4 December 2015

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION – FSN2015163
Kirschner Wire 1.6mm w/Drill Tip, L 200mm (sterile)

Please note that this is a Medical Device Field Safety Notification only; it is not required to return any of the affected products.

Please distribute this information to appropriate personnel at your facility.

Part Description, Part and Lot Numbers

Part Description	Part Numbers	Lot Numbers
Kirschner Wire Ø 1.6 mm, with drill tip, length 200 mm	02.113.001	All
Kirschner Wire Ø 1.6 mm, with drill tip, length 200 mm, sterile	02.113.001S	All

Dear Sir/Madam,

Synthes GmbH is initiating a Field Safety Notification for the Kirschner Wire for the above mentioned Part- and Lot Numbers. Kirschner Wire implants are indicated for a wide range of orthopaedic trauma applications including stand-alone device for fracture fixation and fracture fixation in conjunction with other fixation systems.

Our records indicate that your facility may have the affected product(s) subject to this Field Safety Notification or has been using the affected product(s) from a loan set.

Synthes asks that you review the information contained in this Field Safety Notification and complete the Verification Section located on page three of this notification.

Reason for the Field Safety Notification

The Kirschner wire is made from Co35Ni35Cr20Mo10 (MP35N) which is a cobalt based alloy containing 35% nickel. However, the label and technique guide incorrectly indicate that the devices are made of stainless steel.

The product is shipped with an insert which references the potential risk of allergy/hypersensitivity reactions, but there is no specific information on the label or in the technique guide with regards to the percentage of nickel content in the devices.

Potential hazard

For patients with known nickel sensitivity, products labelled as containing stainless steel should be avoided since stainless steel contains nickel and an alternate product is generally chosen.

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
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Business Reg No. 52836279L Company Reg No. 197402104W

Implanted wires or unintentionally retained fragments that are left in the patient pose a potential risk of an Adverse Tissue Reaction which could be worse in a population sensitive to nickel. As MP35N is a more corrosion-resistant alloy and more biocompatible than stainless steel, the likelihood of a patient being exposed and sensitized to a higher amount of nickel or other alloys is low compared to a product manufactured from stainless steel. Therefore, the risk for an Adverse Tissue Reaction is lower than if the product was made of stainless steel. MP35N is considered implant-grade quality.

Customer immediate actions:

Please take the following actions:

- Review the instructions listed in this notification.
- Forward this notice to anyone in your facility that needs to be informed.
- If any of the affected products has been forwarded to another facility, contact that facility and provide them with a copy of this letter.
- Complete the Verification Section (page 3 of this letter) and return the completed Verification Section to your local DePuy Synthes contact person.
- 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 in page three of this notification.
- Keep a copy of this notice.

We sincerely apologize for any inconvenience that this issue may create. Should you have any questions please do not hesitate to contact your DePuy Synthes sales consultant or contact person.

Thank you for your attention and cooperation.

Yours sincerely,

[redacted]

Lee, Ching Hwee
Senior Regulatory Affairs Specialist

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Verification Section

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Part Description	Part Numbers	Lot Numbers
Kirschner Wire Ø 1.6 mm, with drill tip, length 200 mm	02.113.001	All
Kirschner Wire Ø 1.6 mm, with drill tip, length 200 mm, sterile	02.113.001S	All

Please check (√) accordingly:

☐ We have located the Kirschner Wire Ø 1.6 mm, with drill tip, length 200 mm (sterile) within our stock, and acknowledge receipt of the updated information.

☐ We acknowledge receipt of this information, but do not have Kirschner Wire Ø 1.6 mm, with drill tip, length 200 mm (sterile) in stock.

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____ _____

Customer Name Title

_____ _____

Signature & Date Stamp ***(Stamp shall bear facility name)***

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.

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