

Understanding MRI Safety Labeling

The MR environment has unique safety hazards for patients with implants, external devices and accessory medical devices. Implants, medical devices and other equipment used in or near the MR environment should be labeled as

MR Unsafe, **MR Conditional** or **MR Safe**.

MR Unsafe items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.

MR Conditional items may safely enter the MRI scanner room only under the very specific conditions provided in the labeling. Patients should not be scanned unless the device can be positively identified as MR Conditional AND the conditions for safe use are met.

The conditions for safe use will be different based on the intended use of the device.

For **items intended to enter the bore of the MRI system**, the MRI Safety labeling should be matched with the MRI system for:

- Static field strength
- Maximum spatial field gradient
- dB/dt limitations (usually only applicable to active implants)
- SAR limits
- Any other conditions needed for safe use of the device; for example, restrictions on the types of coils that may be used

When present, information about expected temperature rise and artifact extent may inform the risk/benefit decision of whether or not a patient should undergo an MRI examination. Expected temperature rise and artifact extent information are not conditions that must be met.

Items NOT intended to enter the bore of the MRI system usually have Gauss line positioning restrictions or requirements to tether or affix the device to an unmovable part of the room.

MR Safe items pose no safety hazards in the MR environment. They may be placed anywhere in the MR environment. Patients with MR Safe devices have no scanning restrictions.

