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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

26 May 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014772
Osteotomy Guiding Device (OGD)

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers	
Osteotomy Guiding Device	03.108.015	120577	3641347
		3136775	3657433
		3193457	8524559
		3388186	8729076

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned part and lot numbers of the Osteotomy Guiding Device (OGD). The OGD is indicated for closed wedge osteotomies at the femur and tibia that require removal of a bone wedge. The OGD aids in the precise placement of K-wires to define the cutting plains.

Our records indicate that you may have inventory that is impacted by this recall.

Reason for the Recall:

The affected OGDs were manufactured out-of-specification. The nonconformance could lead to difficulty in assembling the device or could result in jamming of the K-wires and guide sleeve.

Potential hazard:

The nonconformance may result in surgical delay if the user has difficulty inserting the K-wires through the guide sleeves. In the event that the user has difficulty inserting the guide sleeves or K-wires, the user may attempt to repeat these steps which could lead to further surgical delay. OGD is an optional instrument. If needed, surgeon can choose to use free-hand technique without OGD to complete the index osteotomy procedure.

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 have 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.

Synthes GmbH
ALBERT BECKERS ON BEHALF OF PIERRE VAN IWAARDEN.

Pierre van Iwaarden
Field Action Manager
26-MAY-2015

On behalf of Charles Goldberg

Charles Goldberg
Worldwide Director Complaint Management

Cc:

DePuy Synthes

Account Name: _____

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014772
Osteotomy Guiding Device

Verification Section

Part Description / Part Number:

Part Description	Part Number	Lot Numbers	
Osteotomy Guiding Device	03.108.015	120577	3641347
		3136775	3657433
		3193457	8524559
		3388186	8729076

____ 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 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.