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DePuy Synthes
COMPANIES OF Johnson&Johnson

To the ATTENTION of:
Hospital Personnel

27 October 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015095
Expert™ Tibial Nail Ø 9.0 mm, cannulated, length 270 mm

Part Description, Part- and Lot Numbers

Part Number	Part Description	Lot numbers
04.004.334	Trauma Expert Tibial Nail	3018420, 3405573

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary recall of two lots of the Expert™ Tibial Nail Ø 9.0 mm, cannulated, length 270 mm. The Expert Tibial Nail 9mm is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions. Please refer to the above affected product listing.

Our records indicate that you may have inventory that is subject to this recall.

Recall
It has been determined that for two lots the nail was anodized green and should have been blue.

Potential Patient Impact
If the nonconformance is identified pre-operatively, it will not cause any patient harm. In the event the user identifies the nonconformance intra-operatively prior the nail insertion, it may cause negligible or marginal surgical delay to retrieve the correct nail. In the event the user has implanted a nonconforming nail (incorrectly anodized in green color), she/he would then be attempting to insert the same green color locking screws into the nail. The green color locking screw has a larger diameter than that of the nonconforming nail hole. The mismatch may potentially cause Bone Damage, Intra-operative Bone Fracture, and extended 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 to your local DePuy Synthes sales organisation 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 product listed below 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.

If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter. Furthermore, keep awareness and a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes contact person.

Thank you for your attention and cooperation.

Synthes GmbH

Paul Bielderman MD
Field Action Manager

David Carvin
Quality Manager

Account Name: _____

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☐ We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.

☐ We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

Returned devices (including lot number and quantity):

_____

Name/Title (please print):

_____

Address:

_____

Phone Number: _____

Signature and Date: _____

RGA # (If applicable):_____

Please complete and return this page your local DePuy Synthes contact person

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.