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Last month, American Society for Testing Materials (ASTM) International published a new version of ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment. The standard describes the test methodology to measure the torque induced in a medical device when it is placed in a magnetic resonance imaging (MRI) scanner for the purpose of determining whether the induced torque would pose a hazard to the patient being scanned.

Magnetic Resonance (MR) Safety and Compatibility Testing of Medical Devices

With the ubiquitous use of MRI as a clinical imaging modality coupled and increasing number of patients with implantable medical devices, MR safety and compatibility of medical devices is receiving heightened regulatory scrutiny. In order to determine if an implanted device is safe in an MR scanner, a series of tests is required to be conducted, which are defined by the following standards and technical specification:

- ASTM F2052-15
- ASTM F2119-07(2013)
- ASTM F2182-11a
- ASTM F2213-17

These standards are commonly accepted by the U.S. Food and Drug Administration and other regulatory bodies around the world. If a medical device manufacturer desires their patients to undergo MR imaging safely, they must conduct the testing from the above standards appropriate for their device and indications for use. Depending on the test results, the manufacturer must include the appropriate device labeling to notify patients, clinicians, and MR technicians about the MRI scanning conditions to which a patient can be safely exposed.

Updates to ASTM F2213

ASTM F2213 describes the test methodology by which medical devices can be evaluated to determine the extent of rotational torque they experience in an MR environment (“torque testing”). Devices that exhibit significant torque may cause serious adverse events that can even lead to patient death. The current version of ASTM F2213 was updated to include new experimental approaches to conduct torque testing. The methods vary in experimental complexity and applicability for certain types of devices; i.e., some methodologies are only applicable to devices that experience little to no torque, while others are necessary for devices that experience significant torque. A round robin test to determine precision and bias for the different approaches described in the test method is planned for 2018.
**How Exponent Can Help**

Exponent routinely conducts MR safety and compatibility evaluations of medical devices. Exponent’s consultants are able to identify the appropriate standard test methods that apply to a given type of device. Our staff regularly interprets those standards and the relevant FDA Guidance Documents pertaining to MR safety and compatibility to develop a comprehensive experimental testing and/or computational simulation approach to evaluate device MR compatibility. Exponent is accredited to ISO 17025 to conduct the ASTM tests and can recommend the appropriate device labeling for use, support marketing efforts, and guide submissions to regulatory authorities.

For more information on the services we can provide, please visit us at [www.exponent.com](http://www.exponent.com) and view our [MRI Compatibility Numerical Simulation & Testing](http://www.exponent.com) page.