Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland

Tel. +41 61 965 61 11
Fax +41 61 965 66 01
www.synthes.com

SYNTHES®

To the ATTENTION of:
Operating room manager

17 October 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
405.436	Cannulated Screw Ø 3.5mm, self-drill., L 38/12mm	3723094

Dear Sir/Madam

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

Synthes received complaint about a mix-up of Cannulated screw. The device was labeled as 405.436, lot # 3723094 instead of 405.438, lot # 3723092. No patient harm has been noted.

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

Cannulated Screw Ø 3.5mm, self-drill., L 38/12mm

Verification Section

Part Number	Part Description	Lot Number
405.436	Cannulated Screw Ø 3.5mm, self-drill., L 38/12mm	3723094

☐ 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: _____