Designation: F 2213 – 02

Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F 2213; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the measurement of the magnetically induced torque produced by the static magnetic field in the magnetic resonance environment on passive implants (implants that function without the supply of electrical power) and the comparison of that torque to the equivalent torque applied by the gravitational force to the implant.

1.2 This test method does not address the issue of magnetically induced force due to spatial gradients in the static magnetic field.

1.3 The torque considered here is the static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

A 340 Terminology of Symbols and Definitions Relating to Magnetic Testing[2]

F 1542 Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips[3]

F 2052 Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment[3]

F 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants[3]

F 2182 Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging[3]

2.2 *IEC Standard:*

60601-2-33 Ed. 2.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2002[4]

3. Terminology

3.1 *Definitions*—For the purposes of this test method, the definitions in 3.1.1-3.1.18 shall apply:

3.1.1 *diamagnetic material*—a material whose relative permeability is less than unity.

3.1.2 *ferromagnetic material*—a material whose magnetic moments are ordered and parallel producing magnetization in one direction.

3.1.3 *magnetic induction or magnetic flux density (B in T)*—that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_0 is the static field in an MR system. Plain type indicates a scalar (for example, *B*) and bold type indicates a vector (for example, ***B***).

3.1.4 *magnetic field strength (H in A/m)*—strength of the applied magnetic field.

3.1.5 *magnetic resonance (MR)*—resonant absorption of electromagnetic energy by an ensemble of atomic particle situated in a magnetic field.

3.1.6 *magnetic resonance diagnostic device*—a device intended for general diagnostic use to present images which reflect the spatial distribution or magnetic resonance spectra, or both, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images or spectra, or both, may also be produced.

3.1.7 *magnetic resonance (MR) environment*—area within the 5 gauss (G) line of an MR system.

3.1.8 *magnetic resonance equipment*—medical electrical equipment which is intended for *in-vivo* magnetic resonance examination of a patient. The MR equipment comprises all parts in hardware and software from the supply mains to the

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[2] *Annual Book of ASTM Standards*, Vol 03.04.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from the International Electrotechnical Commission (IEC), 3 rue de Varembe, Case postale 131, CH-1211, Geneva 20, Switzerland.

display monitor. The MR equipment is a Programmable Electrical Medical System (PEMS).

3.1.9 *magnetic resonance examination (MR Examination)*—process of acquiring data by magnetic resonance from a patient.

3.1.10 *magnetic resonance imaging (MRI)*—imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei.

3.1.11 *magnetic resonance system (MR System)*—ensemble of MR equipment, accessories including means for display, control, energy supplies, and the MR environment.

3.1.12 *magnetically induced displacement force*—force produced when a magnetic object is exposed to the spatial gradient of a magnetic field. This force will tend to cause the object to translate in the gradient field.

3.1.13 *magnetically induced torque*—torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque.

3.1.14 *magnetization (M in T)*—magnetic moment per unit volume.

3.1.15 *medical device*—an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component, part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

3.1.16 *paramagnetic material*—a material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force.

3.1.17 *passive implant*—an implant that serves its function without the supply of electrical power.

3.1.18 *tesla, (T)*—the SI unit of magnetic induction equal to 10^4 gauss (G).

4. Summary of Test Method

4.1 The static field in a magnetic resonance system produces a torque on an implant that acts to align the long axis of the object with the magnetic field. The torque is evaluated using a torsional pendulum method. An implant is placed on a holder suspended by a torsional spring. The apparatus is placed in the center of the magnetic resonance equipment magnet 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 angle of the implant is determined. The maximal magnetic torque is compared to the worst case gravity torque, defined as the product of device length and weight.

5. Significance and Use

5.1 This test method is one of those required to determine if the presence of a passive implant may cause injury to the person with the implant during a magnetic resonance examination and in the magnetic resonance environment. Other safety issues which should be addressed include magnetically induced force (see Test Method F 2052) and RF heating (see Test Method F 2182).

