

16 December 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015126
PFNA, PFNA-II, DFN, & PFN Nails, PFNA & PFNA-II Blades, and PFNA & PFNA-II End Cap Extensions

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Descriptions	Part Numbers	Lot Numbers
See Attached List		

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Proximal Femoral Nail Antirotation (PFNA) Nails, PFNA-II Nails, Distal Femoral Nails (DFN), Proximal Femoral Nails (PFN), PFNA Blades, PFNA-II Blades, PFNA End Cap Extensions and PFNA-II End Cap Extensions. The Proximal Femoral Nail Antirotation (PFNA) and the Proximal Femoral Nail Antirotation II (PFNA-II) Systems are developed for the treatment of proximal femur and combinations of proximal and shaft fractures of the femur. The Distal Femoral Nail (DFN) was developed for the stabilization of fractures in which a retrograde approach is indicated. The Proximal Femoral Nail (PFN) system was developed for the treatment of pertrochanteric, intertrochanteric and high subtrochanteric fractures. Please note, this recall is an extension of R2014081.

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

Reason for the Recall

It was discovered that the above part and lot numbers may have the incorrect anodized colour.

Potential hazard

An implant with the incorrect anodized colour would not cause harm to the patient. If the user identifies the nonconformity during surgery, marginal surgical delay may occur while an alternate implant is located. Please note that PFNA, PFNA-II, DFN, & PFN Nails, PFNA & PFNA-II Blades, and PFNA & PFNA-II End Cap Extensions were manufactured correctly, with the exception of the anodized coding.

Customer immediate actions:

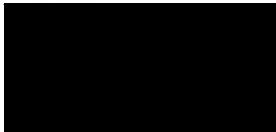
1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.

2. Review, complete, sign and return the attached reply form on page 4 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
Senior Regulatory Affairs Executive

Attachment 1 – List of Affected Products

Part Descriptions	Part Numbers	Lot Numbers
DFN ø10 nail cannulated L200 TAN green	451.782	2664232
PFNA End Cap extension 0 T40 TAN	04.027.000S	2681953
PFNA Blade perforated L120 TAN	04.027.039S	2816407
PFNA-II Blade L85 TAN	04.027.052S	2739323
PFNA-II Blade L90 TAN	04.027.053S	2579511
PFNA-II Blade L90 TAN	04.027.053S	2799965
PFNA-II Nail ø12 XS 125° L170 TAN	472.103S	2723806
PFNA-II Nail ø10 XS 130° L170 TAN	472.105S	2813293
PFNA Nail ø11 125° L240 TAN	472.261S	2812685
PFNA Nail ø10 long r 125° L340 TAN	472.275S	2806520
PFNA Nail ø10 sm 130° L200 TAN	472.375S	2692465
PFNA-II Nail ø10 long r 130° L380 TAN	473.020S	2794884
PFNA-II Nail ø10 long le 125° L260 TAN	473.050S	2779480
PFNA-II End Cap extension 0 TAN	473.170S	2571237
PFNA-II End Cap extension 0 TAN	473.170S	2736028
PFNA-II Nail ø11 130° L240 TAN	473.806S	2803359
PFNA-End Cap extension 5 T40 TAN	04.027.001S	7721983
PFNA-II Nail ø10 XS 130° L170 TAN	472.105S	7736069
PFNA-II Nail ø10 130° L240 TAN	473.805S	7717734
PFN Nail ø10 db re 130° L340 TAN green	473.345	7948514
PFN Nail ø10 db li 125° L340 TAN green	473.540	8539004
DFN Nail ø9 solid L360 TAN green	451.708	7792253
DFN Nail ø10 db L320 TAN green	451.786	8710070
DFN Nail ø12 db L340 TAN green	451.827	8441821
PFNA Nail ø10 125° L240 TAN	472.260S	7913867
PFNA Nail ø10 130° L240 TAN	472.265S	8664414
PFNA Nail ø11 130° L240 TAN	472.266S	8766159
PFNA Nail ø10 kl 125° L200 TAN	472.370S	7750439
PFNA Nail ø11 kl 125° L200 TAN	472.371S	7913875
PFNA Nail ø9 kl 125° L200 TAN	472.430S	8653388
PFNA Nail ø9 kl 125° L200 TAN	472.430S	8653395
PFNA Nail ø9 long re 130° L300 TAN	04.023.104S	8114237
PFNA-Blade perforated L90 TAN	04.027.033S	7995990
PFNA-II Nail ø9 XS 125° L170 TAN	472.100S	8539177
PFNA-II Nail ø10 XS 130° L170 TAN	472.105S	8212200
PFNA-II Nail ø10 XS 130° L170 TAN	472.105S	8841635
PFNA-II Nail ø11 XS 130° L170 TAN	472.106S	8728689
PFNA-II Nail ø10 kl 125° L200 TAN	472.111S	8761883
PFNA-II Nail ø9 kl 130° L200 TAN	472.114S	7818607
PFNA-II Nail ø9 kl 130° L200 TAN	472.114S	7913870
PFNA-II Nail ø10 kl 130° L200 TAN	472.115S	7888584
PFNA-II-Blade L95 TAN	04.027.054S	7837852
PFNA-II-end cap extension 0 TAN	473.170S	9032368

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Dear Sir/Madam,

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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.