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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

22 October 2013

URGENT MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number

Part Number	Part Description	Lot Number
352.085	SynReam Medullary Reamer Head Ø 8.5 mm	20141 through 24510

Dear Madam / Dear Sir,

Synthes is initiating a voluntary recall of the above mentioned articles and lots of the SynReam Medullary Reamer Head Ø 8.5 mm. Our records indicate that you may have inventory that is impacted by this removal.

Description of problem:

The possibility exists for intraoperative reamer head breakages which could also allow for un-retrieved fragments of non-implant grade material.

Patient risk:

There are two potential patient harms associated with the breakage of the reamer head. Significant surgical delays (greater than 15 minutes) could result due to the presence of a reamer head that breaks during use. Secondary incisions and X-Rays may be required to aid in and confirm device removal. In addition, the reamer head is composed of non-implant grade material therefore the retention of non-implant grade material can result in minor bone damage where additional intervention is optional but not required. In a worst case scenario there is the potential for an adverse tissue reaction to occur. In this situation the patient will be symptomatic requiring treatment. Non-surgical treatment may not be effective and the disease could progress requiring revision surgery or reoperation. If treated in time, no permanent impairment is expected.

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 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 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 Synthes GmbH.

7. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes Sales Representative.

Thank you for your attention and cooperation.

Synthes GmbH

Claudia Allemann
Field Action Manager

Stephan Müller 22. OCT. 2013
VP Quality Mgmt Systems & Sy Quality OPS

Cc:

NOTICE: MEDICAL DEVICE REMOVAL R2013031

Verification Section

Part Number	Part Description	Lot Number
352.085	SynReam Medullary Reamer Head Ø 8.5 mm	20141 through 24510

☐ 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 quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____