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DePuySynthes

To the ATTENTION of:
Operating room manager

11 June 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
09.213.022S – 09.213.070S	Dynamic Locking Screw Stardrive® Ø 3.7 mm, self-tapping, length 22 - 70 mm, Cobalt-Chrome Alloy (CoCrMo), sterile	all lots
09.223.032S – 09.223.090S	Dynamic Locking Screw Stardrive® Ø 5.0 mm, self-tapping, length 32 - 90 mm, Cobalt-Chrome Alloy (CoCrMo), sterile	all lots

Dear Sir/Madam

Synthes is initiating a voluntary recall of all lots of the Dynamic Locking Screws (DLS) Ø 3.7 mm and the Dynamic Locking Screws Ø 5.0 mm. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

The voluntary recall is being initiated following customer complaints of DLS 3.7 and 5.0 mm breakages at the distal tip of the pin identified after successful healing and during planned implant removal of the whole construct.

Patient risk:

There have been no reports of permanent impairment associated with the reason for this recall to date. However, DePuy Synthes is aware that significant elongation of surgical time has occurred in planned implant removals which involved a broken DLS screw. Additional information is available for the Health Care Providers in your institution; please provide the attached letter to those health care providers who have used DLS.

Patients who have had procedures using the Synthes DLS 3.7 and 5.0mm should be followed under routine standard of care at their institution.

Customer immediate actions:

1. Immediately identify and quarantine all unused product listed above in a manner that ensures the affected product will not be used.
2. Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days. Credit or replacement will be provided based on product availability.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to Synthes GmbH.
7. Maintain a copy of this notice with the affected product

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

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH

i.V. A. Vieth

Claudia Allemann
Field Action Manager

CHARLES GOLDSEN
FOR MARKUS WIEN
4/11/13

Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL

Dynamic Locking Screws Ø 3.7 mm
Dynamic Locking Screws Ø 5.0 mm

09.213.022S - 09.213.070S
09.223.032S - 09.223.090S

Verification Section

☐ We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.

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

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Name of hospital: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

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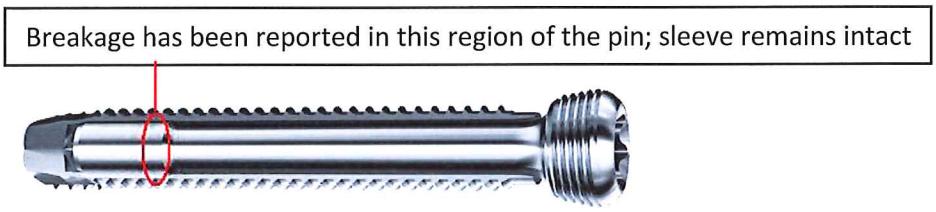
SYNTHES®

10 June, 2013

Dear Dr.< Surgeon name > :

This letter is to inform you that we are initiating a voluntary recall of Synthes 3.7mm and 5.0mm Dynamic Locking Screws (DLS). This recall affects all lots globally. We would like to provide you with additional information to help you understand how this recall may be relevant in patient management decisions for patients who have the screws implanted at present.

We initiated this voluntary recall because Synthes Trauma received product complaints for the Synthes 3.7mm and 5.0mm DLS that identified that DLS pin breakage during planned implant removal, after uneventful and successful healing of the fracture. In the reported complaints, the pin breakage was noted to be at the distal end of the pin.



The following information is derived from complaints reported to Synthes to date. Of the eight planned surgical removals of the constructs for which Synthes has data, five patients had at least one break of 5.0mm DLS at the distal end of the pin. Seven of the 30 screws removed during these procedures were broken. One of the five surgical removals was reported to be prolonged by 45 minutes. We are providing this information for reference as it may be relevant to your ongoing patient management decisions. It is important to note that according to the information that we have received to date, this pin breakage issue has not impacted product functionality.

Patients who have had procedures using the Synthes 3.7mm and 5.0mm DLS should be followed per routine standard of care at your institution. During the post-surgical period with an implanted DLS, if a patient complains of symptoms or develops signs suggestive of a clinical issue, you should institute your standard diagnostic evaluation and treatment for these types of events. If the evaluation suggests that the implant should be removed, please contact your institution's Synthes Sales Consultant in order to obtain the required instrumentation for removal.

If you have a product complaint or have identified an adverse event in a patient, please report this to your local Synthes sales representative.

Should you have any further questions, please feel free to contact me directly.

Yours sincerely,

C Fang, MD

W. Christopher Fang, MD
Worldwide Vice President
Strategic Medical Affairs and Medical Sciences
Synthes Trauma