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DePuy Synthes

To the ATTENTION of:
Hospital Personnel, including Imaging Department Personnel

14 April 2014

URGENT: VOLUNTARY MEDICAL DEVICE FIELD SAFETY NOTIFICATION (LABELLING CORRECTION)

Part Description / Part Number

Part Description	**Part Number**	**Lot Number**
Synthes Trauma External Fixation System (Small, Medium, Distraction Osteogenesis (DO) Ring and Large)	Please refer to Attachment 1	
Affected Labelling	**Number**	**Revision**
Please refer to Attachment 1		

Please note that this is a Medical Device Labelling Update only, it is not required to return the Synthes Trauma External Fixation System (Small, Medium, DO Ring, and Large).

Dear Valued Customer,

Synthes GmbH is initiating a Medical Device Labelling Update related to the Synthes Trauma External Fixation System. Our records indicate that you may have inventory that is subject to this Field Safety Notification. Synthes asks that you review the information contained in this Field Safety Notification and complete the Verification Section on page 4.

Description of the problem:

Labelling changes have been made to Synthes External Fixation Systems (Small, Medium, Large and DO Ring) related to MR conditions as a result of changes in required testing protocols to designate a product MR Safe, MR Conditional, or MR Unsafe. Metal devices are no longer identified as MR Safe and as a result Synthes Ex-Fix Systems are no longer labelled MR Safe. **The Synthes Ex-Fix Systems are now identified as MR Conditional and these systems may enter the MR environment but must be positioned as follows:**

- **Normal Operating Mode**:
  - Synthes Small and Large External Fixation Systems: positioned outside the MRI bore

  - Synthes Medium External Fixation and Distraction Osteogenesis: 7cm or less from within the outside edge of the MRI bore
- **First Level Controlled Mode**:
  - All Synthes Ex - Fix Systems: completely outside of the MRI bore.

Refer to the MRI Information section of your product's insert.

Potential hazard:
Use of the Synthes Ex-Fix Systems in the bore of the MRI or within 7cm of the outside edge of the bore, whether they are marked "MR Safe" or "MR Conditional", may result in heating of the device greater than 6 degrees Celsius. This heating may produce a thermal injury of soft tissue or bone damage resulting in patient discomfort or pain. It is not expected this would require surgical intervention or additional hospitalization but may require medical intervention appropriate to any thermal injury sustained.

Background:
The methodology used by the medical device industry for testing and marking products, ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment,* as well as current FDA Guidelines, provide a uniform marking system to indicate what MR conditions have been determined to be acceptable for a medical device. They provide MR labelling terms and associated visual icons intended to reduce injuries when potentially hazardous items are brought into the MR environment. The standard terminology is:

- **MR Safe** — used for items that are non-conducting, non-metallic and non-magnetic, such as a plastic Petri dish, and pose no known hazards in all MR environments.
- **MR Conditional** — used for an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Conditions that define the MR environment include static magnetic field strength, radio frequency fields, specific absorption rate, and artefact distortion around the image. For MR conditional items, the item labelling includes results of testing sufficient to characterize the behaviour of the item in the MR environment.
- **MR Unsafe** — defines an item that is known to pose hazards in all MRI environments, such as a pair of ferromagnetic scissors.

Customer immediate actions:

1. All Synthes External Fixation devices should be treated as MR Conditional.
2. Synthes asks that you review the information contained in this Labelling Notification and complete the Verification Section located on page 4.
3. Discard outdated revisions of the Technique Guides noted in the table on page 9.
4. Update your records with updated Labelling Information.
5. Forward this Field Safety Notification to anyone in your facility that needs to be informed, especially those personnel that conduct MR testing.
6. If the Verification Form is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual.
7. Updated product literature can be located on the Synthes website at http://syntheskyo.com/global_trauma_kyo/home/home.htm or contact DePuy Synthes for hardcopy.

8. Please see the attached insert for current conditions for use in the MR environment.
9. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

We apologise for any inconvenience that this Field Safety Notification may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Synthes GmbH

Pierre van Iwaarden
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

MEDICAL DEVICE FIELD SAFETY NOTIFICATION
FSN20131470

Synthes Trauma External Fixation System "MR Conditional"

Verification Section

Part Description	Part Number	Lot Number
Synthes Trauma External Fixation System (Small, Medium, DO Ring, and Large.)	Please refer to Attachment 1	
Affected Labelling	**Number**	**Revision**
Please refer to Attachment 1		

Please note that this is a Medical Device Labelling Update only, it is not required to return the Synthes Trauma External Fixation System (Small, Medium, DO Ring, and Large).

☐ We have located the Synthes Trauma External Fixation System (Small, Medium, DO Ring, and Large) within our stock, and acknowledge receipt of this information.

☐ We acknowledge receipt of this information but do not have the Synthes Trauma External Fixation System (Small, Medium, DO Ring, and Large).

