HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Trauma External Fixation System

(Small, Medium, Distraction Osteogensis (DO) Ring and Large)

Priority 2 – Warning

HPRA Safety Notice: SN2014(36) **Issue Date: 12th August 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Manufacturer: Synthes GmbH	V20584

ISSUE
The Health Products Regulatory Authority (HPRA) has been notified of a change in the labelling and instructions for use of the Synthes Trauma External Fixation System. These devices are now designated as 'MR-Conditional'. Etch marked devices, distributed prior to this labelling change are labelled 'MR-Safe'. Affected devices must be treated as 'MR-Conditional'. These systems may enter the MR environment, but to ensure patient safety during scanning, patients must be positioned according to the product labelling and Instructions for Use (IFU).

ACTION OR RECOMMENDATIONS
The HPRA advises users to: 1 Identify all affected part numbers and follow the instructions as outlined in the manufacturer's field safety notices. 2 Treat Synthes Trauma External Fixation devices as 'MR-Conditional' including affected devices etch marked as 'MR-Safe'.

3	Download or request the new instructions for use.
4	Review the updated labelling of the device and update your records accordingly.
5	Ensure relevant staff are aware of the field safety notices and updated labelling information. Please also provide a copy of the field safety notice and updated labelling to any other persons/organisations where these devices have been transferred.

TARGET GROUPS

Medical Directors	Risk Managers
MRI Department Staff	Hospital Consultants
Director of Radiology	Medical Physicists
Radiographers	Biomedical / Clinical Engineering Staff
Radiologists	

BACKGROUND

Synthes has issued two field safety notices in relation to this issue. An updated field safety notice was issued on the 4th July 2014 containing additional part numbers omitted in the original FSN of the 14th April 2014.

Following changes to the ASTM F2503 Standard on Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, the 'MR-Safe' designation can only be applied to items that are non-conducting, non-metallic and non-magnetic. Synthes have initiated this Field Safety Corrective Action to inform users of the new device labelling and IFU. Failure to follow the updated information may result in thermal injury to soft tissue, bone damage, patient discomfort and pain.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Dr. Pierre van Iwaarden, Field Action Manager Synthes GmbH Luzernstrasse 21 Zuchwil 4528 Switzerland	Telephone: +41 32 720 49 33 Fax: E-mail: vaniwaarden.pierre@synthes.com Website:

Enquiries to the **distributor** should be addressed to:

N/A	N/A

HPRA CONTACT INFORMATION		
All **adverse incidents** relating to a medical device should be reported to:		
Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: Fax: E-mail: Website:	+353-1-6764971 +353-1-6344033 devicesafety@hpra.ie www.hpra.ie