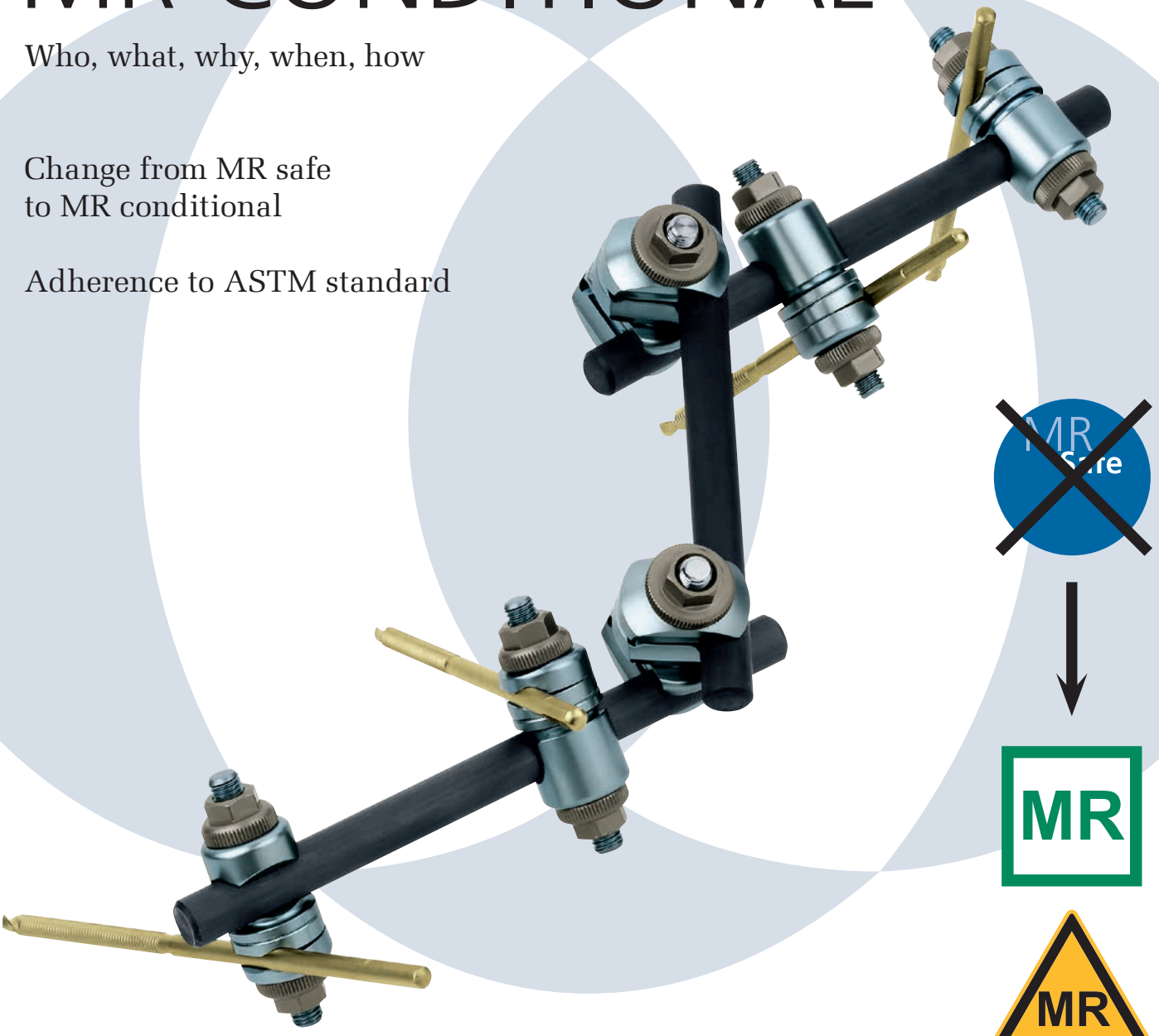
DePuy Synthes
TRAUMA
COMPANIES OF Johnson & Johnson

MR SAFE – MR CONDITIONAL

Who, what, why, when, how

Change from MR safe
to MR conditional

Adherence to ASTM standard



Instruments and implants approved
by the AO Foundation.

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INTRODUCTION

In August of 2005, ASTM (American Society for Testing and Materials) updated ASTM F 2503 "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment". New marking requirements for devices used in MR environments define a device as being MR conditional if "the device has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use."