5.2 If the maximal torque is less than the product of the longest dimension of the implant and its weight, then the magnetically induced deflection torque is less than the worst case torque on the implant due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field. This is conservative; it is possible that greater torques would not pose a hazard to the patient.

5.3 This test method alone is not sufficient for determining if an implant is safe in the MR environment.

6. Apparatus

6.1 The test fixture is depicted in Fig. 1. It consists of a sturdy structure supporting a holding platform supported by a torsional spring. Materials should be non-ferromagnetic. The device may be taped or otherwise attached to the holding platform. The supporting structure will have fixed to it a protractor with 1° graduated markings and the holding platform will have a marker so that the angle between the basket and the support structure can be measured. The supporting structure is rotated with the turning knob. The equilibrium angle between the supporting structure and the holding platform outside the magnetic field represents the zero torque angle. The torque inside the magnet is equal to the product of the deflection angle and spring constant. The torsional spring diameter should be chosen so that the maximal deflection angle is less than 25°. A photograph of a torque apparatus is shown in Fig. 2.

7. Test Specimens

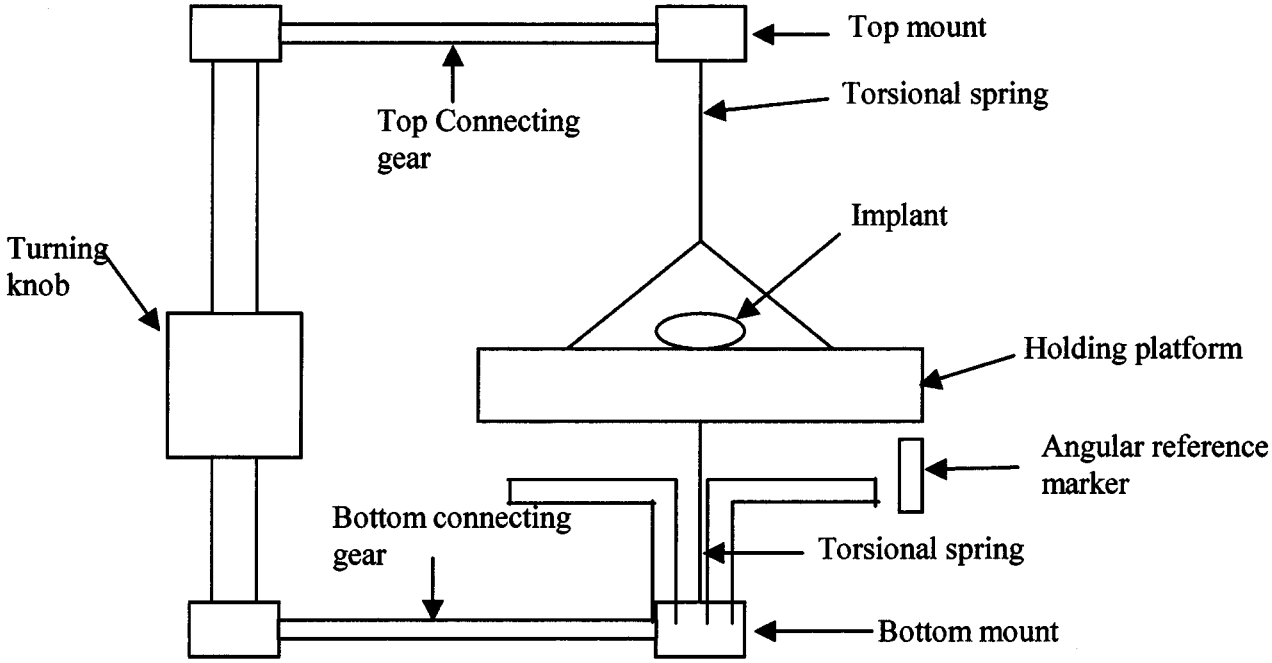
7.1 For purposes of device qualification, the device evaluated according to this test method should be representative of manufactured implant devices that are in the finished sterilized condition.

