

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

19 October 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
498.955	CerviFix Pedicle Clamp	3772088

Dear Sir/Madam

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

Synthes received complaints about two incorrectly labeled products. ClickX locking caps (part #04.606.000, lot #3772836) were labeled as CerviFix Pedicle Clamps (part #498.955, lot #3772088). No patient harm has been noted.

Synthes is requesting that you immediately:

1. cease using the products from the above mentioned lot
2. examine your inventory and remove parts with the above mentioned lot number.

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



Manager Complaint Handling Unit

Director Quality EMEA



Cc:

NOTICE: MEDICAL DEVICE RECALL**CerviFix Pedicle Clamp**
Verification Section

Part Number	Part Description	Lot Number
498.955	CerviFix Pedicle Clamp	3772088

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: _____