

The highly anticipated Standard Practice for Marking Medical Devices for Safety in the Magnetic Resonance Environment by American Society for Testing and Materials (ASTM) has arrived.

As recommended by ASTM Intl.; The intent of this practice is to provide needed information about the safety of items in and near MR scanners using a compact and easily recognized set of symbols and terms. The terms MR safe and MR compatible as first defined in 1997 in the FDA draft guidance document, "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems," have been used to describe the safety of devices in and near MR systems. However, there has been a great deal of confusion surrounding this terminology. An incorrect assumption is often made. Users often incorrectly assume that items labeled MR safe or MR compatible are safe or compatible for any MR environment. MR environments vary in terms of magnetic field strength and RF conditions. This new system eliminates much of that confusion.

MR Safe — an item that poses no known hazards in all MR environments.



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MR Conditional — an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.



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Products **NOT** marked with a designation have been tested under the past methods and are currently being re-evaluated under the new ASTM Standards. Products will be updated continually.

For more information on the ASTM Standard visit http://www.astm.org and search for F2503-05

For more helpful information pertaining to MR Safety, you can visit www.MRI-Planning.com www.MRISafety.com www.radiology.upmc.edu/MRsafety

hazards in all MR environments.

MR Unsafe — an item that is known to pose

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