Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com/

DePuy Synthes

To the ATTENTION of:
Operating Room Manager

28 May 2014

Part Description	Part Numbers	Lot numbers
Guide Wire Ø 3.2 mm, length 400 mm	357.399	7528889;7560756; 7567092 7583847; 7592959; 7530182; 7561337; 7567692; 7584396; 7593772; 7559782; 7561643; 7569386; 7588691; 7594896; 7560829; 7562800; 7569471; 7589236; 7594058; 7561332; 7565795; 7583667; 7589696; 7594057;

Dear Valued Customer,

Synthes GmbH is issuing a voluntary Field Safety Notification related to the above mentioned lots of the Guide Wire Ø 3.2 mm, length 400 mm. This Field Safety Notification is similar to the Field Safety Notification FSN 2013071 (25.03. 2014). However, please be aware that this Field Safety Notification addresses a different material mislabeling and that different LOT numbers are involved.

Our records indicate that you may have inventory that is subject to this Field Safety Notification. Synthes kindly requests you to review the information contained in this Field Safety Notification and complete the Verification Section at the end of this letter.

Description of the problem:
The Guide Wire Ø 3.2 mm, length 400 mm was mislabeled with an incorrect raw material.
The label incorrectly declares Molybdenum instead of Wolfram and Nickel as alloyed elements. The correct labelling is "CoCrWNi Alloy".

Potential hazard:
There is a potential harm associated with the mislabeled product for Adverse Tissue Reaction. During the normal course of the surgery, this risk is decreased as the guide wire is not retained in the body after the procedure is completed. However in the case of a broken guide wire, a fragment may be retained after surgery. In this case, a patient with a sensitivity to nickel, could develop a moderate Adverse Tissue Reaction which may manifest as allergic reactions or the formation of tumor-like masses, also called pseudo-tumors.

Requested Immediate Customer actions:

1. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.

2. Forward this notice to anyone in your facility that needs to be informed.

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3. If any product listed below has been forwarded to another facility, contact that facility and provide them with this letter.

4. Maintain a copy of this notice.

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

We apologise for any inconvenience that this voluntary 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.

Synthes GmbH

Dr. med. Maria I. Behrens MDRA

Field Action Manager

CHARLES GOLDSTEIN ON BEHALF OF

Markus Wien

Director Quality Assurance Operations

Synthes GmbH
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☐ We have located the identified product in stock; a copy of this letter is being retained for our records.

☐ We do not have any identified product in stock. We have retained a copy of this letter for our records.

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____