



Magnetic Resonance Imaging (MRI) Safety Information for Lanterna Medical Technologies Implants

Magnetic Resonance Imaging (MRI) is a commonly accepted and widely used diagnostic medical procedure. It is often safe to perform MRI on an individual that has an orthopaedic implant device. The main issues affecting the safety of passive implants (medical devices that serve their function without the supply of power) in the MR environment involve magnetically induced displacement force and torque and radio frequency (RF) induced heating. The MR static field induces displacement forces and torques on ferromagnetic materials. However, both ferromagnetic and non-ferromagnetic metallic devices of certain geometries may experience heating caused by interactions with the RF field. Of secondary concern is the possibility of image artifacts that can compromise image quality.

Implant Movement

Lanterna's metallic implants are manufactured using one or more of the following **non-ferromagnetic** materials: commercially pure titanium (CP Titanium), Ti-6Al-4V alloy, and Co-Cr alloys (ASTM F75, F562, and F90).

Internal testing previously reported by the Orthopedic manufacturer Zimmer Inc. Reported the following:

*" Zimmer metallic implants are manufactured using one or more of the following **non-ferromagnetic** materials: commercially pure titanium (CP Titanium), Ti-6Al-4V alloy, Ti-6Al-7Nb alloy, several Co-Cr alloys (ASTM F75, F562, and F90), tantalum (Trabecular Metal™ Material), and the following implant grade stainless steels: 316L, REX 734, 22-13-5 and Biodur 108. Zimmer's internal testing has revealed that although each metallic material exhibits a small but measurable magnetic attraction in the 1.5 Tesla and 3.0 Tesla environments, the maximum magnetic force exerted on a device (stainless steel) is less than 25% of the force exerted on the device due to gravity¹. None of the metallic materials exhibited any torque movement in 1.5 Tesla and 3.0 Tesla MR environments. Therefore, no movement or deflection of Zimmer devices manufactured from the aforementioned metallic materials is expected in 1.5 Tesla and 3.0 Tesla MR environments¹."*

The polymer (plastic) materials used in the manufacture of some lanterna implants are non-metallic and non-ferromagnetic and pose no risk of movement or deflection due to exposure to the MR environment.

Implant Heating

In regards to RF induced heating, one recent publication states:

".....to date, there has been no report of a patient being seriously injured as a result of excessive heat that developed in a "passive" metallic implant or device. However, heating is potentially problematic for implants that have an elongated shape or those that form a conducting loop of a certain diameter²."

The RF induced heating of Lanterna's metallic implants have never been tested therefore no results are

currently available.

However, Patients, Surgeons and the public should note that there are several different manufacturers and generations of MRI systems available, and even after testing is done, Lanterna will not be able to make any claims regarding the safety of Lanterna's implants and devices with any specific MR system.

Conclusion

Given the fact that:

- To date there has been no report of a patient being seriously injured as a result of excessive heat that developed in a non active metallic implant or device
- Lanterna's implants are manufactured from identical materials and specifications as the tested Zimmer materials, Lanterna is confident that Lanterna's materials will exhibit similar characteristics to the tested materials when exposed to magnetic fields and or forces.
- Even after testing Lanterna will not be able to make any claims regarding the safety of Lanterna's implants and devices with any specific MR system³

Lanterna believes that the benefits to the patients far outweigh any risks and therefore, accepts the residual risks of using the aforementioned metallic materials for the manufacture of its implants.

Approval by /Date	Name	Signature
President, 2013-10-30	Horace Hale	

References

1. Zimmer Research Report_WA_2179_10_Rev.1
2. F. G. Shellock, "Reference Manual for Magnetic Resonance Safety, Implants, and Devices", 2008 edition, pg:136
3. T. Gilk, "M.R.I. Safety and implanted medical devices, 2011. Presentation downloaded from the web