NEW TERMINOLOGIES

The ASTM developed the testing standards (ASTM F 2052 ASTM F 2213, ASTM F 2182) for the current MR safe and MR compatible, and are now revising the technical terms. The ASTM developed a new set of terms with associated icons. The "NEW" terms, MR safe, MR conditional and MR unsafe, are defined by the ASTM document as follows:

MR TERMS

The new **MR safe** will be a much higher standard than currently and will be absolute. To obtain the new MR safe designation, objects must be completely free of all metallic components. It must be completely non-metallic, non-conductive, and not RF reactive. Everything that receives the new MR safe designation must be equally safe at all field strengths, gradients and sequences. Objects getting the new designation will have to be fabricated very carefully from non-conductive materials such as rubber, plastics, ceramics, select polymers, wood and fiberglass.

The bulk of objects, including most contemporary medical implants and devices, will receive the **MR conditional** designation. This means that the object or device is safe under certain tested conditions, and those conditions should be enumerated on the product, its packaging or in the enclosed literature. Nearly everything that carries either the current MR safe or MR compatible designations would be switched to MR conditional under the new standard.

MR unsafe – an item that is known to pose hazards in all MRI environments. MR unsafe items include magnetic items such as a pair of ferromagnetic scissors.

MR CONDITIONAL

According to the new ASTM F 2503 standard, the surgical technique will include the following information (if applicable):

If the device is MR conditional, the device was tested under nonclinical conditions according to the worst-case scenario.

Nonclinical testing demonstrated that, when used in the specific configurations stated in DePuy Synthes labeling, the articles of the _____ system are MR conditional. These articles can be scanned safely after placement of the frame under the following conditions:
Static magnetic field of ____ Tesla
Highest spatial gradient field of ____ Gauss/cm
Maximum whole body averaged specific absorption rate (SAR) of ____ W/kg for ____ minutes of scanning.

In nonclinical testing, the system showed a maximum observed heating for a frame of ____°C at a whole body averaged specific absorption rate (SAR) of ____ W/kg.

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FREQUENTLY ASKED QUESTIONS

1. The radiologist is about to put a patient with a DePuy Synthes External Fixation Frame into the MRI. What condition(s) must be met to ensure the safety of the patient?

In order to ensure patient safety in an MRI, all the DePuy Synthes implants must be MR conditional and the applicable product labeling must be followed regarding field conditions and limits. DePuy Synthes CFRE (Carbon Fibre Reinforced Epoxy) rods are considered MR conditional, but not DePuy Synthes stainless steel tubes. If one of the DePuy Synthes implants is not MR conditional, or a non-DePuy Synthes part is used, then the patient should not enter into the MRI.

2. Where will DePuy Synthes supply the appropriate information concerning MR parameters that will allow patients to be safely scanned in an MRI while wearing a DePuy Synthes MR conditional Ex Fix Frame?

The surgical technique will outline parameters that provide radiologists with important information to ensure that patients with our MR conditional products can be safely scanned. The packaging labeling will have the MR conditional symbol to designate that the product is MR conditional; however, the surgical technique should always be referred to for tested field conditions and limits.

3. Implant grade 316L is also known as a magnetic stainless steel. Is it acceptable to use this material?

Commercial grade 316L may be slightly magnetic while Implant grade 316L is totally nonmagnetic.

4. What makes a DePuy Synthes product MR conditional?

All DePuy Synthes products designated as MR conditional are made only from specific nonmagnetic materials such as:

CP Titanium and Titanium Alloys; Implant Quality Stainless Steels; Cobalt-Base Alloys; Reinforced Polymers such as CFRE (Carbon Fibre Reinforced Epoxy); Unreinforced Polymers such as PolyEtherEtherKetone (PEEK), Unreinforced polymers can be classified as MR Safe if they are used alone

5. What are the possible side effects of putting non-MR safe or non- MR conditional parts in the MRI?

Potential complications of putting a non-MR safe or non-MR conditional part in the MR field are:

- Torsional forces can cause the device to twist in MR field
- Displacement forces can pull the device into the MR field
- Induced currents can cause peripheral nerve stimulation
- Radio Frequency (RF) induced currents can cause heating of the device that is implanted in the patient

6. Are there any other product changes?

There will be no further changes to MR conditional parts. The part numbers will remain the same and the material and design will remain the same. The appearance of the part will remain the same, other than the removal of the MR safe etching and the addition of the MR conditional symbol where possible.

