SHELLOCK
R & D SERVICES, INC.

7551 Veragua Drive
Playa Del Rey, CA 90293
(310) 291-6890 Telephone
http://www.MagneticResonanceSafetyTesting.com

REPORT

Magnetic Field Interaction Testing Performed at 3-Tesla on Product (VK462 with UNS-S43000 Pins) from The Viking Corporation

Project Conducted by:
Frank G. Shellock, Ph.D.

05/03/16

Presented to:
Jason Watson
Project Engineer
The Viking Corporation
210 N. Industrial Park Drive
Hastings, MI 49058

This report pertains to magnetic field interaction testing conducted at 3-Tesla on the following product from The Viking Corporation:

Product - VK462 with UNS-S43000 Pins

IMPORTANT NOTE: This product is intended for use inside of the MRI environment (e.g., in the MRI system room). However, it will not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner) during its actual operation (i.e., scanning). As such, the assessment of magnetic field interactions for this product specifically involved an evaluation of translational attraction according to its intended use (i.e., mounted in the ceiling of the MRI system room) in relation to exposure to a 3-Tesla MR system, *only.* Evaluations of MRI-related heating and artifacts were not conducted and are considered unnecessary.

Important Note: Functional testing was not conducted on this device to ensure that it operates properly in the 3-Tesla MRI environment.

MR system: 3-Tesla, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field scanner

© 2016, SHELLOCK R & D SERVICES, INC.

Test site: University of Southern California Hospital, Los Angeles, CA

MAGNETIC FIELD RELATED, TRANSLATIONAL ATTRACTION

For the assessment of translational attraction, a test was conducted known as the "deflection angle test", which is described in the following publications:

(1) American Society for Testing and Materials (ASTM) International Designation: F2052-15 Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment.
(2) Shellock FG, Morisoli SM. Ex vivo evaluation of ferromagnetism, heating, and artifacts for heart valve prostheses exposed to a 1.5 Tesla MR system. Journal of Magnetic Resonance Imaging. 4:756-758, 1994.
(3) Shellock FG, Detrick MS, Brant-Zawadski M. MR-compatibility of Guglielmi detachable coils. Radiology. 203: 568-570, 1997
(4) Edwards, M-B, Taylor KM, Shellock FG. Prosthetic heart valves: evaluation of magnetic field interactions, heating, and artifacts at 1.5 Tesla. Journal of Magnetic Resonance Imaging. 12:363-369, 2000.
(5) Shellock FG, Shellock VJ. Stents: Evaluation of MRI safety. American Journal of Roentgenology 173:543-546, 1999.
(6) Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. Journal of Magnetic Resonance Imaging, 13:152-157, 2001.
(7) Shellock FG. Biomedical implants and devices: assessment of magnetic field interactions with a 3.0-Tesla MR system. Journal of Magnetic Resonance Imaging. 16:721-732, 2002.
(8) Shellock FG, Gounis M, Wakhloo A. Detachable coil for cerebral aneurysms: *In vitro* evaluation of magnet field interactions, heating, and artifacts at 3-Tesla. American Journal of Neuroradiology 2005;26:363-366.

The American Society for Testing and Materials (ASTM) International Designation: F2052 Standard method for measurement of magnetically induced displacement force on passive implants or related items in the MRI environment was carefully followed for this test.

The product was attached to a special test fixture to measure the deflection angle in the MR system. The test fixture consisted of a sturdy structure capable of holding the device in position without movement and contained a protractor with 1˚-graduated markings, rigidly mounted to the structure. The 0˚ indicator on the protractor was oriented vertically. The test fixture had a plastic bubble level attached to the top to ensure proper orientation in the MR system. Sources of forced air movement within the MR system bore were turned off during the measurements.

The device was suspended from a thin, lightweight string (weight, less than 1% of the weight of the device) that was attached at the 0˚ indicator position on the protractor. The length of the string was long enough so that the device could be suspended from the test fixture and hang freely in space. Motion of the string with the device was not constrained by the support structure of the protractor.

Measurements of deflection angles for the VK462 with UNS-S43000 Pins were obtained at the position in the 3-Tesla MR system according to its intended use, considering a possible worst-case scenario. That is, the defection angle test apparatus was positioned one foot from the opening of the bore of the MRI system. The direction of the magnetic field for the 3-Tesla scanner is horizontal.

The test fixture was positioned to record the highest deflection angle for the VK462 with UNS-S43000 Pins one foot from the opening of the bore of the MRI system, as stated above. The device was held on the test fixture so that the string was vertical and then released. The deflection angle for the VK462 with UNS-S43000 Pins from the vertical direction to the nearest 1-degree was measured three times and a mean value was calculated.

RESULTS AND DISCUSSION

The findings for translational attraction for the VK462 with UNS-S43000 was 24-degrees. This information should be considered in view of the deflection angle measurement recommendation provided by the ASTM, which states:

"If the implant deflects less than 45˚, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field."

Therefore, the VK462 with UNS-S43000 that underwent testing *passed* the ASTM acceptance criteria for deflection angle with respect to exposure, according to its intended use, in association with a 3-Tesla MR system. The VK462 with UNS-S43000 will not present an additional risk or hazard in the 3-Tesla MRI environment with regard to translational attraction, movement, or migration.

