05 May 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015146
Recall of 3.5mm Locking Screws
Stardrive®, Self·Tapping & Hex Drive, Self·Tapping

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers
Locking Screw Stardrive®, Self·tapping.	412.104S	9137946
	412.105S	9211047
Locking Screw Hex Drive, Self·Tapping	413.016	9043572
	413.016	9109629
	413.016	9137919
	413.016	9199768
	413.016	9215837

Synthes GmbH is initiating a medical device recall of the above specified lots of 3.5mm Locking Screws. Stardrive®, Self·Tapping & Hex Drive, Self·Tapping screws for plates are intended for temporary fixation, correction or stabilization of bones in various anatomical regions.

Our records indicate that you may have inventory, including loaner sets, which are impacted by this recall.

Reason for the Recall

Packages of the affected StarDrive Locking Screw lots mistakenly include a Hex Drive Locking Screw, with labels and etchings on the screws for a StarDrive Locking Screw part number and lot number.

Packages of the affected Hex Drive Locking Screw lots mistakenly include a StarDrive Locking Screw, with labels and etchings on the screws for a Hex Drive Locking Screw part number and lot number.

Potential Patient Impact:

The non-conformance may result in surgical delay. There is a visual difference between a Hex Drive recess and a Star Drive recess. The difference between the two screws would likely be visually detected during the preoperative period as the recess would not match the other screw heads or fit onto the screwdriver once the sterile package has been opened. If the discrepancy is identified inside the operative theatre, the user may replace it with a

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

screw of the correct recess, leading to surgical delay while a replacement screw is procured.

Customer immediate actions:

Please verify whether you have any of the affected products and take the actions listed below, as appropriate. If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter.

If you **DO HAVE** any of the identified affected product please take the following steps:

- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Keep a copy of this communication with any affected product(s) identified above.
- Complete the Verification Section (page 4 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their Lot Number. Please include your name, title, address, telephone number and signature in the spaces provided.
- Return the completed Verification Section to your local DePuy Synthes contact person.
- Contact your local DePuy Synthes sales organisation to arrange the return of the affected devices and for a free of charge replacement.

If you **DO NOT HAVE** any of the identified affected product(s), please take the following steps:

- Complete the attached Verification Section (page 4 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device recall information.
- Return the completed Verification Section to your local DePuy Synthes contact person.

We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

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Yours Sincerely,

Lee, Ching Hwee
Associate Manager, Regulatory Affairs

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Please check (√) accordingly:

☐ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

☐ We located the identified product in stock; returned quantity is documented below:

Product Code	(Lot Number)	Quantity (Number in "Eaches")

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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