7.2 For purposes of device qualification, the implant should not be altered in any manner prior to testing.

8. Procedure

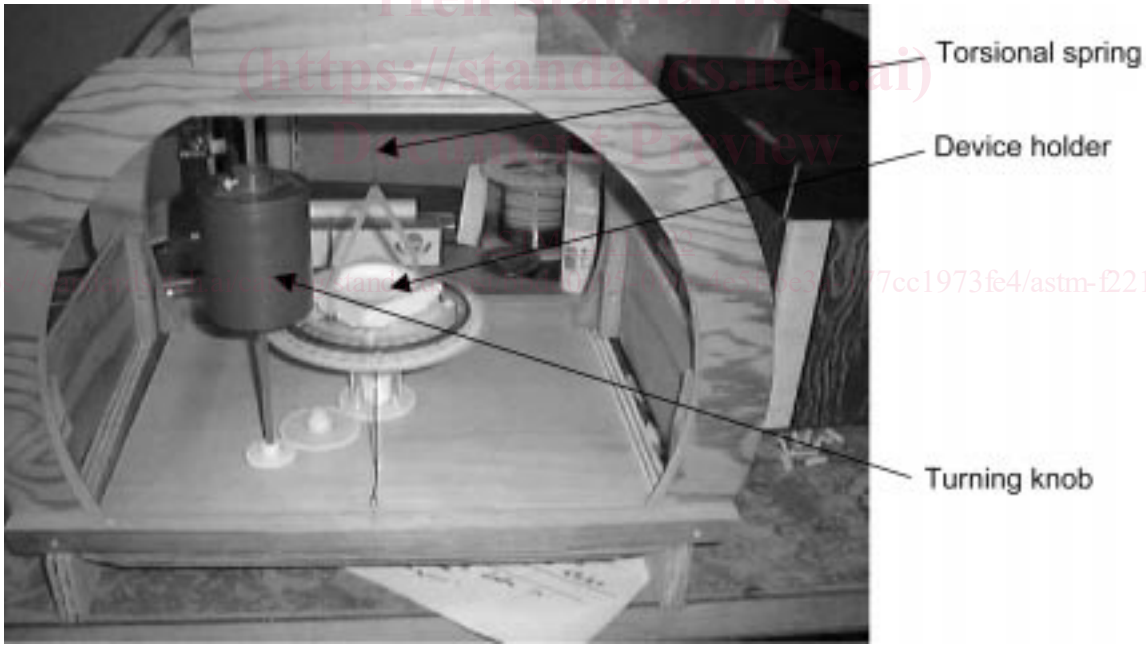
8.1 Fig. 1 depicts the test fixture, which is placed in the middle of the magnet where the magnetic field is uniform. The test device is placed on the holding platform with one of its principal axes in the vertical direction. The entire apparatus is placed in the center of the magnet in the region of uniform magnetic field. Rotate the fixed base and measure the deflection of the device with respect to the base at 10° increments for angles between 0° and 360°. Note that at angular values where the angular derivative of the torque changes sign, there will be an abrupt change in deflection angle as the device swings to the next equilibrium position. Try to measure the deflection angle as close as possible to this swing so that the maximal torque will be determined.

8.2 Repeat the process in 8.1 twice, once for each of the other two principal axes of the device in the vertical direction.



NOTE—The angular reference marker is used to locate the angular marks on protractors connected to the bottom mount and the holding platform.

FIG. 1 Diagram of the Torque Apparatus



NOTE—The turning knob is used to to rotate the mounts supporting the torsional pendulum.

FIG. 2 Photograph of an Apparatus for Measurement of Magnetic Torque

9. Calculation

9.1 The torque is $\tau = k\Delta\theta$ where $\Delta\theta$ is the deflection angle of the basket from its equilibrium position relative to the fixed base outside the magnet and k is the spring constant.

10. Report

10.1 The report shall include the following for each specimen tested:

10.1.1 Implant product description including dimensioned drawing(s) or a photograph with dimensional scale.

10.1.2 A diagram or photograph showing the three configurations of the implant during the test.

10.1.3 Implant product identification (for example, batch, lot number, type number, revision, serial number, date of manufacture).