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REPORT
Evaluation of Magnetic Field Interactions at 3-Tesla for Teleflex Medical Products

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EXECUTIVE SUMMARY

Based on the MRI testing information, the following products will not present an additional hazard or risk to a patient relative to the use of an MR system operating with a static magnetic field of 3-Tesla or less:

Rusch Larygoscope handle

Rusch Macintosh size 4 fiber-optic laryngoscope blade

Therefore, these products are considered "MR-conditional" according to the specific conditions used for this assessment (see attached recommended labeling and the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, West Conshohocken, Pennsylvania, 2005).

Important Note: These devices are not intended for use during the operation of an MR system for an MR imaging procedure.

For medical implants and devices, the objectives of magnetic resonance imaging (MRI) testing are to determine the presence of magnetic field interactions, heating, and artifacts in association with the use of an MR system. Because these products are not intended for use during MR imaging, it is only necessary to assess them for magnetic field interactions. Accordingly, evaluations of magnetic field interactions (deflection angle and torque) were conducted at 3-Tesla on the following:

Name of each device:
Rusch Larygoscope handle

Rusch Macintosh size 4 fiber-optic laryngoscope blade (marked 070906)

Materials for each device:
Rusch Larygoscope handle: Brass head, Aluminum barrel, carbon-zinc battery, contact and springs are stainless steel.

Rusch Macintosh size 4 fiber-optic laryngoscope blade: Heat treated stainless steel, gold plated fiber-optic bundle.

Intended use: These devices are intended to allow for the direct viewing of the laryngeal structures and are used during tracheal intubation.

Important Note: These devices are not intended for use during the operation of an MR system for an MR imaging procedure.

The samples of the products that underwent testing were representative of the manufactured finished versions and not altered prior to or after testing.

MAGNETIC FIELD INTERACTIONS
Testing for magnetic field interactions involved evaluations of translational attraction and torque at 3-Tesla MR system, for the following:

Rusch Larygoscope handle with battery

Rusch Macintosh size 4 fiber-optic laryngoscope blade

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) Designation: F 2052-02 Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment. In: Annual Book of ASTM Standards, Section 13, Medical Devices and Services, Volume 13.01 Medical Devices; Emergency Medical Services. West Conshohocken, PA, pp; 1576-1580.

(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: F2052-02 Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment was carefully followed for this test.

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

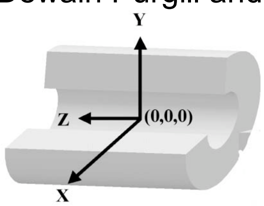
Test site: University of Southern California Hospital, Los Angeles, CA

Each device 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 each 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 also had a plastic bubble level device attached to the top to ensure proper orientation in the MR system during the test procedure. Sources of forced air movement within the MR system bore were turned off during the measurements.

Each 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 20-cm, which was long enough so that each 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 each device were obtained at the position in the 3-Tesla MR system that produced the greatest magnetically induced deflection. This point was determined for the MR system using gauss line plots, measurements, and visual inspection to identify the location where the spatial magnetic field gradient was the greatest. The location was marked by tape to facilitate measurements of the deflection angles for each device.

The direction of the magnetic field for the 3-Tesla scanner is horizontal. The highest spatial gradient for the 3-Tesla MR system (Excite, General Electric Healthcare, Milwaukee, WI) occurs at a position that is 74-cm from isocenter of the scanner. The magnetic spatial gradient at this position is 720 gauss/cm (Personal Communication, Dewain Purgill and Daniel J. Schaefer, General Electric Healthcare, Milwaukee, WI).



The coordinate system shown above references the MR system used for the tests in this report. The locations indicated in this report are referenced to this diagram. Note the orientations of the MR system with respect to the direction of the coordinates, X, Y, and Z. The X=0, Y=0, and Z=0 positions, or "isocenter" is at the center of the MR system's magnet. At this location, the magnetic field is homogeneous and the static spatial magnetic gradients are effectively zero (0).

The test fixture was positioned to record the highest deflection angle for each device. The device was held on the test fixture so that the string was vertical and then released. The deflection angle for each device from the vertical direction to the nearest 1-degree was measured three times and a mean value was calculated.

Qualitative Assessment of Torque

The next evaluation of magnetic field interaction was conducted to qualitatively determine the presence of magnetic field-induced torque for each device. This procedure involved the use of a flat plastic material with a grid on the bottom.

Each device was placed on the test apparatus in an orientation that was 45-degrees relative to the static magnetic field of the 3-Tesla MR system. The use of 45-degree increments is deemed adequate and appropriate for a qualitative assessment of torque for an implant or device, based on reports published in the peer-reviewed literature (see reference list below).

The test apparatus with the device was then positioned in the center of the MR system, where the effect of torque from the static magnetic field was determined to be the greatest (i.e., based on a previous magnetic field survey and the well-known characteristics for the 3-Tesla MR system with a horizontal magnetic field used for this evaluation).

