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SYNTHES

This information is not approved for distribution in the United States and Canada.

This information applies to Synthes Trauma products only.

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Synthes Trauma implants in the MR environment

To whom it may concern

Implants made of Stainless Steel alloy, Cobalt-based alloy, commercially pure Titanium and Titanium-based alloy meet standards with respect to magnetically induced displacement force (ASTM F 2052) and magnetically induced torque (ASTM F 2213) at a static magnetic field of up to 3.0 Tesla and a spatial gradient field of up to 45 mT/cm.

Thermal heating, resulting from interaction of the electromagnetic radio frequency (RF) field with the implant and the surrounding tissue, is the primary known risk associated with the presence of Synthes Trauma implants in the MR environment. Thermal heating depends on various factors and under certain worst-case condition local temperature near implants can reach critical levels. At present safe limits for local, temporary temperature increase in different tissues and anatomic regions are debated by experts. Synthes performed tests for specific families of devices with respect to thermal heating (ASTM F 2182). Excessive temperature rise is typically observed for implants consisting of long and thin metallic parts such as Kirschner-wires, cerclage wires, Schanz- and Steinman pins or Ex Fix frames that may form large eddy current loops. Risk of thermal heating is also highest when the implant is placed close to or at the center of the bore of the RF coil and if the MR equipment is operated outside normal operating mode. Synthes recommends following guidance of the international standard IEC 60601-2-33 (1), consulting an experienced person or contacting Synthes. As a general rule, for implants outside the RF coil there is minimal risk of thermal heating.

Instruments, such as drill bits and older ExFix clamps may be ferromagnetic or contain ferromagnetic parts posing a higher risk of magnetically induced torque or displacement and should not be exposed to MR environment. Please note that debris of such instruments which may remain in the patient pose a potential risk.

External Fixation Frames include Schanz screws and Kirschner wires which are worst case implants with respect to thermal heating. Peripheral nerve stimulation or heating sensation have occasionally been reported for Schanz screw implants fastened to External Fixation frames under specific conditions of use. In addition External Fixation constructs have a higher probability to be placed inside the RF coil during MR imaging. For these reasons, Synthes has performed extensive tests at 1.5 T and 3.0 T. Information about specific conditions is available at Synthes including detailed information about thermal heating for different frame configurations.

Pelvic C-Clamp (xxx.000.899)[2)]
Large External Fixator (xxx.000.237)
Distraction Osteogenesis Ring System (xxx.000.643)
Medium External Fixator (xxx.000.237)
Small External Fixator (xxx.000.182)
Small External Fixator, radioluscent, sterile (xxx.000.389)
Elbow Hinge Fixator (xxx.000.663)
Distal Radius Fixator (xxx.000.182)
[2)] Identification number of technique guide, "xxx" indicates language of the document

Artifacts are generated by all conducting objects which are placed in or close to the scanned area. These artifacts may hinder interpretation of results. Size of artifacts will depend on implant dimensions, alloy composition, and scanning sequence. For Synthes implants with the same implant size and configuration, commercially pure Titanium or Titanium-based alloys generate fewer artifacts than Cobalt-based alloys which in turn generate fewer artifacts than Stainless Steel implants. Spin echo and turbo spin echo pulse sequences will reduce the amount of artifact when compared to a fast field effect or gradient echo pulse sequences. In general, artifacts can be expected to be small when the implants are outside the scanned area

Summary
Synthes Trauma implants pose remote risk to patient safety if they are located outside the RF coil and the field parameters are below 3.0 T and 45mT/cm. If imaging is necessary with an implant at or close to the center of the RF coil increased risks due to thermal heating and imaging artifacts must be considered. Precautions as specified in IEC 60601, such as medical supervision, must be followed. Selected Synthes Trauma products (e.g. ExFix) are being labeled as "MR Conditional" already. For these products the specific data regarding field conditions are available in the instructions for use.

Synthes experience over the years indicates that clinical MR heating at 1.5 and 3.0T have not been observed or reported for Synthes implants.

Reference [1] IEC 60601-2-33 Ed.3: Medical electrical equipment- Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis, International Electrical Commission, 2010.

Sincerely,
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