


TECHNICAL DOCUMENTATION		
Product: Dyna Dental Implants, Abutments and Attachments		
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MRI statement

INTRODUCTION

Magnetic resonance imaging (MRI) describes a widely used medical imaging technique based on a magnetic field, electric field gradient and radio waves to depict tissues or organs. The dental implants and most abutments under evaluation are made of titanium Ti6Al4V-ELI. This material was used, beside biocompatibility and mechanical properties, due to its classification as non-ferrous metal, meaning that it does not contain iron in appreciable amounts. Therefore, titanium and its alloys are generally considered uncomplicated during MRI and are especially not mentioned as a contraindication for MRI. Pure titanium as well as titanium alloy represent the gold standard regarding dental implantation.

According to clinical data found during the evaluation of MRI risks in recently available scientific literature, susceptibility artefacts are clearly the focus of current research, heating and migration effects have been pushed to the background. Full evaluation reports "Examination MR risks 01 IIb" and "Examination MR risks 01 IIa"




In combination with the necessary mechanical properties, biocompatibility and clinical experience, the described data according to MRI compatibility of titanium implants and abutments, justify the use of these materials. Especially regarding use of 1.5 Tesla, the described materials meet the state of the art.

The attachments are made of stainless steel (316L) and neodymium magnets. Whereas stainless steel may be without interaction with MRI treatment the corresponding EFM magnet abutments and Keepers are made of Pd/Pt/Co alloy (palladium, platinum, cobalt). The magnet attachment as well as the EFM abutments and keepers should be viewed critically and removed before any MRI scan.

STATEMENT

Implants and abutments under evaluation are neither clearly classified as "MR safe", "MR unsafe" nor MR conditional", even if a significant risk is not to be expected on the basis of the available data. The devices are therefore defined as "safety in MRI not evaluated"

Dental Magnets and EFM abutments and keepers made of Pd/Pt/Co alloy should be removed from the oral area before MRI; however, it is not always in the best interest of the patient. From a safety perspective, magnets should always be removed and the fixation of EFM abutments and keepers should be inspected before and after MRI.

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