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To the ATTENTION of:
Operating room manager

03 October 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
03.401.085	Guide Extension Epoca, rigid, w/Quick Coupling	T964234

Dear Sir/Madam

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

Complaints were received stating that the reamer became loose from the rigid guide extension during the OR-procedure. In one case, the reamer got stuck and had to be removed manually. The incidents happened during the MPE Phase. No patient harm noted.

A new, improved design is available now.

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

Guide Extension Epoca, rigid, w/Quick Coupling

Verification Section

Part Number	Part Description	Lot Number
03.401.085	Guide Extension Epoca, rigid, w/Quick Coupling	T964234

☐ 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: _____