21 January 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015166
LCP Distal Tibial Plates and Expert™ A2FN Nail

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
LCP Distal Tibial Plate 3.5 anterolateral, left, 9 holes, length 132mm Stainless Steel Sterile	241.445S	8361311
Expert™ A2FN, Nail ∅ 11.0mm, Right, Cannulated length 360mm, Titanium Alloy (TAN), light green Sterile	04.009.452S	3632731

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the LCP Distal Tibial Plate and Expert™ A2FN Nail. The LCP Distal Tibial Plate is intended for temporary fixation, correction or stabilization of bones in various anatomical regions. The Expert™ A2FN nail is indicated for fractures in the femoral shaft.

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

Reason for the Recall

It was discovered that the outer packaging and the inner pouch of the above mentioned parts and lots may not be sealed; thus the implants are potentially not sterile.

Potential Patient Impact:

In the event that the plate or nail is implanted despite unsealed peel pouches, infection and adverse tissue reaction may occur. In the event that an unsealed outer packaging is identified by the circulator, surgical delay may occur while an alternative plate or nail is located within the surgical suite or while the circulator critically evaluates the inner pouch to ensure it is sealed.

In the event that an unsealed outer peel pouch goes unnoticed and the non-sterile outside of the inner peel pouch is introduced into the sterile field, infection and adverse tissue reaction may occur as the outside of the inner peel pouch is considered contaminated.

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

In the event that the inner and outer peel pouch are discovered to be unsealed, surgical delay could occur as the circulator would need to either locate an alternative product in the surgical suite or clean and sterilize the plate or nail.

Customer immediate actions:

1. Immediately identify and quarantine all unused 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
Senior Regulatory Affairs Executive

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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 have 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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