





DePuySynthes Trauma External Fixator Systems
MR-CONDITIONAL LABELING UPDATE




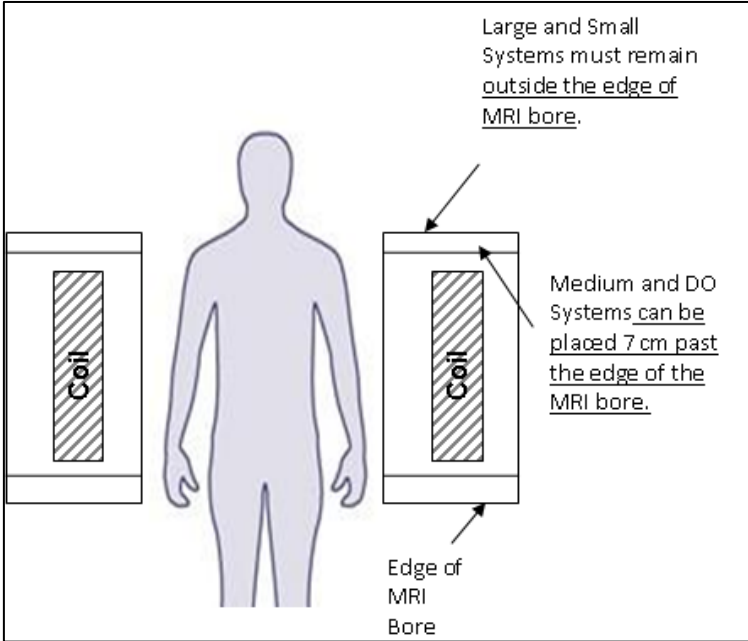
Affected Product *

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

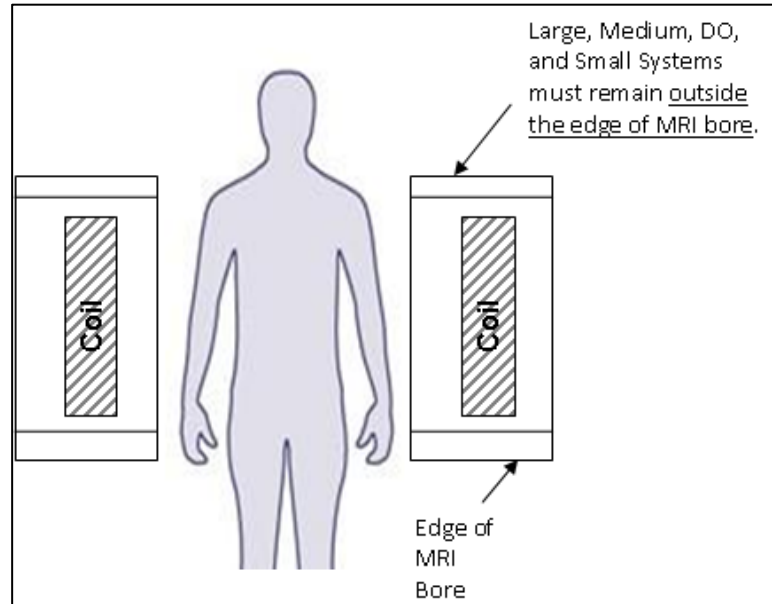
* External Fixation systems not listed here have not been evaluated for safety and compatibility in the MR environment, nor have been tested for heating or migration in the MR environment.

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

<p>LABELING CHANGE</p>	<p>All DePuySynthes Ex-Fix systems listed above are now labeled with the FDA accepted MR-Conditional symbol.</p>	
<p>HOW DOES THE LABELING CHANGE AFFECT ME?</p>	<p>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.</p> <p>Updated External Fixation product literature can be referenced at www.DepuySynthes.com.</p>	
<p>KEYS FOR SAFETY AND EFFICACY</p>	<p>It is important to verify that every component on the frame is produced by DepuySynthes.</p> <p>For current labeling of DePuySynthes External Fixation systems please refer to package insert or technique guide for each system.</p>	
<p>PARAMETERS FOR MRI SCANNING</p>	<p>A patient with DePuySynthes External Fixation devices may be scanned after placement of the Fixator under the following conditions:</p> <p>1) <u>Normal Operator Mode (1.5T / 3.0T) *</u></p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;">  </div>	

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 product Insert for complete MR Conditions.

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

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