Each device was directly observed for possible movement with respect to alignment or rotation relative to the static magnetic field of the 3-Tesla MR system. Having the investigator inside the bore of the MR system during the test procedure facilitated the observation process. The device was then moved 45 degrees relative to its previous position and again observed for alignment or rotation. This process was repeated to encompass a full 360 degrees rotation of positions for each device in the 3-Tesla MR system. The entire procedure was conducted three times and a mean value was calculated for each device with it orientated along its long axis and short axis.

The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild or low torque, the device slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the device aligned gradually to the magnetic field; +3, strong torque, the device showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the device showed very rapid and very forceful alignment to the magnetic field.

Peer-reviewed, scientific publications that support performance of the test to qualitatively assess magnetic-field related torque for a metallic implant or device in association with an MR system are, as follows:

(1) Shellock FG, Detrick MS, Brant-Zawadzki MN. MR compatibility of Guglielmi detachable coils. Radiology 203:568-570, 1997.
(2) Shellock FG, Shellock VJ. MR-compatibility evaluation of the Spetzler titanium aneurysm clip. Radiology. 206:838-841, 1998.
(3) Shellock FG, Shellock VJ. Evaluation of cranial flap fixation clamps for compatibility with MR imaging. Radiology. 207:822-825, 1998.
(4) Shellock FG, Kanal E. Yasargil aneurysm clips: evaluation of interactions with a 1.5 Tesla MR system. Radiology. 207:587-591, 1998.
(5) Kanal E, Shellock FG. Aneurysm clips: effects of long-term and multiple exposures to a 1.5 Tesla MR system. Radiology. 210:563-565, 1999.
(6) Shellock FG, Shellock VJ. Stents: Evaluation of MRI safety. American Journal of Roentgenology. 173:543-547, 1999.
(7) 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.
(8) Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. Journal of Magnetic Resonance Imaging, 13:152-157, 2001.
(9) 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.
(10) 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.

Important Note: According to the American Society for Testing and Materials (ASTM) International, F2213-04, Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment,

> "X1.2 There are other possible methods for evaluation of the magnetic torque on an implant in the magnetic resonance environment."

Therefore, the above-indicated procedure is considered to be one such method that is acceptable for the evaluation of torque for a metallic implant or device. Notably, there is substantial support in the peer-reviewed literature for the qualitative torque measurement method utilized in this report (see reference list indicated above).

RESULTS AND DISCUSSION

Tables 1 summarizes the results of the tests performed to determine magnetic field interactions for the products that underwent testing. The mean deflection angle (i.e., the maximum deflection angle level) measured for the Rusch Larygoscope handle with battery was 14-degrees. The mean deflection angle (i.e., the maximum deflection angle level) measured for the Rusch Macintosh size 4 fiber-optic laryngoscope blade was 32-degrees.

The findings for translational attraction for devices that underwent testing 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, all devices 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. These devices will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment with regard to translational attraction.

The qualitatively measured torque at 3-Tesla for the Rusch Larygoscope handle with battery was 0 (zero) and +1 for the Rusch Macintosh size 4 fiber-optic laryngoscope blade. As such, these devices will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment or less with regard to torque. Notably, torque was assessed in the center of the MR system and these devices would not be used at this position during the actual intended use.

Importantly, because of the relative minor translational attraction (14 and 32-degrees, respectively) and lack of torque or low torque (qualitatively determined) at 3-Tesla, it is deemed unnecessary to conduct a quantitative evaluation of torque for these devices.

In summary, the test findings for these devices indicated that relatively minor magnetic field interactions exist in association with exposure to a 3-Tesla MR system.

RECOMMENDED MRI LABELING

MRI Information. The following devices were determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005:

Rusch Larygoscope handle with battery (brass head, Aluminum barrel, carbon-zinc battery, contact and springs are stainless steel)

Rusch Macintosh size 4 fiber-optic laryngoscope blade

Non-clinical testing demonstrated that these devices are MR Conditional according to the following conditions:

-Static magnetic field of 3-Tesla or less

-Highest spatial gradient field of 720-Gauss/cm or less

Important Note: These devices are not intended for use during the operation of an MR system for an MR imaging procedure.

IMPORTANT NOTE: If you plan to submit this information to the United States Food and Drug Administration or other regulatory agency to obtain a labeling claim relative to this MRI testing information, please provide me with the content to review to ensure proper presentation of the labeling information.

DISCLAIMER

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Table 1. Evaluation of magnetic field interactions at 3-Tesla.

