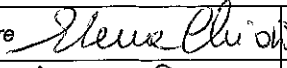
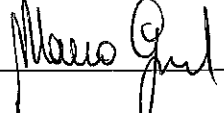

 Carbostent & Implantable Devices	<i>Research & Development</i>	Rev.
	Magnetic Resonance Imaging (MRI)	A
	Safety and Compatibility of Ni-Ti (NiTiNol) alloy devices	Pag.
		1/4

Magnetic Resonance Imaging (MRI)

“Safety and Compatibility of Ni-Ti (NiTiNol) alloy devices”

Revision history	Revision
New emission	A

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	<i>Research & Development</i>	Rev.
	Magnetic Resonance Imaging (MRI)	<i>A</i>
	Safety and Compatibility of Ni-Ti (NiTiNol) alloy devices	Pag.
		2/4

INTRODUCTION


The main issues affecting the safety and compatibility of passive implants in the MR environment concern magnetically induced displacement force and torque, radio frequency (RF) heating, image artefacts and noise.

The MR static field induces displacement forces and torques on magnetic materials. The magnitude of these effects is dependent on the geometry and mass of the object and its magnetic susceptibility, as well as the characteristics of the MR system's magnetic field (Ref. 1). Translational attraction and/or torque may cause movement or dislodgment of a ferromagnetic implant resulting in an uncomfortable sensation or injury to a patient or individual.

RF heating in the body is created by currents induced by the RF excitation pulses applied during MR scanning. Reports (Ref. 2) have indicated that only minor temperature changes occur in association with MR procedures involving metallic objects that are passive implants (e.g., those that are not electronically-activated). Therefore, heat generated during an MR procedure performed at 3-Tesla involving a patient with passive metallic implant does not appear to be a substantial hazard.

The presence of an implant may produce an image artifact that may appear as a void region or as a geometric distortion of the true image. If the image artifact is near the area of interest, the artifact may make the MR scan uninformative or may lead to an inaccurate clinical diagnosis, potentially resulting in inappropriate medical action (Ref. 3).

RF noise, which often appears as static on the image, can be caused by a medical device located anywhere in the MR procedure room. RF noise is a result of excessive electromagnetic emissions from the medical device that interfere with the proper operation of the MR scanner. Primary concerns with noise include again the production of a void where anatomical information is needed as well as the production of artifacts that may be misdiagnosed as pathology.

	<i>Research & Development</i>	Rev.
	Magnetic Resonance Imaging (MRI)	A
	Safety and Compatibility of Ni-Ti (NiTiNol) alloy devices	Pag.
		3/4

MAGNETIC RESONANCE IMAGES (MRI) SAFETY AND COMPATIBILITY OF Ni-Ti ALLOY DEVICES


CID self-expanding stents are made of Ni-Ti alloy, which properties are in accordance with specifications of ASTM F2063.

Although well known good MRI compatibility properties of the material, especially compared to AISI 316L Stainless Steel (Ref. 4), as a precautionary measure, in the IFU it is suggested that patients who have received a stent should not undergo magnetic resonance imaging (MRI) until the stent is fully endothelialised (approx. 8 weeks).

Regarding artifacts evaluation during MR imaging, since they depend both by magnetic permeability of materials and geometry of stent, and test parameters (impulse frequency, field amplitude), it is not possible to state that Ni-Ti alloy devices are free from artifacts.

For this reason the following precaution has been introduced in the IFU:

" The stent might affect the magnetic field, creating artefacts in the MRI images".

	<i>Research & Development</i>	Rev.
	Magnetic Resonance Imaging (MRI)	<i>A</i>
	Safety and Compatibility of Ni-Ti (NiTiNol) alloy devices	Pag.
		4/4

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