

**To the ATTENTION of:  
Operating Room Manager**

08 March 2016

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – R2016005**  
**Proximal Femoral Nail (PFN) ø 10.0mm cannulated, left, 130°, L 380mm**  
**Proximal Femoral Nail (PFN) ø 10.0mm cannulated, right, 130°, L 380mm**

Part Description, Part and Lot Numbers

Product Descriptions	Part Numbers	Lot Numbers
Proximal Femoral Nail (PFN) ø 10.0mm cannulated, left, 130°, L 380mm	473.585	2226945
Proximal Femoral Nail (PFN) ø 10.0mm cannulated, right, 130°, L 380mm	473.385	2226946; 2282830

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary recall of the above mentioned Part and Lot Numbers of the PFN ø 10.0mm cannulated, left, 130°, L 380mm and PFN ø 10.0mm cannulated, right, 130°, L 380mm. The PFN is intended to treat stable and unstable proximal femoral fractures including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures, and combinations of these fractures.

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

**Reason for the Recall:**

Following a complaint received, it was discovered that PFN ø 10.0mm cannulated, left, 130°, L 380mm was etched as a left nail, but bent as a right nail. Following further investigation, it was determined that two additional lots (mentioned above) may be affected by this issue and were etched as a right nail, but bent as a left nail.



Etched as a left nail  
Part (473.585) = PFN – Left side at 130°  
TAN

Bent as a right nail  
Part (473.385) = PFN – Right side at 130°  
TAN

**Potential hazard:**

If a part is etched with the incorrect side, the nonconformance may likely not be discovered until the surgeon goes to implant the nail. A surgeon would likely identify the incorrect bend and request a replacement nail. If identified at this time, a slight surgical delay would result while the situation is assessed and next steps determined. If the surgeon

discovers the nail deformity before inserting the nail into the patient's femur, he/she could locate another PFN or change the size and complete the surgery. Surgical Delay may possibly result depending on the availability of a sterile replacement/alternate.

In the event that a surgical team member does not identify a possible nonconformance prior to insertion, the surgeon may experience difficulty inserting the nail. The likely scenario would involve the surgeon removing the partially inserted nail and assessing the issue. As stated in the correlating surgical technique guide, "Carefully insert the nail manually as far as possible into the femoral opening. Slight twisting hand movements help insertion. If the nail cannot be inserted, select a smaller nail size". Thus, if a possible incorrect bend is not detected, the surgeon may possibly assume that the difficulties with insertion are due to the nail being too large and identify a smaller nail to use instead.

However, if the surgeon continues to insert a nail into the left medullary canal (e.g. incorrectly labeled "Left" with a bend designed for a right femur), Bone Fracture-Intra-op may possibly result. A subsequent Surgical Delay may also result. The patient's medullary canal for each leg would require a different curve/bend which would likely be detected by a surgeon as he/she begins to insert the nail. In the event that an intraoperative fracture occurs, it would likely be treated at that time.

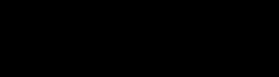
**Customer immediate actions:**

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.

DePuy Synthes



David Carvin  
Quality Manager  
CC:

Account Name: \_\_\_\_\_

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**Verification Section**

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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):

\_\_\_\_\_

\_\_\_\_\_

Name/Title (please print): \_\_\_\_\_

Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Signature and Date: \_\_\_\_\_

**Please complete and return this page to your local DePuy Synthes sales organization.**

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.