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Arrow® You-Bend™ Hemodialysis Catheter MRI Advisory

MRI Information:

Non-clinical testing has demonstrated that Arrow® You-Bend™ Hemodialysis catheters are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- static magnetic field of 1.5 Tesla (1.5T) or 3.0 Tesla (3.0T)
- spatial gradient field of 720 Gauss/cm or less
- Normal Operating Mode – Maximum whole-body Specific Absorption Rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

3.0T Radio Frequency (RF) Heating:

In non-clinical testing with body coil excitation, Arrow You-Bend Hemodialysis catheters produced a maximal differential temperature rise of 0.1ºC when exposed to a maximum SAR of 3.4 W/kg for 15 minutes of MR scanning in a 3.0 Tesla MR system (Siemens Trio, SYNGO MR A30 4VA30A software, Munich, Germany). Scaling of the SAR and observed heating indicates that a SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0ºC.

1.5T Radio Frequency (RF) Heating:

In non-clinical testing with body coil excitation, Arrow You-Bend Hemodialysis catheters produced a maximal differential temperature rise of 0.5ºC when exposed to a maximum SAR of 1.4 W/kg for 15 minutes of MR scanning in a 1.5 Tesla MR system (Siemens Espree, SYNGO MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that a SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0ºC.

⚠ **Caution: RF heating behavior does not scale with static field strength. Devices which do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength. Heating results for any static field strengths not tested are unknown.**

MR Artifacts:

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact followed the approximate contour of the device and extended radially up to 1.1 cm from the implant in tests performed in accordance with ASTM F2119-07.

Other:

Magnetically induced displacement force and torque testing indicated that the implants posed no known risks in the MRI environment.

It is recommended that, while scanning, the bendable extension lines be positioned away from the catheter body and from each other in order to reduce the potential for artifact effects or radio frequency interactions.

Refer to enclosed product Instructions for Use (IFU) for specific indications, procedural technique(s) and potential complications associated with CVC insertion procedures.

Rx only.

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Teleflex®

MR Conditional