Magnetic Resonance Imaging (MRI)

"Safety and Compatibility of L605 Cr-Co alloy devices"

Revision history	Revision
New emission	A

Prepared by:	Elena CHIONO *R&D Documentation Specialist*	*Signature* Elena Chiono	*Date* 10/03/11
Approved by:	*Marco GARD* *Senior product qualification engineer*	*Signature* Marco Gard	*Date* 10/03/2011

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.

MAGNETIC RESONANCE IMAGES (MRI) SAFETY AND COMPATIBILITY OF L605 CR-CO ALLOY DEVICES

CID Cobalt-Chromium stents are made of Cr-Co alloy (L605 or Stellite 25), which properties are in accordance with specifications of ASTM F90-01; the alloy is non ferromagnetic and therefore intended for use in the MR environment.

In a study (Ref. 4), concerning magnetic characterization of Cr-Co alloy devices, side effects such as RF-induced heating and magnetically induced displacement force and torque have not been recorded with systems operating at 1.5 Tesla or lower (Ref. 5).

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 vessel has fully healed (approx. 8 weeks). In the IFU it is also reported: "*Data taken from the literature have not, however, pointed out side effects such as RF-induced heating and shifting due to systems operation at 1.5 Tesla or lower following MRIs on devices made of cobalt chromium alloys.*

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 L605 Cr-Co alloy devices are free from artifacts.

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

" MRI image quality may be compromised if the area concerned lies close to or is in the same position as the stent".

References

1. FDA Guidance, Draft Doc. "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems" 1997
2. Shellock F.G "3.0-Tesla MR Safety Information for Implants and Devices," Safety Information
3. Guidance for Industry and FDA Staff, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", 2008
4. Shellock F.G., Shellock V.J. "Metallic Stent: Evaluation of MRI Imaging Safety", Am J Roentgenol 1999; 173:543-547
5. Wang Yi &C., "Quantitative Evaluation of Susceptibility and Shielding Effect of Nitinol, Platinum, Cobalt-Alloy and Stainless Steel Stents", Magnetic Resonance in Medicine 2003; 49:972-976.