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SYNTHES®

To the ATTENTION of:
Operating room manager

16 October 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
03.630.130	FACET WEDGE Trial Implant w/Rasp small cannulated	1219945

Dear Sir/Madam

Synthes is initiating a Medical Device Product Removal related to the above mentioned medical device.

Complaints were received stating that the Trial / Rasp for FACET WEDGE small (03.630.130) broke in-situ leading to remaining part in the facet joint. The remaining part could be removed and patient adequately treated with FACET WEDGE. The removal part caused an extension of the OR time. No patient harm has been noted.

A new, improved design will be available within the next few weeks.

Synthes is requesting that you immediately cease using the product and please examine your inventory for the above part numbers and remove them.

If you have any questions, please contact your Synthes Sales Consultant.

We apologize for the inconvenience caused.

Thank you for your attention and cooperation.

Synthes GmbH

[redacted]

Manager Complaint Handling Unit

[redacted]

Director Quality EMEA

Cc:

NOTICE: MEDICAL DEVICE RECALL

FACET WEDGE Trial Implant w/Rasp small cannulated

Verification Section

Part Number	Part Description	Lot Number
03.630.130	FACET WEDGE Trial Implant w/Rasp small cannulated	1219945

☐ We have located the identified product in stock; returned quantity is documented below, and have retained a copy of this letter for our records.

☐ We do not have any identified product in stock; returned quantity is zero, and have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity):

_____

_____

_____

_____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

[redacted]