

To whom it may concern

Confirmation

The metallic materials used for Synthes implants are Stainless Steel (316L, DIN 1.4441), pure Titanium (Ti cp) and Titanium alloys (Ti6Al7Nb and Ti6Al4V). These materials are corresponding to the international standards ASTM F 138 and ISO 5832-1 (316L), ASTM F 67 and ISO 5832-2 (Ti cp), ASTM F 1295 and ISO 5832-11 (Ti6Al7Nb), and ASTM F136 (Ti6Al4V).

All these materials are considered to be paramagnetic (non – ferromagnetic) and hence exhibit only negligible residual magnetism, even in a highly cold worked condition.

The behavior of Synthes implants in the human body during Magnetic Resonance Imaging (MRI) procedures has been thoroughly assessed by L. Eschbach of the Dr. h.c. Robert Mathys Foundation. In 2003, he published the booklet “10 Frequently Asked Questions about Magnetic Resonance Imaging in Patients with Metal Implants” and concluded that Synthes metallic implants do not pose any threat to the patient (for instance heating or displacement). Titanium implants produce less MRI artifacts than Stainless Steel, but artifacts can be kept to a minimum by proper choice of MRI parameters.

All Synthes metallic implant materials are “MR safe” and can be utilized in or around Magnetic Resonance Imaging (MRI) equipment without risk or harm to the patient and staff.

Synthes
Manager Materials and Testing



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Oberdorf, September 8, 2006