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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

4 December 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015127
SYNREAM MEDULLARY REAMER HEAD ∅ 13.5MM

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Number
SynReam Medullary Reamer Head ∅ 13.5mm	352.135	F-17180

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Number of the SynReam Medullary Reamer Head ∅ 13.5mm, which is a part of the Synthes Reaming System.

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:

The affected part number and lot listed above is etched as dimension 13.5mm while the actual dimension is 14mm.

Potential hazard:

If a 14mm reamer head is labeled and etched as a 13.5mm, there is the potential that the surgeon would be advancing 1.0mm versus 0.5mm; thus, there is a risk of the reamer head jamming. Surgical delay could occur as the reamer head is removed from the medullary canal and bone debris is removed or the reamer head is replaced with another reamer head.

Additionally, as the surgeon is advancing the reamer head size by 1.0mm, they would likely identify additional resistance than anticipated. This discrepancy may go undetected and result in no subsequent harm. However, the 1.0mm increment advancement, rather than 0.5mm increment as anticipated, may potentially result in bone damage.

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

[redacted]

Field Action Manager

[redacted]

Quality Manager

Cc:

DePuy Synthes

Account Name: _____

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SYNREAM MEDULLARY REAMER HEAD ∅ 13.5MM

Verification Section

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
SynReam Medullary Reamer Head ∅ 13.5mm	352.135	F-17180

____ 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.