For the Attention of the Operating Surgeon:

IMPORTANT INFORMATION

ON THE SYNTHES

LOW-PROFILE WRIST FIXATOR, MR CONDITIONAL

DESCRIPTION

The Synthes Low-Profile Wrist Fixator consists of frame elements that form a construct intended to treat fractures of the distal radius. The Low-Profile Wrist Fixator provides stabilization of fractures via pins (Schanz screws) inserted proximally and distally to a fracture and connected by an external bridging frame consisting of two Low-Profile Wrist Fixator Clamps, a carbon fiber rod and two protective end caps. The Low-Profile Wrist Fixator is available as a complete sterile assembly.

INDICATIONS

The Synthes Low-Profile Wrist Fixator is intended for stabilization of fractures of the distal radius.

POSSIBLE COMPLICATIONS

Complications involving external fixation devices may include the following:

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

MRI Information

Synthes Low-Profile Wrist Fixator 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 Low-Profile Wrist Fixator devices demonstrated that when used in the specific configurations stated in Synthes labeling, are MR Conditional. Representative Synthes Low-Profile Fixator devices used in a typical construct included; clamps, rods and various attachments. A patient with a Synthes Low-Profile Wrist Fixator may be scanned safely after placement of the fixator 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 a wrist 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 Low-Profile Fixator 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 Low-Profile Fixator frame have been evaluated in the MRI chamber and worst case artifact information is provided below. Overall, artifacts created by Synthes Low-Profile Fixator 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 5cm from the device.

WARNING

Do not place any radio frequency (RF) transmit coils over the external fixation frame.

STERILIZATION

These devices are offered STERILE only. The parameters are for re-sterilization of the individual sterile device. Re-sterilization of the sterile device may only be performed if the device has been opened, but not used. Re-sterilization of the sterile 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 steam sterilization information, please refer to:

http://www.depuysynthes.com/hcp/cleaning-sterilization

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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Note: For recognized manufacturer, refer to the product label.