DePuy Synthes TRAUMA
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DePuySynthes Trauma External Fixator Systems

MR-CONDITIONAL LABELING UPDATE

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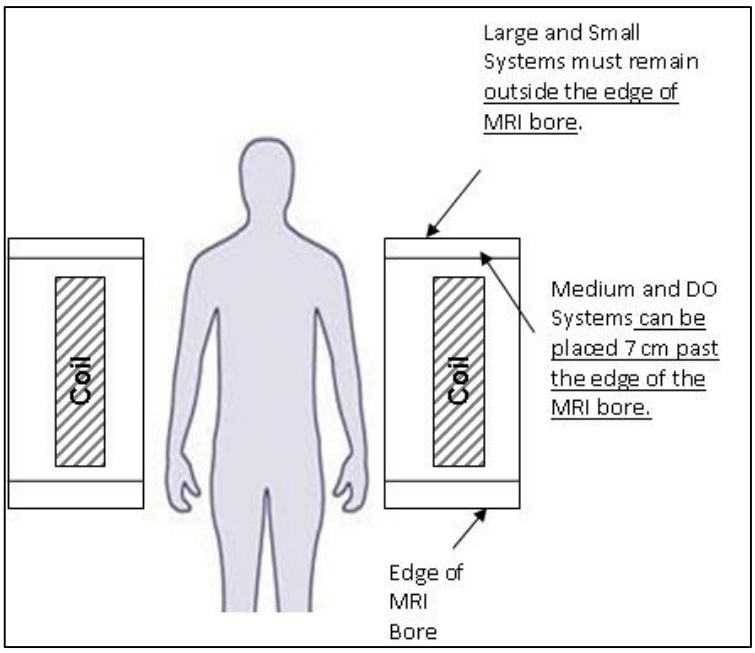
Affected Product *

Small External Fixator	
Medium External Fixator	
Large External Fixator	
Distraction Osteogenesis System (DO)	

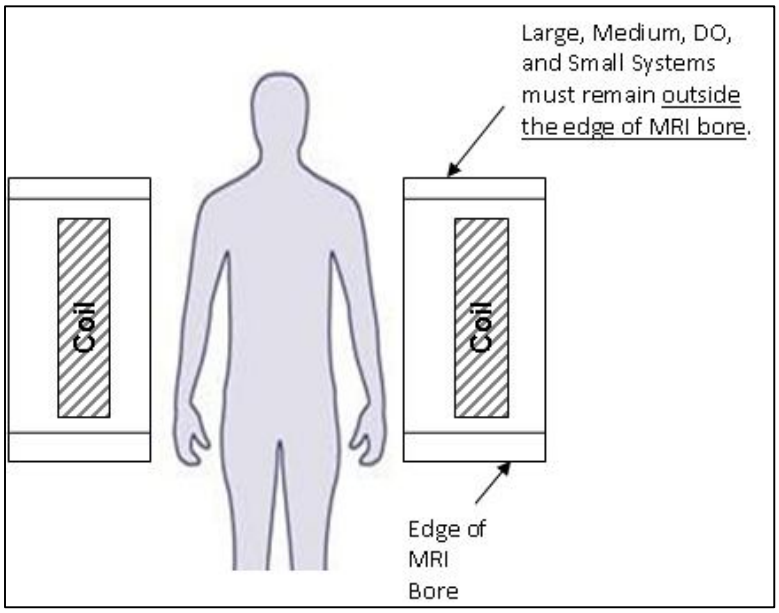
* *External Fixation systems not listed here have not been evaluated for safety and compatibility in the MR environment, nor have been tested for heating or migration in the MR environment.*

IMPORTANT-All DePuySynthes External Fixation products etched MR-Safe or labeled with MR-Safe conditions, should be considered only MR-Conditional and used in accordance with MR-Conditional Labeling.

Details

LABELING CHANGE	All DePuySynthes Ex-Fix systems listed above are now labeled with the FDA accepted **MR-Conditional symbol.** 
HOW DOES THE LABELING CHANGE AFFECT ME?	**All DePuySynthes External Fixation products etched MR-Safe or labeled with MR-Safe conditions, should be considered only MR-Conditional and used in accordance with MR-Conditional Labeling.** Updated External Fixation product literature can be referenced at www.DepuySynthes.com For more information, contact your local DePuy Synthes representative
KEYS FOR SAFETY AND EFFICACY	It is important to verify that every component on the frame is produced by DepuySynthes. For current labeling of DePuySynthes External Fixation systems please refer to package insert or product literature for each system. For more information please contact your local DePuy Synthes representative.
PARAMETERS FOR MRI SCANNING	A patient with DePuySynthes External Fixation devices may be scanned after placement of the Fixator under the following conditions: 1) Normal Operator Mode (1.5T / 3.0T) * 

2) First Level Controlled Mode (1.5T / 3.0T) *



** The field strength of a magnet is measured in **Tesla (T)**.*

IMPORTANT- Current labeling does not allow DePuySynthes external fixation frames to be placed completely inside the bore of MRI scanners. Please reference the current product insert for complete MR Conditions. For more information please contact your local DePuy Synthes representative.

IMPORTANT-THIS GUIDANCE APPLIES ONLY TO PRODUCT PRODUCED OR REPROCESSED BY DEPUYSYNTHES

Updated External Fixation literature can be referenced at www.DePuySynthes.com