averaged specific absorption rate (SAR) of 1.5 W/kg to minimize the risk of heating.
- Instruct the patient to immediately alert the MR system operator of any problems (heating, shocks, etc.) so the operator can immediately terminate the MRI procedure, if needed.
- Provide the patient with a means to alert the MR system operator of problems (e.g., heating, shocks, etc) so the operator can immediately terminate the MRI procedure, as needed.
- Monitor the patient continuously during the MRI examination and be prepared to respond in the event of an emergency.

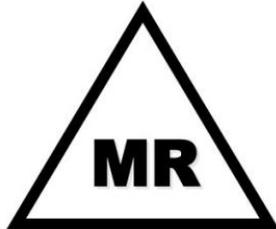
Definitions:

“**MR-safe**” defined by ASTM F2052-02: The device, when used in the MR-environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. Importantly, the specific conditions used for assessment of MR safety must be specified”.

Additional instructions for use in MR environments based on testing performed in 2010 according to ASTM F2052-06e1, Standard Test Method for Measurement of Magnetically Induced Displacement force on Passive Implants in the Magnetic Resonance Environment

MR system: 3-Tesla

MRI Information



MR Conditional

The **DeRoyal Foley Catheter with Temperature Sensor** was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Non-clinical testing demonstrated that the DeRoyal Foley Catheter with Temperature Sensor is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the DeRoyal Foley Catheter With Temperature Sensor produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: *Highest temperature change* +4.2°C

Therefore, the MRI-related heating experiments for the DeRoyal Foley Catheter with Temperature Sensor, 18-Fr at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +4.2°C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the DeRoyal Foley Catheter With Temperature Sensor, 18-Fr, REF 81-080718. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,956-mm ²	159-mm ²	3,262-mm ²	763-mm ²
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Important Note: This labeling information pertains to MRI conditions at 3-Tesla ONLY (no other MR system field strength/frequency, higher or lower).

Additional MRI Information:

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

Special Instructions: The position of the wire and connector of the DeRoyal Foley Catheter with Temperature Sensor has an important effect on the amount of heating that may develop during an MRI procedure. *Accordingly, the DeRoyal 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. The wire and connector must not touch the patient.*

Additional instructions include the following:

- (1) The DeRoyal Foley Catheter with Temperature Sensor should not be connected to the temperature monitoring equipment during the MRI procedure.
- (2) If the DeRoyal 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 DeRoyal 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 3-Tesla, ONLY.
- (8) At 3-Tesla, the MR system reported whole body averaged SAR should not exceed 2.9-W/kg for 15-min of scanning (per pulse sequence).