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

Attachment 1

Part Description	Part Number	Lot Number
Pins etc. For Large External Fixator - MR Conditional Devices	293.350 to 293.360	ALL
	293.400 to 293.490	
	293.500 to 293.590	
	293.620 to 293.690	
	293.720 to 293.790	
	293.830 to 293.890	
	293.930 to 293.940	
	294.300	
	294.430 to 294.460	
	294.520 to 294.570	
	294.650 to 294.680	
	294.710 to 294.760	
	294.769	
	294.771 to 294.779	
	294.782 to 294.788	
	294.792 to 294.798	
	494.769	
	494.771 to 494.779	
	494.782 to 494.788	
	494.792 to 494.798	
	294.450SHA to 294.460SHA	
	294.520SHA to 294.570SHA	
	294.670SHA to 294.680SHA	
	294.730SHA to 294.760SHA	

	294.776SHA to 294.779SHA	
	294.782SHA to 294.788SHA	
	294.796SHA	
	494.784SHA to 494.786SHA	
Large External Fixation - MR Conditional Devices	390.002 to 390.013	ALL
	394.790 to 394.793	
	394.800 to 394.890	
	394.900 to 394.920	
Small External Fixation - MR Conditional Devices	390.041	ALL
	395.600 to 395.670	
	395.680 to 395.688	
	395.578	
	176.440S	
	898.000	
Medium & DO Ring External Fixation - MR Conditional Devices	292.410	ALL
	390.026 to 390.037	
	390.051	
	394.055	
	395.690 to 395.693	
	395.779 to 395.798	
	03.311.010 to 03.311.015	
	03.311.020 to 03.311.025	
	03.311.031 to 03.311.038	
	03.311.041 to 03.311.048	
	03.311.050 to 03.311.059	
	03.311.060 to 03.311.061	
	03.311.061.01	
	03.311.061.10	

	03.311.062	
	03.311.070 to 03.311.071	
	03.311.081 to 03.311.084	
	03.311.090 to 03.311.092	
	03.311.106 to 03.311.108	
	03.311.110 to 03.311.115	
	03.311.120 to 03.311.125	
	03.311.130 to 03.311.135	
	03.311.140	
	03.311.171 to 03.311.175	
	03.311.201 to 03.311.205	
	03.311.212 to 03.311.215	
	03.311.220 to 03.311.250	
	03.311.308 to 03.311.318	
	03.311.320 to 03.311.324	
	03.311.344 to 03.311.348	
	03.311.350	
	03.311.373 to 03.311.378	
	03.311.380	
	03.311.391 to 03.311.397	
	03.311.406	
	03.311.412	
	03.311.418	
	03.311.425	
	03.311.450	
	03.311.451	
	03.311.808	
	03.311.810 to 03.311.818	

	03.311.820 to 03.311.824	
	03.311.844 to 03.311.848	
	03.311.850	
	03.311.873 to 03.311.878	
	03.311.880	
	03.311.891 to 03.311.892	
	03.311.896 to 03.311.897	
	03.311.910 to 03.311.918	
	03.311.940 to 03.311.948	
	03.311.960 to 03.311.968	
	03.311.970	
	03.311.980 to 03.311.988	
	03.311.990	
Wire and Schanz Screw - MR Conditional Devices	292.750	ALL
	294.550	
	03.311.031S	
	03.311.032S	
	03.311.033S	
	03.311.041S	
	03.311.042S	
	03.311.043S	
Wrist - MR Conditional Devices	03.304.220S	ALL
	03.304.222S	
	03.304.320S	
	03.304.322S	

Affected Labelling (Surgical Techniques and Flyers)	**Number**	**Updated Revision**	**Outdated Revisions**
SurgTech - External Distal Radius Fixator	036.000.233	AB	AA
SurgTech - Small External Fixator	036.000.182	AC	AA, AB
SurgTech - Small External Fixator, Radiolucent, Sterile	036.000.389	AC	AA, AB
SurgTech - Large and Medium-Size External Fixators	036.000.237	AB	AA
Flyer - Medium External Fixator	036.000.236	AB	AA
Flyer - Large External Fixator	036.000.243	AB	AA
SurgTech - The Distraction Osteogenesis Ring System	036.000.643	AC	AA, AB
SurgTech - Elbow Hinge Fixator	036.000.663	AB	AA
Flyer - Elbow Hinge Fixator	036.000.662	AB	AA
SurgTech - Hydroxyapatite-Coated Schanz Screws	036.000.037	AB	AA
Flyer - Synthes External Fixation. Three dimensions, one system.	036.000.893	AB	AA
Flyer - External Fixation. Rod Systems and Supplements.	036.000.555	AB	AA
Flyer - Synthes Pediatric Solutions	036.000.828	No Update	all
Flyer - External Distal Radius Fixator	036.000.232	No Update	all
Flyer - Small External Fixator	036.000.184	No Update	all
Flyer - Small External Fixator, Radiolucent, Sterile	036.000.388	No Update	all