To the ATTENTION of:
Operating room manager

19 March 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Numbers
473.080	Femoral Neck Screw Ø 11.0 mm, self-tapping, length 80 mm, Titanium Alloy (TAN), pink	5916720

Dear Sir/Madam

Synthes is initiating a medical device removal regarding the Femoral Neck Screw Ø 11.0 mm, self-tapping, length 80 mm, Titanium Alloy (TAN), pink. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Synthes received a complaint about wrong laser-etching on article 473.080 lot 5916720. The whole lot was etched with the article number 473.085. (The label on the package is correct: 473.080)

Customer immediate actions:

1. Please remove and return the above mentioned articles / lots from your inventory immediately.

2. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH

Field Action Manager

Director Quality Assurance Operations

Cc:

SYNTHES®

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NOTICE: MEDICAL DEVICE REMOVAL

Femoral Neck Screw Ø 11.0 mm, self-tapping, length 80 mm, Titanium Alloy (TAN), pink

473.080, lot # 5916720

Verification Section

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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 quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____