Orthopedic Implants

MRI Safety Information

Scope and purpose of the document

The scope and purpose of this document is to provide information for all OHST Orthopedic Implants regarding their MRI safety and compatibility.

Description of the OHST Orthopedic Implants

OHST Orthopedic Implants are non-active implants of different shapes and materials or material combinations and with or without coating for the use in cemented as well as cementless knee and hip joint replacements.

The document is valid for the following OHST implant systems:

Müller Straight Stem
Bipolar Head
Femoral Head / Unipolar Head
Müller II Cup
Nanos Femoral Neck Prosthesis
Flat-head Screw
SPC Femoral Stem
Primaro Cup
Expersus Femoral Stem
Cement Restrictor
EFK Knee System
ZEN Knee System

The following materials are used in these implants:

Metals and metal alloys
ISO 5832-1 - Stainless Steel
ISO 5832-3 - Ti6Al4V - alloy
ISO 5832-4 - CoCrMo - cast alloy
ISO 5832-9 - FeCrNiMnMoNbN - alloy
ISO 5832-11 - Ti6Al7Nb - alloy
ISO 5832-12 - CoCrMo - forge alloy

Plastics
ISO 5834-2 - UHMWPE - wrought material / XL-PE
Vitamin-E XL-PE

Ceramics
ISO 6474-1 - Al_2O_3
ISO 6474-2 - Al_2O_3 + ZrO_2

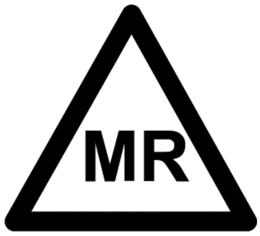
Coatings
TiNbN Coating
TPS (Ti Plasma Spray) coating
BONIT® coating
Hydroxyapatite (HA) coating

Patient population for OHST implant systems:
Sex/ethnicity: No restrictions
Age: No strict age restriction but skeletally mature (usually elder adults)

More information about OHST Orthopedic Implants can be found online at: www.ohst.de/ifu-instructions/

Important information

Based on a systematic risk and literature evaluation, OHST Orthopedic Implants are classified as "**MR Conditional**" and marked with one of the following symbols:



The following parameters were found scientifically valid for a conditional statement for the OHST Orthopedic Implants:

Static magnetic field	1.5T or 3T
Static magnetic field orientation	Horizontal, cylindrical bore
Maximum spatial field gradient	30T/min
RF polarization	Circular polarization
RF transmit coil	Whole body transmit coil OR Head RF transmit-receive coil
RF receive coil	Coil, that only receives / Head RF transmit-receive coil
MR system operating mode	normal
Scan duration and wait time	Not determined
Maximum temperature increase	Not determined
Maximum whole body SAR	Not determined
Artifacts	Not determined
Recommendations for safety	To reduce artifacts (relevant, if the region of interest is around the knee/hip replacement) - Use 1.5 T because the magnitude of metal susceptibility artifact scales linearly with B0. - Prefer spin echo (SE) over gradient echo (GRE) - Use short TE - Use high receiver bandwidth - Reduce flip angle / B1 if possible - Change phase-encoding direction to move artifacts away from the area of interest To reduce heating: - Keep implants outside strong gradient zones (bore entry, periphery). - Use low-output / whisper gradients. - Increase slice thickness to reduce stress. - Run scanner in Normal Mode (whole-body SAR ≤ 2 W/kg). - Increase TR (repetition time). - Reduce flip angle. - Set B1 / SAR mode = low output. - Reduce Echo train length. - Increase Echo spacing. - Insert pauses between sequences.

OHST
medical technology

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