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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

25 September 2013

URGENT MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number

Part Number	Part Description	Lot Number
05.001.178.01S	Irrigation Tube Set, sterile, single pack	3755327 7823268 7823269
05.001.178.05S	Irrigation Tube Set, sterile, pack of 5 units	3755329 7884993

Dear Madam / Dear Sir,

Synthes is initiating a voluntary recall of the above mentioned articles and lots of the Irrigation Tube Set, sterile, due to the possibility of a leakage. Our records indicate that you may have inventory that is impacted by this removal.

Description of problem:

Synthes received a customer complaint for one device reporting a leak. No patient harm was reported.
This leak occurred at the coupling that connects the smaller and larger irrigation tubes, approximately 35cm from the working end of the tubing. The leak was due to an insufficient amount of adhesive applied in the manufacturing process to secure the smaller tubing into the connector. Synthes performed internal testing and confirmed that this issue affected other units in the above mentioned lots.

User risk:

Defective tubing not detected prior to use may be introduced for use with the drill into the operative field. In a worst case scenario, there is the potential for the tubing to leak into the operative field and mix with body fluids. With enough pressure, there is the potential for those fluids to splash back onto the user. If the user is not wearing appropriate PPEs (Personal Protective Equipment), like eye shields, then fluid exposure may occur. If exposure occurs the user would then require immediate irrigation of the exposed area and potential additional

testing and monitoring. Additional medical treatment based upon patient specific findings and the institution's biohazard exposure plan may be required.

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 R2013563

Verification Section

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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 quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____