

16 March 2015

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014081
PFNA and PFNA-II Femoral Nails and PFNA-II Endcaps**

Please distribute this information to the appropriate personnel at your facility

Part Description, Part and Lot Numbers

Part Descriptions	Part Numbers	Lot Numbers
PFNA-II Proximal Femoral Nail \varnothing 10 mm, Small, 130°, Length 200 mm, Titanium Alloy (TAN), Sterile	472.115S	8711483
PFNA-II Proximal Femoral Nail \varnothing 10 mm, Small, 130°, Length 170 mm, Titanium Alloy (TAN), Sterile	472.390S	8749027
PFNA-II Proximal Femoral Nail \varnothing 9 mm, Small, 130°, Length 200 mm, Titanium Alloy (TAN), Sterile	472.114S	8726113
PFNA-II End Cap, Extension, 0 mm, Titanium Alloy (TAN), Sterile	473.170S	8955101

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Proximal Femoral Nail Antirotation (PFNA) and PFNA-II Femoral Nails and PFNA-II Endcaps. 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.

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 color.

Potential hazard

An implant with the incorrect anodized color 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 the PFNA and PFNA-II Femoral Nails and PFNA-II Endcaps were manufactured correctly, with the exception of the anodized coding.

Customer immediate actions:

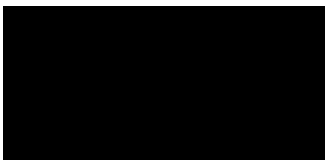
1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 2 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.
8. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

The applicable regulatory agencies are being notified.

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,



Cherie Yip
Regulatory Affairs Specialist

Account Name: _____

**URGENT NOTICE:
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Verification Section

Part Description / Part Number:

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PFNA-II Proximal Femoral Nail ø 10 mm, Small, 130°, Length 200 mm, Titanium Alloy (TAN), Sterile	472.115S	8711483
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____ 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):

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 **(2) two business days** of receipt of the Field Safety Notice.

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.