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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

20 December 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	**Additional lots to be recalled:** 15932 through 19396, 24613 through 25347, 1448284 through 2087630 Please find a detailed list on page 5 of this letter.

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

Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL R2013031_2

Verification Section

Part Number	Part Description	Lot Number
352.085	SynReam Medullary Reamer Head Ø 8.5 mm	**Additional lots to be recalled:** 15932 through 19396, 24613 through 25347, 1448284 through 2087630

☐ 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: _____

List of affected products R2013031 and R2013031_2

Additional oUS Lots R2013031_02			
15932	24613	1513424	2100449
15936	24894	1592694	2100486
16146	24895	2007697	2103582
16715	24896	2007719	2107365
16894	24897	2020706	2108365
17062	24898	2031010	2112651
17094	24917	2041726	2119355
17191	24934	2042005	2119410
17409	25076	2058316	2121826
18059	25137	2063542	2121827
18060	25171	2068756	2143043
18077	25177	2068771	2143090
18078	25178	2068772	2148226
18079	25252	2070344	2148248
18408	25347	2078374	2153894
18646	1448284	2082288	2153897
18684	1462917	2084800	2158487
18805	1466881	2090333	2162802
19206	1481148	2090334	2036056
19396	1496539	2096930	2087630

Lots recalled with R2013031	
20141	22717
20290	22981
20291	23390
20292	23438
20713	23439
20917	23442
21025	23907
21201	23944
21372	24091
21677	24160
21829	24334
21927	24505
22592	24510