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DePuy Synthes
COMPANIES OF Johnson & Johnson

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

4 July 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)	292.400 395.578	All All
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_2

Synthes Trauma External Fixation System "MR Conditional"

Verification Section

Part Description	Part Number	Lot Number
Synthes Trauma External Fixation System (Small, Medium, Distraction Osteogenesis (DO) Ring and Large)	292.400 395.578	All All
Affected Labelling	**Number**	**Revision**
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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

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	obsolete	all
Flyer - External Distal Radius Fixator	036.000.232	obsolete	all
Flyer - Small External Fixator	036.000.184	obsolete	all
Flyer - Small External Fixator, Radiolucent, Sterile	036.000.388	obsolete	all