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DePuy Synthes
Companies of Johnson & Johnson

To the ATTENTION of:
Hospital Personnel

20 October 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2015058
USS II Polyaxial Screws, USS Variable Axis Screws, Universal Reduction Screws

Part Description, Part- and Lot Numbers

Part Number	Part Description	Lot numbers
04.607.054	USS-II Polyaxial Pedicle Screw Ø 7.0 mm with dual core, length 40 mm, Titanium Alloy (TAN)	8919485, 8919481
499.615	USS Variable Axis Screw Ø 6.2 mm with dual core, length 50 mm, Titanium Alloy (TAN)	8926120, 8926110
04.636.755	Universal Reduction Screw, Ø 7.0 mm, length 55 mm	8930943

Dear Sir/Madam,

Synthes GmbH has initiated a voluntary recall of five lots of USS II Polyaxial screws, USS Variable Axis screws, and Universal Reduction screws, which are used as a part of the USS and URS Systems to provide precise and segmental stabilization of the spine in skeletally mature patients. Please refer to the above affected product listing, and be aware that some products in your possession may be affected. Please note that there is no replacement for these products available at this time

Our records indicate that you may have inventory that is subject to this recall.

Reason for the Field Safety Notification
It has been determined that five lots of USS II Polyaxial screws, USS Variable Axis screws, and Universal Reduction screws may have been manufactured with the sandblasted ball head length below specification.

Potential Patient Impact
Sandblasting of the screw head prevents unintended movement/slip of the polyaxial head in a finished construct after the procedure. A reduction in sandblasted area may result in reduced friction on the screw head. Subsequently, the resistance to polyaxial movement/slip may be reduced.

To date there have been no confirmed complaints of polyaxial/reduction screw movement or slip potentially related to a reduced area of sandblast. For patients with affected USS/URS screws implanted, there is no recommendation for prophylactic removal. Patients should be monitored in accordance with standard practice for the USS/URS treatment process.

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 DePuy 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 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 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 DePuy Synthes.

7. Keep a copy of this notice.

If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter. Furthermore, keep awareness and a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this Field Safety notification may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes contact person.

Thank you for your attention and cooperation.

Synthes GmbH

[redacted]

Paul Bielderman MD
Field Action Manager

[redacted]

Michael Jacene
Sr. Manager, Quality Systems

DePuy Synthes
COMPANIES OF Johnson & Johnson

Account Name: _____

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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 lot number and quantity):
_____

Name/Title (please print):
_____

Address:
_____

Phone Number: _____

Signature and Date: _____

RGA # (If applicable):_____

Please complete and return this page your local DePuy Synthes contact person

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.