For the Attention of the Operating Surgeon:

IMPORTANT INFORMATION

ON THE SYNTHES

DISTRACTION OSTEOGENESIS SYSTEM, MR CONDITIONAL

DESCRIPTION

The Synthes Distraction Osteogenesis System, MR Conditional is an external ring fixation system. The system is comprised of wires and Schanz screws that are attached to rings with bolts, nuts, and/or clamps; rods that interconnect the rings; and connecting plates, hinges, standoffs, posts and supports that complete the assembly of the fixator.

The Synthes Distraction Osteogenesis System, MR Conditional is a versatile system that is fully customizable. An individualized frame should be constructed for each case to suit the specific situation.

INDICATIONS

The Synthes Distraction Osteogenesis System, MR Conditional is intended to provide treatment for long bone fractures (open and closed) of adult and pediatric patients that require external fixation. Specifically, the components can be used for:

- Pseudoarthrosis or non-unions of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformities
- Correction of segmental bony or soft tissue defects

POSSIBLE COMPLICATIONS

Complications involving external fixation devices may include the following:

- pin-tract infection
- pin loosening
- delayed union
- nonunion
- malunion
- soft tissue impalement

MRI INFORMATION

Synthes Distraction Osteogensis System devices are labeled *MR Conditional* according to the terminology specified in ASTM F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Non-clinical testing of Synthes Distraction Osteogenesis Fixation devices demonstrated that when used in the specific configurations stated in Synthes labeling, are *MR Conditional*. Representative Synthes Distraction Osteogenesis Fixation devices used in a typical construct included; clamps, rods and various attachments. A patient with a Synthes Distraction Osteogenesis External Fixation frame may be scanned safely after placement of the frame under the following conditions:

- Static magnetic field of 1.5-Tesla when the fixation frame is positioned:
  - 7cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or;
  - Completely outside of the MRI bore in First Level Controlled Mode
- Static magnetic field of 3.0-Tesla when the fixation frame is positioned:
  - 7cm or less from within the outside edge of the bore of the MRI at Normal Operating Mode or;
  - Completely outside of the MRI bore in First Level Controlled Mode
- Highest spatial gradient magnetic field of 900-Gauss/cm or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2-W/kg for the Normal

Operating Mode and 4 W/kg for the First Level Controlled Mode for 15 minutes of scanning

- Use only whole body RF transmit coil, no other transmit coils are allowed, local receive only coils are allowed

Note:

In non-clinical testing, the Synthes external fixation frame was tested in several different configurations. This testing was conducted with the construct position 7cm from within the outside edge of the MRI bore.

– The results showed a maximum observed heating for the distraction osteogenesis fixation frame of 6°C for 1.5T and less than 1°C for 3.0T with a machine reported whole body averaged SAR of 2 W/kg.

Patients may be safely scanned in the MRI chamber at the above conditions. Under such conditions, the maximal expected temperature rise is less than 6°C. Because higher in-vivo heating cannot be excluded, close patient monitoring and communication with the patient during the scan is required. Immediately abort the scan if the patient reports burning sensation or pain. To minimize heating, the scan time should be as short as possible, the SAR as low as possible and the device should be as far as possible from the edge of the bore. Temperature rise values obtained were based upon a scan time of 15 minutes.

The above field conditions should be compared with those of the user's MR system in order to determine if the item can safely be brought into the user's MR environment. If placed in the bore of the MR scanner during scanning, Synthes MR Conditional External Fixation devices may have the potential to cause artifact in the diagnostic imaging.

All components of Synthes External Fixation frames must be identified as MR Conditional prior to being placed in or near an MR Environment

Artifact Information:

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Synthes Distraction Osteogenesis Fixation construct and it may be necessary to optimize MR imaging parameters in order to compensate for the presence of the fixation frame.

Representative devices used to assemble a typical Synthes Distraction Osteogenesis Fixation frame have been evaluated in the MRI chamber and worst case artifact information is provided below. Overall, artifacts created by Synthes Distraction Osteogenesis Fixation devices may present issues if the MR imaging area of interest is in or near the area where the Fixation frame is located.

– For FFE sequence: Scan duration: 3min, TR 100ms, TE 15ms, flip angle 15° and SE sequence: Scan duration: 4min, TR 500ms, TE 20ms, flip angle 70°radio echo sequence, worst-case artifact will extend approximately 10cm from the device.

WARNING

- Do not place any radio frequency (RF) transmit coils over the external fixation frame.
- Do not place the device across the growth plate in pediatric patients.

STERILIZATION

These devices are offered NONSTERILE only. Resterilization of the device may only be performed if the device has been opened, but not used. Resterilization of the device should not be performed if the device packaging is damaged upon receipt or if the device has been contaminated by bodily fluids.

For detailed cleaning and sterilization instructions, please refer to: www.depuysynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided. The parameters are for sterilization of the individual nonsterile device.

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.

CAUTION:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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