4 December 2015

URGENT MEDICAL DEVICE RECALL – R2015123
Recall of Version 1, 3.1 & 3.2 of the PFN/PFNA Insertion Handle

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Synthes GmbH is initiating a medical device recall of the below specified lots of Versions 1, 3.1 & 3.2 of the PFN/PFNA Insertion Handle. The PFN/PFNA Insertion Handle 357.012 is made to insert PFN/PFNA/PFNAII/PFNA augmented nails.

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

Part Description	Part Number	Lot Number			
Insertion Handle for PFN/PFNA	357.012	1001	1002	1006	1008
		1012	1015	1017	1019
		1001913	1007048	1008229	1008230
		1009094	1015569	1015849	1018861
		1021038	1021039	1021040	1021041
		1021044	1021045	1021046	1021051
		1021047	1021048	1021050	1041119
		1037978	1041117	1041118	1041123
		1041120	1041121	1041122	1041334
		1041124	1041125	1041333	1860401
		1041868	1041888	1811954	1911588
		1860402	1860810	1893461	1955322
		1920902	1920904	1939597	3007222
		1959882	1998944	1998945	3024229
		3007243	3007247	3024228	3086983
		3061690	3073276	3079047	3094722
		3087336	3087338	3087493	3115143
		3104468	3115140	3115141	3167215
		3167210	3167213	3167214	3204088
		3167216	3167218	3173563	N2002
		3215818	3220493	N2001	N2006
		N2003	N2004	N2005	2002
		2003	2004	2005	2006

Reason for the Recall

The insertion handle may break when struck with a hammer during the nail insertion process.

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
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Pictures: Example of broken Insertion Handles 357.012

Potential hazard

The surgeon would likely immediately notice a breakage of the insertion handle and a surgical delay would likely occur as the surgeon disassembles the insertion handle and a replacement is located within the surgical suite. The parts would likely need to be dismantled and re-assembled if a replacement is available. In the event that a replacement handle cannot be located, the nail would likely be exchanged for another proximal femoral nail. The degree of surgical delay would be affected by the point in the surgical procedure when the break occurs i.e. if the nail has been fully inserted or not. In addition, depending on the availability of alternative parts, a worst case scenario would result in cancellation and re-scheduling of surgery.

The handle is made from a composite carbon fiber epoxy laminate with stainless steel inserts, the materials are non-implant grade. Thus, any fragment left in the patient may result in an Adverse Tissue Reaction. However, the operative site would be likely be irrigated with copious amounts of irrigant and suctioned to reduce the foreign debris.

Customer immediate actions:

Please verify whether you have any of the affected products and take the actions listed below, as appropriate. If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter.

If you **DO HAVE** any of the identified affected product please take the following steps:

- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Keep a copy of this communication with any affected product(s) identified above.
- Complete the Verification Section (page 4 & 5 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their Lot Number. Please include your name, title, address, telephone number and signature in the spaces provided.

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- Return the completed Verification Section to your local DePuy Synthes contact person.
- Contact your local DePuy Synthes sales organisation to arrange the return of the affected devices and for a free of charge replacement.

If you **DO NOT HAVE** any of the identified affected product(s), please take the following steps:

- Complete the attached Verification Section (page 4 & 5 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device recall information.
- Return the completed Verification Section to your local DePuy Synthes contact person.

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 or contact person.

Thank you for your attention and cooperation.

Yours sincerely,

[redacted]

Lee, Ching Hwee
Senior Regulatory Affairs Specialist

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Verification Section

Part Description, Part Number and Lot Numbers

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		3167216	3167218	3173563	N2002
		3215818	3220493	N2001	N2006
		N2003	N2004	N2005	2002
		2003	2004	2005	2006

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.

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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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