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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

19 August 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014779
Cannulated Headless Compression Screw, Length 22 mm, Thread 8.0 mm

Dear Sir/Madam,

Synthes GmbH is initiating a medical device recall of the specified lot of the Cannulated Headless Compression Screw, Length 22 mm, Thread 8.0 mm listed below.
Our records indicate that you may have inventory that is impacted by this recall.

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Number
HCS - Headless Compression Screw Ø 3.0 mm, self-drilling, cannulated, length 22/8 mm, Titanium Alloy (TAN), gold	04.226.122	9052930

Cannulated Headless Compression Screw, Length 22 mm, Thread 8.0 mm, is intended for fixation of intra-articular and extra-articular fractures and nonunion of small bones and small bone fragments, arthrodesis of small joints, bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellium, radial head and radial styloid.

Reason for the Recall
A package labeled with Part Number 04.226.122 (3.0 mm, cannulated headless compression screw, length 22 mm, thread 8 mm) actually contained Part Number 04.226.022 (3.0 mm, cannulated headless compression screw, length 22 mm, thread 4.0 mm).

Potential hazard
Any delay in surgical proceedings would be expected to be marginal as the complete set of implants and instruments is very likely to contain the expected screw and shaft thread length.

Customer immediate actions
Please verify whether you have any of the affected products and take the following actions, 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 for a free of charge service.

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

[redacted]

Paul Ames
Field Action Manager

[redacted]

Anne Brisson
Senior Quality Manager, Product Safety and Performance

Cc:

DePuy Synthes

Account Name: _____

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Verification Section

Part Description / Part Number:

Part Description	Part Number	Lot Number
HCS - Headless Compression Screw Ø 3.0 mm, self-drilling, cannulated, length 22/8 mm, Titanium Alloy (TAN), gold	04.226.122	9052930

____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.