4 February 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015124
Extraction Screw for PFNA Blade

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
Extraction Screw for PFNA Blade	356.825	2089467; 2090743; 2101443; 2103560; 2107022; 2107094; 2109115; 2114311; 2119302; 2125711; 2127225; 2135962; 2145558; 2155648; 2162089; 2163636; 2168449; 2186602; 2187918; 2193852; 2203709; 2216008; 2225226; 2225992; 2234804; 2238532; 2238533; 2257480; 2257481; 2263698; 2265892; 2311442; 2324437; 2354073; 2357959; 2370086; 2389952; 2401175; 2416428; 2442559; 2443570; 2450764; 2458359; 2475991; 2484015; 2485474; 2498270

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Extraction Screw for PFNA Blade. The Extraction Screw for PFNA Blade is a part of the PFNA and PFNA II Systems.

Our records indicate that you may have inventory that is impacted by this recall.

Reason for the Recall

Through a complaint investigation, it was discovered that the affected lots of the Extraction Screw could break or disassemble from the instrument. This may interfere with removal of the PFNA and PFNA-II Blade from the patient.

Potential Patient Impact:

In the event that the PFNA blade cannot be removed, surgical delay would likely occur as the situation is assessed and the next steps are determined. The extraction screw (356.825) is used with the PFNA and PFNA-II and it is possible that another extraction screw (356.825) or the newer version (P/N 03.010.411) may be available. However, it is possible the issue could result in a reoperation to remove the blade and nail at a later date.

Additionally, breakage or damage to the extraction screw would likely result in surgical delay while the damage is assessed. The point in surgery when it was determined that the extraction screw broke would likely impact the delay. If determined intraoperative, that

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
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Business Reg No. 52836279L Company Reg No. 197402104W

the extraction screw was broken, the surgical suite would be searched for a replacement or alternative for blade removal.

During use, unnoticed breakage of the non-implant grade Extraction screw may also result in adverse tissue reaction.

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.