29 Apr 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2016028
Cortex Screw Ø 4.5mm, self-tapping, length 20mm, Pure Titanium

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
Cortex Screw Ø 4.5mm, self-tapping, length 20mm, Pure Titanium	414.820	2610310
Cortex Screw Ø 4.5mm, self-tapping, length 20mm, Pure Titanium	414.820S	3485895

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the 4.5 mm Cortex Screws. These screws are used with various LCP Plates 4.5/5.0.

Our records indicate that you may have inventory that is impacted by this recall or have affected product(s) from a loan set.

Reason for the Recall

Two lots of 4.5mm Cortex Screws, length 20mm, may contain a 4.5mm Cortex Screw that is 22mm in length. The screws are both etched and labeled with the above 20mm Part numbers.

Potential Patient Impact:

The outside package labeling and the etching on the product would indicate to the user that the screw is 2mm shorter than its actual length of 22mm. For non-sterile products, there is an opportunity to detect the issue if the screw is measured prior to placement into the tray/module. Once the screw enters the operating room, either sterile or unsterile, the user should measure the screw prior to insertion. If detected at this time it may result in a surgical delay while a replacement is obtained or if the surgeon inserts the screw, determines it was the wrong length on radiographic imaging, and then removes and replaces it.

In addition, the potential harm of Damage to Surrounding Structures including damage to articular surface during insertion could occur, depending upon the location and angle of screw. A screw that is too long can also result in Soft Tissue Damage (Soft Tissue

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
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Business Reg No. 52836279L Company Reg No. 197402104W

Irritation) if not recognized during the procedure. At this time there have been no reports of patient involvement.

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected products listed above in a manner that ensures the affected products will not be used.

2. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.

4. Forward this notice to anyone in your facility that needs to be informed.

5. If any of the affected products 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 DePuy Synthes.

7. Keep a copy of this notice.

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.

Yours Sincerely,

[redacted]

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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