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TECHNICAL BULLETIN

From: The VS/Access Port Systems Strategic Marketing *To: All affiliates*

B. Braun Access Port Systems

Issue: Are the B. BRAUN PICC-Cel catheters MRI compatible?

Following our recent Technical Bulletin (TB.AP Nr. 2-2010) concerning changes in the way that MRI compatibility is reported on medical products and the availability of more recent tests into the MRI compatibility of the Celsite® access ports we have pleasure in sending you the Technical Bulletin for the Celsite® PICC-Cel catheters.

The following text will appear in the IFU's, which will be available in 26 languages. The results below apply to the Ultrasite® needle free valve as there is no metal contained in the catheter.

The labelling of the Celsite® PICC-Cel boxes will include the MR Conditional logo. 

We would like to explain again what is MRI and the classifications used to indicate if devices can be used safely inside the MRI scanner.

Therefore we can conclude that the Celsite® PICC-Cel catheters are "compatible" with MRI.

What is an MRI scan*?

Magnetic Resonance Imaging is primarily a medical imaging technique most commonly used in radiology to visualize the internal structure and function of the body. MRI provides much greater contrast between the different soft tissues of the body than computed tomography (CT) does, making it especially useful in neurological (brain), musculoskeletal, cardiovascular, and oncological (cancer) imaging. Unlike CT, it uses no ionizing radiation, but uses a powerful magnetic field to align the nuclear magnetization of (usually) hydrogen atoms in water in the body. Radio frequency (RF) fields are used to systematically alter the alignment of this magnetization, causing the hydrogen nuclei to produce a rotating magnetic field detectable by the scanner.

*For more details refer to Annex 1.

What are the classifications?

The classifications are:

- MR Safe refers to an item that poses no known hazards, such as displacement, rotation, heating or artifacts, in all MR environments, e.g. glass, wood, plastic,
- MR Conditional refers to an items e.g. access ports, needles, filters, stents, that have been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use,
- MR Unsafe refers to an item that is known to pose hazards in all MR environments, eg ferro-magnetic instruments, pacemakers.

What tests were performed?

The below tests were performed using an MRI scanner of 3T.

When determining which category a device falls into several different tests are performed according to ASTM International (American Society for Testing and Materials) standards. These tests are for:
1.1 ASTM F2052-06 "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"-** test for magnetically induced displacement of the device.
1.2 ASTM F2213-06 "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"-** test for magnetically induced torque.
1.3 ASTM F2182-09 "Standard Test Method Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"-** test for radio-frequency induced heating (passive implants only)**.**
1.4 ASTM F2119-07 "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"-** test for evaluation of artifacts (passive implants only), evaluated as a % of the device dimensions.

**See Annex 2 for more detailed information

MR Information

General Information

According to IEC Standard 60601-2-33(2008), the scanner must be operated in Normal Operating Mode (defined as the mode of operation of the MR system in which none of the outputs have a value that causes physiological stress to the patient):

- The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg
- The head SAR must be < 3.2 W/kg

Device Information

MR Conditional

The ULTRASITE valve 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 ULTRASITE valve is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla and 1.5-Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.9W/kg for 15 minutes of scanning

MRI-Related Heating

In non-clinical testing, the ULTRASITE valve produced the maximum temperature rise during MRI performed for 15-min (i.e., per pulse sequence) in 3-Tesla (Excite HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems, as:

MRI Condition	MR System Reported, Maximum Whole Body Averaged SAR (W/kg)	Calorimetry Value (W/kg)	Highest Temperature Change	Time for MRI (per pulse sequence)
3-T / 128-MHz	2.9	2.7	1.6 °C	15 min

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 ULTRASITE valve. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Annex 1

Basic principles of MRI

Magnetic resonance imaging is primarily a medical imaging technique most commonly used in radiology to visualise the internal structure and function of the body. MRI provides much greater contrast between the different soft tissues of the body than computed tomography (CT) does, making it especially useful in neurological (brain), musculoskeletal, cardiovascular, and oncological (cancer) imaging. Unlike CT, it uses no ionising radiation, but uses a powerful magnetic field to align the nuclear magnetisation of (usually) hydrogen atoms in water in the body. Radio frequency (RF) fields are used to systematically alter the alignment of this magnetisation, causing the hydrogen nuclei to produce a rotating magnetic field detectable by the scanner. This signal can be manipulated by additional magnetic fields to build up enough information to construct an image of the body.

The body is mainly composed of water molecules which each contain two hydrogen nuclei or protons. When a person goes inside the powerful magnetic field of the scanner these protons align with the direction of the field.

A second radio frequency electromagnetic field is then briefly turned on causing the protons to absorb some of its energy. When this field is turned off the protons release this energy at a radio frequency which can be detected by the scanner. The position of protons in the body can be determined by applying additional magnetic fields during the scan which allows an image of the body to be built up. These are created by turning gradients coils on and off which creates the knocking sounds heard during an MR scan.

Diseased tissue, such as tumors, can be detected because the protons in different tissues return to their equilibrium state at different rates. By changing the parameters on the scanner this effect is used to create contrast between different types of body tissue.

Contrast agents may also be injected intravenously to enhance the appearance of blood vessels, tumors or inflammation. Contrast agents may also be directly injected into a joint in the case of arthrograms, MR images of joints. Unlike CT, scanning MRI uses no ionising radiation and is generally a very safe procedure. However some metal implants and devices cannot be used. Patients with some metal implants, cochlear implants, and cardiac pacemakers are prevented from having an MRI scan due to effects of the strong magnetic field and powerful radio frequency pulses.

MRI is used to image every part of the body, and is particularly useful for neurological conditions, for disorders of the muscles and joints, for evaluating tumours, and for showing abnormalities in the heart and blood vessels.

Annex 2

ASTM Standards

The new ASTM standards consists of four separate tests

1.1 ASTM F2052-06 "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"

A medical device is suspended by a string at the point in a magnetic field that will produce the greatest magnetically induced deflection. The angular deflection of the string from the vertical is measured. If the device deflects less than 45°, then the magnetically induced deflection force is less than the force on the device due to gravity (its weight) and thus considered an acceptable result.

1.2 ASTM F2213-06 "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"

A medical device is placed on a holder suspended by a torsional spring. The apparatus is placed in the center of the magnetic reasonance equipment where the magnetic field is uniform. The torque is determined from the measurement of the deflection angle of the holder from its equilibrium position. The frame holding the spring and holder assembly is rotated and the torque as a function of the angle of the implant is determined. The maximal magnetic torque is compared to the worst case gravity torque, defined as the product of the maximum linear dimension of the device and the device weight and thus considered an acceptable result.

1.3 ASTM F2182-09 "Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging"

The implant to be tested is placed in a phantom material that simulates the electrical and thermal properties of the human body. Fiber optic temperature probes are placed at locations where the induced heating is expected to be greatest. The phantom is placed in an MR system with a cylindrical bore. An RF field with SAR of at least 1W/kg averaged over the volume of the phantom is applied . The temperature rise at the sensors is measured during the approximately 15 min of RF application. Temperature measurements at one or more locations away from the device serve as the control. The temperature rise is considered acceptable if it is less than what is deemed clinically significant.

1.4 ASTM F2119-07 "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"

Pairs of spin echo images are generated both with and without the implant in the field of view. Image artifacts are assessed by computing difference outside the region corresponding to the implant between reference and implant images. Once the worst case conditions using the spin echo

pulse sequence are ascertained, a pair of gradient echo images are acquired under the same conditions. The acceptable degree of artifact is once again defined as being less than clinically significant. In the testing we have provided the maximum zone around the device in which there is an image artifact.