

**To the ATTENTION of:
Operating Room Manager**

12 November 2015

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015146
Recall of 7 lots of 3.5mm Locking Screw
Stardrive®, Self-Tapping.**

Dear Sir/Madam,

Synthes GmbH is initiating a medical device recall of the below specified lots of 3.5mm Locking Screws.

Our records indicate that you may have inventory that is impacted by this recall.

Part Description, Part-Lot Numbers.

Part Description	Part Number	Lot Number
Locking Screw Stardrive®, self-tapping.	412.104S	9137946
	412.105S	9211047
	413.016	9043572
	413.016	9109629
	413.016	9137919
	413.016	9199768
	413.016	9215837

Stardrive®, Self-Tapping screws for plates are intended for temporary fixation, correction or stabilization of bones in various anatomical regions.

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.

Potential hazard

The nonconformance 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 theater, the user may replace it with a 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 3 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:

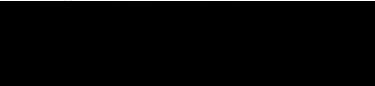
- Complete the attached Verification Section (page 3 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device recall information.
- Return the completed Verification Section to your local DePuy Synthes contact person.

The applicable regulatory agencies are being notified.

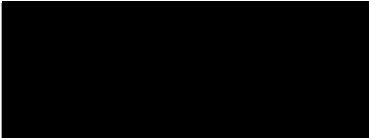
We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant or contact person.

Thank you for your attention and cooperation.

Synthes GmbH



Paul Ames
Field Action Manager



David Carvin
Quality Manager

Account Name: _____

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Verification Section

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	413.016	9137919
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____ We have located the identified product in stock; returned quantity is documented below.

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

RETURNED DEVICES (including quantity):

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page your local DePuy Synthes sales organization.

Note: If the Verification Section 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 on this page of the notification.