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Neo-Fit MRI Compatibility Testing

1. Overview:

Marketing Department that Magnetic Resonance Imaging MRI compatibility is a market requirement for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder. Engineering hired an outside consultancy firm, Shellock R & D Services, Inc., of Los Angeles, CA to analyze the market requirements and perform the appropriate industry-standard tests that will allow for MRI-Conditional labeling of this instrument.

2. Scope:

The consultant informed Engineering that in the case that a device contains any metallic components at all, the appropriate testing and labeling term for that device would be that it can be labeled as "MR Conditional". "MR Conditional" labeling means that a device has been tested and has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. The magnetic field conditions that define the MRI environment as stated by Marketing in Special Project # 1572 on February 11, 2011 are MR conditional in 3.0 Tesla magnetic inductivity MRI machine.

3. References:

3.1. American Society for Testing and Materials (ASTM) International, Designation: F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

3.2. American Society for Testing and Materials (ASTM) Designation: F 2052-06e1, Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment.

3.3. American Society for Testing and Materials (ASTM) International, F2213-06, Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment.

3.4. American Society for Testing and Materials International, Designation F2182–09, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.

3.5. American Society for Testing and Materials (ASTM) International Designation: F2119-07, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

4. Equipment:

MR system: 3-Tesla, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field scanner

5. Results:

5.1. Magnetic Field Interactions: The findings for translational attraction for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder was 34-degrees. The Neo-Fit Neonatal Endotracheal Tube Grip/Holder that underwent testing passed the ASTM acceptance criteria for deflection angle with respect to exposure to the 3-Tesla MR system used in this evaluation. The Neo-Fit Neonatal Endotracheal Tube Grip/Holder will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment with regard to translational attraction or migration. The qualitatively measured torque at 3-Tesla for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder was 0, no torque. As such, this device will not

present an additional risk or hazard to a patient in the 3-Tesla MRI environment or less with regard to torque.

5.2. MRI-Related Heating: The highest temperature change measured for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder was 1.7°C. The local SAR at the reference probe position with the implant present was 3.2-W/kg. Therefore, the MRI-related heating experiment for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder at 3-Tesla using a transmit/receive RF body coil at an MR system reported, whole body averaged SAR of 2.9-W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to 1.7°C. This change in temperature is not considered to be physiologically consequential for a human subject.

5.3. Artifact Test: For the Neo-Fit Neonatal Endotracheal Tube Grip/Holder, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were "moderate" (based on a scale of small, moderate, and large) in size in relation to the size and shape of this device. The gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence for this device. Overall, the artifacts for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder may present problems if the MR imaging area of interest is in or near the area where this device is located.

6. Results Summary:

6.1. The Neo-Fit Neonatal Endotracheal Tube Grip/Holder was determined to be MR-conditional.

6.2. Labeling based on these test results incorporating the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503 that may be permanently marked to indicate the MR environment to which a specific item may safely be exposed, and recommend information that should be included in the marking is shown on page 19 of the report (attached). According to the standard, it is recognized that direct marking on the item is not practical for implants and certain other medical devices. Where direct marking is not practical, this practice recommends that the marking be included in the labeling and on patient information cards.

7. Approvals:

7.1. Dir. Of Engineering: [signature] 3/4/11

7.2. Vice Pres., BA/RA: [signature] 04/14/2011

7.3. Engineer: Matthew Carlson 03/18/11

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MRI LABELING BASED ON THE TEST RESULTS (Note: use verbatim)

MRI Information

MR Conditional

The **Neo-Fit Neonatal Endotracheal Tube Grip/Holder** was determined to be MR-conditional.

Non-clinical testing demonstrated that the Neo-Fit Neonatal Endotracheal Tube Grip/Holder 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 Neo-Fit Neonatal Endotracheal Tube Grip/Holder 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 +1.7°C

Therefore, the MRI-related heating experiments for the Neo-Fit Neonatal Endotracheal Tube Grip/Holder 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 +1.7°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 Neo-Fit Neonatal Endotracheal Tube Grip/Holder. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 20-mm relative to the size and shape of the Neo-Fit Neonatal Endotracheal Tube Grip/Holder.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,980-mm^2	1,453-mm^2	4,381-mm^2	3,678-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Disclaimer

The recommended labeling information is provided as an example of proper labeling for this product based on the latest information from the Food and Drug Administration and 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. The issued labeling may be modified by the manufacturer, as needed. The manufacturer of this product is ultimately responsible and liable for damages involved in the use of the MRI-related labeling. The author or Shellock R & D Services, Inc. shall not be held liable for the product labeling or damages related to the use of this labeling.