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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

8 December 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015077
Universal Femoral Nails

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
SUN- Simplified Universal Femoral Nail, ∅ 11.0mm, Length 360mm, Stainless Steel	272.136	2126916
Universal Femoral Nail ∅ 12.0mm, Length 380mm, Stainless Steel	274.220	2092149
Universal Femoral Nail ∅ 10.0mm, Length 380mm, Stainless Steel	274.020	2075226
Universal Femoral Nail ∅ 11.0mm, Length 400mm, Stainless Steel	274.130	2191091

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Universal Femoral Nails. The Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus.

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:

It was discovered that the Universal Femoral Nails listed above, were not bent according to specifications.

Potential hazard:

In the event that the nonconforming Femoral Nail enters the Operative Theatre, surgical delay may occur if the surgeon changes the nail, possibly with a different size, to complete the surgery.

In the event that a surgical team does not identify the nonconformance prior to insertion and the nail is implanted, the surgeon may experience difficulty inserting the nail. The likely scenario would involve the surgeon removing the partially inserted nail and assessing the issue. However, if the surgeon continues to insert the straight nail into the medullary canal, this may result in bone fracture and surgical delay.

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 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

Pierre van Iwaarden
Field Action Manager

David Carvin
Quality Manager

Cc:

DePuy Synthes

Account Name: _____

URGENT NOTICE:
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Verification Section

Part Description, Part- and Lot Numbers

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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.