Medical Cylinder Valves in Magnetic Resonance (MR) Environment

Background

Interactions and malfunctions of medical devices such as cylinders, valves, regulators etc. with the Magnetic Resonance environment has resulted in serious injuries and deaths. Cylinder valves need to be tested to demonstrate that they pose no known hazards in the MR environment within defined conditions.



Classification of MR terms to label medical devices as per ASTM F 2503

MR Safe

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, non-metallic and non-magnetic e.g., cotton blanket or silicone catheter.



MR Conditional

An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radio frequency fields.

MR Unsafe

An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment e.g., a pair of ferromagnetic scissors.









Testing

Testing for magnetic field interactions involves evaluation of translational attraction known as the "deflection angle test" as per ASTM F2052.

A predefined MR system is used for assessment of magnetic field interactions. The test item is attached to a special non-metallic test apparatus which measures the deflection angle. As per ASTM F2052, if the device deflects less than 45°, then the magnetically induced deflection force is less than the force on the device 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.

Markings

Tekno Valves **MYC-10C** series pin index valves are third party non-clinical tested for suitability in use up to 3-Tesla or less and marked as per ASTM F2503.

To download product catalogue of **MYC-10C** <u>Click here</u>



