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DePuy Synthes
companies of Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

16 June 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015026
TFNA Helical-Blade Impactor

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Number
TFNA Helical-Blade Impactor	03.037.024	T102762

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of one lot of the TFNA Helical-Blade Impactor of the TFN-ADVANCED™ Proximal Femoral Nailing System. The TFNA System is intended for treatment of proximal femoral fractures.

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

Reason for the Recall:

The height of one of the three guiding pins of the TFNA Helical-Blade Impactor may potentially be oversized. If the guiding pin were to be oversized, the TFNA Helical-Blade Impactor (part number 03.037.024) would not be able to pass through the Guide Sleeve (part number 03.037.017).

03.037.017 Guide Sleeve, yellow

Potentially oversized guiding pins

03.037.024 TFNA-Helical Blade Impactor

Potential hazard:

If the TFNA Helical-Blade Impactor is not able to pass through the Guide Sleeve, there is the potential for surgical delay while an alternative trauma set is located to complete the procedure.

In the event that the screw inserter or implants are not available and a different system is used, the nail would need to be removed before switching to a different system. The potential

harm involved in removing an implanted TFNA and inserting an alternative nail may result in bone fracture intra-operatively.

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.

Synthes GmbH

[redacted]

Field Action Manager

[redacted]

Worldwide Director Complaint Management

Cc: [redacted]

DePuy Synthes

Account Name: _____

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015026
TFNA Helical-Blade Impactor

Verification Section

Part Description / Part Number:

Part Description	Part Number	Lot Number
TFNA Helical-Blade Impactor	03.037.024	T102762

____ 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.