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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0987.1-2016

Implants for Surgery - Magnetic Resonance Compatibility - Part 1: Safety Marking

外科植入物 磁共振兼容性 第1部分：安全标记

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Foreword

YY/T 0987 Implants for Surgery - Magnetic Resonance Compatibility is divided into the following parts:

---Part 2: Magnetically Induced Displacement Force Test Method;

---Part 3: Evaluation of MR Image Artifacts from Passive Implants;

---Part 5: Magnetically Induced Torque Test Method.

This is the first part of YY/T 0987.

This Part was drafted in accordance with the rules in GB/T 1.1-2009.

This Part was formulated in accordance with the Act of Redrafting and ASTM F2503- 2008 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

In comparison with ASTM F2503-2008, this Part has the following technical differences:

---In terms of the scope of application of the standard, this Part is also applicable to other medical devices or items that enter the magnetic resonance environment. If this Part conflicts with relevant laws and regulations, the laws and regulations shall prevail.

---In terms of normative references, this Part has made some adjustment with technical differences, so as to adapt to the technical conditions in China. The condition of such adjustment is intensively reflected in Chapter 2 “Normative References”. Please see the specific adjustment below:

Please be noted that certain contents in this document might involve patents. The institution that issues this document shall not undertake any responsibility of identifying these patents.

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee 110 on Implants for Surgery and Orthopedic Devices of Standardization Administration of China (SAC/TC 110).

The main drafting organizations of this Part: China Food and Drug Administration, Tianjin Medical Devices Quality Supervision and Testing Center, MicroPort Scientific Corporation (Shanghai).

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1 Scope

This Part of YY/T 0987 specifies safety marking of medical devices and other items in the magnetic resonance (MR) environment, so as to provide prompt message on safety.

magnetic resonance environment can also refer to this Part for safety marking.

This Part has the following purposes:

(1) Suggest that an item, that might enter MR environment, should be permanently marked, so as to indicate whether this item is safe in MR environment;

(2) Suggest the information that shall be included in the marking.

Sometimes it is not realistic to directly mark on implants and certain medical devices. When it is impossible to directly mark on them, it is suggested to mark on labels and patients' information cards.

This Part does not include the content of image artifact, because artifact does not belong to the issue of safety.

This Part adopts numerical value under international system of units as the standard; numerical value in the brackets shall merely be considered as reference.

This Part does not attempt to elaborate all the involved safety questions, even though those safety questions are related with the usage. Determining appropriate safety and health specifications and clarifying the applicability of management limit before application is the responsibility on the users of this Standard.

2 Normative References

The following documents are indispensable to the application of this Standard. In terms of references with a specified date, only versions with a specified date are applicable to this Standard. The latest version (including all the modifications) of references without a specified date is also applicable to this Standard.

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 Hazard

3.2 Item

Item refers to medical devices or other items that might be brought to MR environment.

3.3 Magnetically Induced Displacement Force

3.4 Magnetically Induced Torque

Magnetically induced torque refers to the torque generated by magnetic item in magnetic field. This torque drives magnetic item to align along a torque-free balanced direction.

3.5 Magnetic Induction, Magnetic Flux Density

Magnetic induction or magnetic flux density refers to the magnetic field strength measured through induced electromotive force generated by the force or magnetic flux change that acts on any point of current element in that point's loop in the magnetic field.

3.6 Magnetic Resonance; MR

Magnetic resonance refers to atomic particle swarm's resonance absorption of electromagnetic field energy in the magnetic field.

3.7 Magnetic Resonance (MR) Environment

Magnetic resonance environment refers to the space within 0.5 mT (5G) line in MR system, including the whole three-dimensional space around MR scanner. When 0.5 mT line is included in Faraday cage, the whole space shall be deemed as magnetic resonance (MR) environment.

3.8 Magnetic Resonance System MR System

Magnetic resonance system refers to the combination of magnetic resonance equipment, accessories (including display, control and energy supply devices) and controlled entry zone (if provided).

3.9 MR Conditional

MR conditional refers to items that do not generate already known hazards under specific MR environment and specific working conditions. In magnetic field, the specific MR environment includes magnetic field strength, magnetic field spatial gradient, magnetic field time variation rate (dB/dt), radio frequency (RF) field and specific absorption rate (SAR). Other than these, it also might include items' special configuration.

3.10 MR Safe

MR safe refers to items that do not generate already known hazards in all MR environments.

plastic petri dish. Whether items are MR safe can be determined in accordance with scientific theories, not experimental data.

3.11 MR Unsafe

MR unsafe refers to items that generate hazards in all MR environments.

3.12 Medical Device

3.13 Radio Frequency (RF) Magnetic Field