IMPORTANT NOTE: Given the positive findings for translational attraction for the VK462 with UNS-S43000 tested at 3-Tesla, it is not “NONMAGNETIC” nor should it be labeled “NONMAGNETIC”.

© 2016, SHELLOCK R & D SERVICES, INC.

IMPORTANT NOTE: This report is submitted to your company with the intention that it will ONLY be used as an internal document and/or for submission to the United States Food and Drug Administration or other similar regulatory agency or appropriate entity. The use of this report for any other reason is strictly prohibited. Thus, it is prohibited to reproduce, quote, distribute or otherwise exploit this information for any matter other than its intended use. Furthermore, the use of the company name, Shellock R & D Services, Inc., and/or the name of the author of this report, Frank G. Shellock, Ph.D., is prohibited without written permission. Your acceptance of this report signifies that you have read and understand the above.

DISCLAIMER

The information in this report is provided without warranty of any kind, either expressed or implied including without the limitation of implied warranties of merchantability and fitness for a particular purpose. The author of this report, Magnetic Resonance Safety Testing Services, and Shellock R & D Services, Inc. shall not be held liable for any direct, indirect, consequential, special or other damages suffered by the manufacturer of the device or product or by other parties, as a result of the use of the report results, data, or other deliverables. The author of this work disclaim any liability for the acts of any physician, individual, group, or entity acting independently or on behalf of any organization utilizing this information for any medical procedure, activity, service, or other situation.

© 2016, SHELLOCK R & D SERVICES, INC.

FIGURE 1. The VK462 with UNS-S43000 that underwent testing for translational attraction.

© 2016, SHELLOCK R & D SERVICES, INC.

FIGURE 2. The 3-Tesla MR system (General Electric Healthcare, Milwaukee, WI) used for assessment of translational attraction for the VK462 with UNS-S43000.

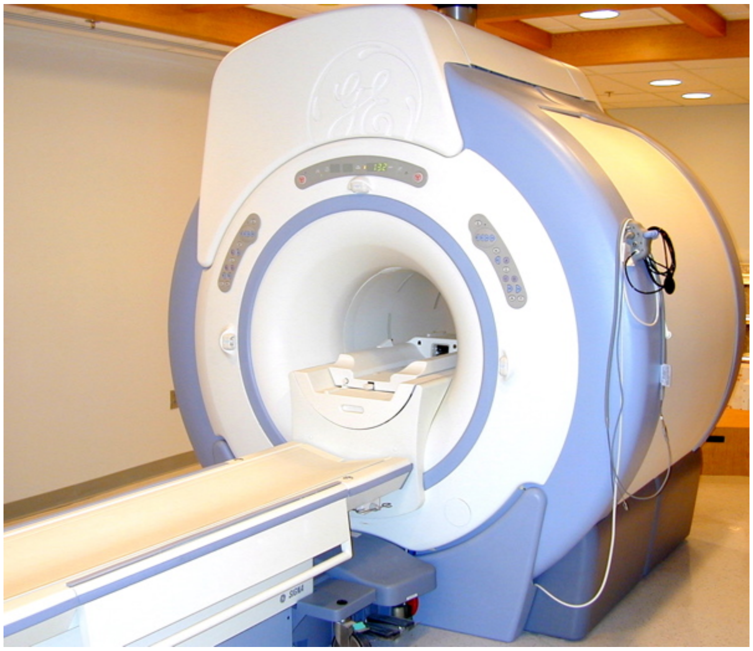
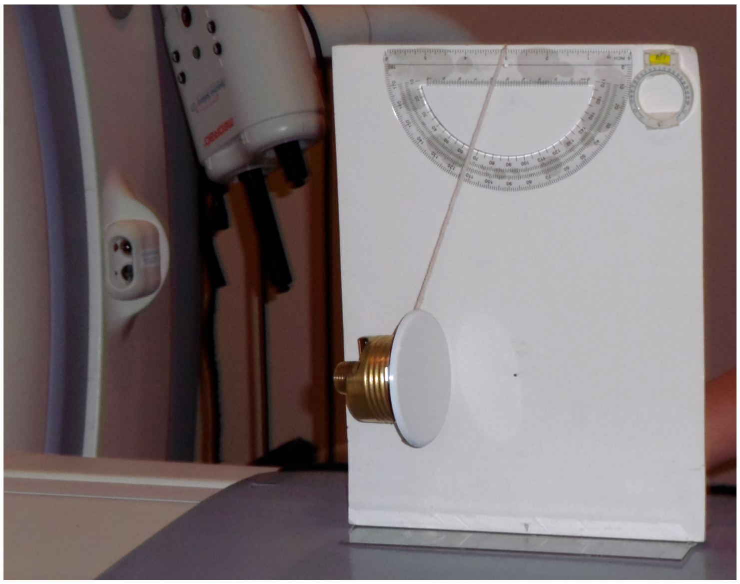


FIGURE 3. Testing the VK462 with UNS-S43000 Pins for translational attraction during exposure to the 3-Tesla MR system. The measurement apparatus was positioned one foot from the opening of the bore of the MRI system to represent a worst-case scenario for the intended use of this product. Note the deflection angles of 24-degrees. This is an acceptable value for this particular product.



© 2016, SHELLOCK R & D SERVICES, INC.