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To the ATTENTION of:
Hospital Personnel

06 November 2015

URGENT NOTICE
MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION – R2015057
Synex Vertebral Body Replacements

Part Number	Part Description	Lot number
495.317	Synex Verterbral Body Replacement – Lumbar Implant with 25x28mm footprint, 0°angle, 26-36mm range	3307407

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary recall of one lot of Synex Vertebral Body Replacements, which are used as a part of the Synex System. 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 one lot of Synex Vertebral Body Replacements may have been manufactured without spikes on the cranial (superior) endplates. Spikes may be missing from one side of the device.

The spikes on the implant allow for increased fixation to the vertebral body endplates intra-operatively prior to being supported by required supplemental fixation (e.g. plate or pedicle screws & rods).

Nonconforming device with location of missing spikes indicated

Conforming device with location of conforming spikes indicated

Potential Patient Impact
In the event that an implant with missing spikes is not recognized intra-operatively and the implant is used, there is a theoretical reduction in the resistance of the device to implant migration. While plausible, an increase in gross migration of the implant as a direct result of the missing spikes on this [0°] implant is not likely. Given the 0° angle of the implant and detectability of the missing spikes, this non-conformance is more likely to result in either minor surgical delay or user dissatisfaction.

To date there have been no confirmed complaints of Patient Harm associated with Synex Vertebral Body Replacements missing spikes. For patients with affected Synex Vertebral Body Replacements implanted, there is no recommendation for prophylactic removal. Patients should be monitored in accordance with standard practice for the Synex treatment process.

<u>As indicated, always combine Synex with an additional, intrinsic stable internal fixator such as TeleFix or USS to bear tensile forces as well as torsion, flexion and extension moments.</u>

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.

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]
Field Action Manager

[redacted]
Sr. Manager, Quality Systems

DePuy Synthes

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.