20 May 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2016030
Flexible Shaft Ø 8.0mm, L 360mm

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
Flexible Shaft Ø 8.0mm, L 360 mm for Extraction System for Solid Medullary Nails	351.430	All Lots distributed prior to 03May2016

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Number of the Flexible Shaft Ø 8.0mm, L 360 mm for Extraction System for Solid Medullary Nails. These devices are reamers intended for bone reaming, for nail implantation in fractures of the upper and lower extremities, as well as for inserting or removing screws/plates as fixation elements during fracture treatment procedures. Our records indicate that you may have inventory that is impacted by this recall.

Please note that these products are discontinued for sale, and there are currently no replacement devices available.

Reason for the Recall

The device did not pass the biological safety evaluation for cytotoxicity following exposure to test conditions. The high growth inhibition levels observed during testing could be attributed to corrosion of the device at solder points. This could potentially be reproduced during use and reprocessing.

Potential Patient Impact:

Should the device develop corrosion while in use, the patient could be briefly exposed to potentially cytotoxic material, the consequences of which could be **Adverse Tissue Reaction**, and **Surgical Delay**. The potential risk to patient of complete unavailability of the product is Bone Fracture Intra-op, Neuro-vascular Damage, Damage to Surrounding Structures, Surgical Delay, and Soft Tissue Damage.

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

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,

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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