Stryker's Total Joint Implants

Magnetic Resonance Imaging Information

1. Introduction

This document is intended to provide Magnetic Resonance Imaging (MRI) information regarding Stryker orthopaedic' implants. With the growing use of MRI scanners to more accurately assess patients, the need to understand how the MRI scanner interacts with passive metallic implants has become ever more necessary. Stryker has performed testing according to ASTM standards to determine the level of safety of their products.

The MR environment includes the static magnetic field (1.5 & 3.0 Tesla most common), the imaging gradient field (in the range of kHz), and the radio frequency (RF) field (1.5-T/64MHz & 3.0-T/128Mhz). Each of these fields interacts with implants in different ways, producing medical device concerns that may be potentially detrimental to an implant recipient. These concerns include: magnetic field interactions (including magnetically induced displacement and rotational force) on the implant, MR induced image artifacts, and RF induced currents resulting in heating.

2. Magnetic Field Interactions

Stryker orthopaedic' implant metallic components may include the following non- ferromagnetic materials: Commercially Pure Titanium (CP-Ti), Titanium Alloys (Ti- 6Al-4V & TMZF), Cobalt Chrome (CoCr), and specific Stainless Steel grades (REX 734). Testing performed on non-ferromagnetic devices included in Appendix I concluded that magnetic field interactions (including magnetically induced displacement and torque) were acceptable.

3. RF-Induced Heating Interactions

The RF field of the MR can interact with a metallic component's geometry causing concern of induced heating. In particular, elongated features (i.e., distal shaft of the femoral stem or bone screws) can form a resonance antenna and result in internal heating. Stryker orthopaedic' components listed in Appendix I were evaluated to determine the extent of induced heating and temperature rises were found to be acceptable.

4. Imaging Artifacts

The static field of an MR system can cause image distortion and signal loss artifacts. These artifacts do not compromise patient safety and therefore are not considered a

performance risk. Testing was carried out to characterize these artifacts and determine to what extent these artifacts will affect image quality.

MR Test Recommendations:

The scope of this document covers devices included in Appendix I. These devices are MR Conditional according to the terminology specified in ASTM F2503, Standard Practice for Marketing Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Non-clinical testing has demonstrated that the devices included in Appendix I are MR Conditional. A patient with any of these devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Telsa and 3.0-Tesla, only
- Maximum spatial gradient magnetic field of 2,310 gauss/cm (23 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system.
- Evaluation was performed using a quadrature body coil only

Under the scan conditions defined above, devices covered in Appendix I are expected to produce a temperature rise of less than 4.1 ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 84 mm from the device when imaged with a gradient echo pulse sequence using a 3.0 T/128 MHz MRI system.

Unless listed in Appendix I, other total joint products have not been evaluated for safety and compatibility in the MR environment. These products have not been tested for heating, migration, or image artifact in the MR environment. The safety of these products in the MR environment is unknown. Scanning a patient with a total joint device not listed in Appendix I may result in patient injury.

Surgeons should warn patients with metallic implants of the potential risks of undergoing a MRI scan. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, implant damage or malfunction, or other undesirable effects. In addition, the presence of a metallic implant can produce an image artifact that may appear as a void region or geometric distortion of the true image. If the image artifact is near the area of interest, it may make the MRI scan uninformative or may lead to inaccurate clinical diagnosis or treatment.

Appendix I

Product Name	Catalog Numbers
Trident II Tritanium Solidback Acetabular Shell	700-04-42A 700-04-44B 700-04-46C 700-04-48D 700-04-50D 700-04-52E 700-04-54E 700-04-56F 700-04-58F 700-04-60G 700-04-62G 700-04-64H 700-04-66H
Trident II Tritanium Clusterhole Acetabular Shell	702-04-42A 702-04-44B 702-04-46C 702-04-48D 702-04-50D 702-04-52E 702-04-54E 702-04-56F 702-04-58F 702-04-60G 702-04-62G 702-04-64H 702-04-66H
Trident II Tritanium Multihole Acetabular Shell	709-04-42A 709-04-44B 709-04-46C 709-04-48D 709-04-50D 709-04-52E 709-04-54E 709-04-56F 709-04-58F 709-04-60G 709-04-62G 709-04-64H 709-04-66H

	709-04-68I 709-04-70I 709-04-72J
Trident II PSL Clusterhole HA Acetabular Shell	742-11-42A 742-11-44B 742-11-46C 742-11-48D 742-11-50D 742-11-52E 742-11-54E 742-11-56F 742-11-58F 742-11-60G 742-11-62G 742-11-64H 742-11-66H
Trident II Clusterhole HA Acetabular Shell	702-11-42A 702-11-44B 702-11-46C 702-11-48D 702-11-50D 702-11-52E 702-11-54E 702-11-56F 702-11-58F 702-11-60G 702-11-62G 702-11-64H 702-11-66H
6.5mm Low Profile Hex Screw	7030-6515 7030-6520 7030-6525 7030-6530 7030-6535 7030-6540 7030-6545 7030-6550 7030-6555 7030-6560
Hex Dome Hole Plug	7060-0000

GSNPS-BUL-9_13072 (also referenced as GSNPS-BULL-9_13072)

Orthopaedics

The information contained in this document is intended for healthcare professionals only.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC, unless otherwise indicated. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.
Please contact your sales representative if you have questions about the availability of products in your area.