Rusch Larygoscope handle (brass head, aluminum barrel, carbon-zinc battery, contact and springs are stainless steel)

	Deflection Angle (degrees)	Torque long axis	Torque short axis
Measurement #1	14	0	0
Measurement #2	14	0	0
Measurement #3	14	0	0
	Deflection Angle (degrees, m ± SD)	**Torque (m ± SD)** long axis	short axis
	14 ± 0	0 ± 0	0 ± 0

Rusch Macintosh size 4 fiber-optic laryngoscope blade

	Deflection Angle (degrees)	Torque long axis	Torque short axis
Measurement #1	32	+1	+1
Measurement #2	32	+1	+1
Measurement #3	32	+1	+1
	Deflection Angle (degrees, m ± SD)	**Torque (m ± SD)** long axis	short axis
	32 ± 0	+1 ± 0	+1 ± 0

FIGURE 1. The products that underwent testing at 3-Tesla.

Bottom, Rusch Larygoscope handle

Top, Rusch Macintosh size 4 fiber-optic laryngoscope blade

FIGURE 2. The 3-Tesla MR system (General Electric Healthcare, Milwaukee, WI) used for MRI testing.

FIGURE 3a. The deflection angle test conducted at 3-Tesla on Rusch Larygoscope handle with battery. Note the deflection angle of 14-degrees measured in the 3-Tesla MR system.

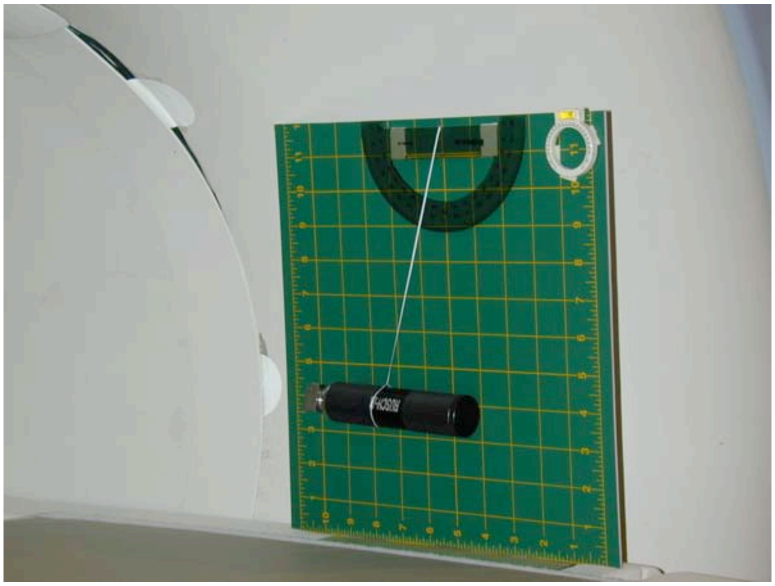

FIGURE 3b. The deflection angle test conducted at 3-Tesla on the Rusch Macintosh size 4 fiber-optic laryngoscope blade. Note the deflection angle of 32-degrees measured in the 3-Tesla MR system.

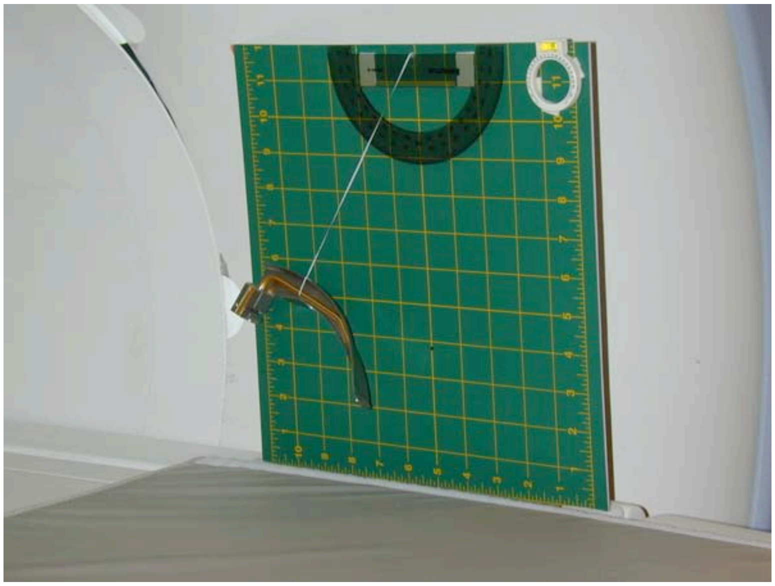

FIGURE 4. The experimental set-up used for the qualitative assessment of torque for the devices. This procedure involved the use of a flat plastic material with a grid on the bottom. Each device was placed on the test apparatus in an orientation that was 45-degrees relative to the static magnetic field of the 3-Tesla MR system. The test apparatus with the device was then positioned in the center of the MR system, where the effect of torque is known to be the greatest and observed for possible alignment or rotation.

a. Rusch Larygoscope handle with battery

b. Rusch Macintosh size 4 fiber-optic laryngoscope blade