

**To the ATTENTION of:  
Operating room manager**

19 October 2012

## **URGENT: MEDICAL DEVICE PRODUCT REMOVAL**

Part Description / Part Number: See attached list

<b>Part Number</b>	<b>Part Description</b>	<b>Lot Number</b>
04.613.516	Cervical Spine Screw Ø 4.0mm, self-drill., L 16mm	7559317
04.613.516S	Cervical Spine Screw Ø 4.0mm, self-drill., L 16mm	7569549

Dear Sir/Madam

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

Synthes received a complaint concerning an item that was incorrectly packaged. An 18mm screw (04.613.518, lot # unknown) was labeled as a 16mm screw (04.613.516S, lot # 7569549). This was detected prior to use. No patient harm has been noted.

Synthes is requesting that you immediately:

1. cease using the products of the above mentioned lots
2. examine your inventory and remove parts of the above mentioned lots

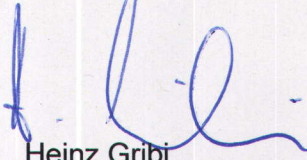
If you have any questions, please contact your Synthes sales consultant.

We apologize for any inconvenience caused.

Thank you for your attention and cooperation.



Synthes GmbH



Heinz Gribi  
Manager Complaint Handling Unit



Markus Wien  
Director Quality EMEA

Cc:



**NOTICE: MEDICAL DEVICE RECALL****Cervical Spine Screw Ø 4.0mm, self-drill., L 16mm**  
**Verification Section**

<b>Part Number</b>	<b>Part Description</b>	<b>Lot Number</b>
04.613.516	Cervical Spine Screw Ø 4.0mm, self-drill., L 16mm	7559317
04.613.516S	Cervical Spine Screw Ø 4.0mm, self-drill., L 16mm	7569549

- 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):

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Name/Title (please print) \_\_\_\_\_

Phone Number: \_\_\_\_\_

Signature and Date: \_\_\_\_\_