

To the ATTENTION of: Operating Room Manager

24 February 2014

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Description / Part Number

Part Number	Part Description	Lot Number
214.844	Cortex Screw Ø 4.5 mm, self-tapping, length 44 mm, Stainless Steel	1707176
214.846	Cortex Screw Ø 4.5 mm, self-tapping, length 46 mm, Stainless Steel	1707181
214.846S	Cortex Screw Ø 4.5 mm, self-tapping, length 46 mm, Stainless Steel, sterile	1712692

Dear Valued Customer,

Synthes GmbH is initiating a voluntary recall of the above mentioned articles and lots of the Cortex Screw Ø 4.5 mm, self-tapping, length 44 and 46 mm, Stainless Steel. Our records indicate that you may have inventory that is impacted by this recall.

Description of the problem:

It was discovered that a Cortex Screw Ø 4.5 mm, self-tapping, length 44 mm, Stainless Steel (214.844) was laser etched with the part number for a Cortex Screw Ø 4.5 mm, self-tapping, length 46 mm, Stainless Steel (214.846). As the two non-sterile lots were produced almost at the same time, it is possible that the Cortex Screw Ø 4.5 mm, self-tapping, length 46 mm, Stainless Steel, (sterile) (214.846, 214.846S) might be laser etched with the part number for a Cortex Screw Ø 4.5 mm, self-tapping, length 44 mm, Stainless Steel (214.844).

Potential hazard:

The discrepancy of screw length may be identified during pre-operative or intra-operative procedures prior insertion. There is the potential that the operative personnel may not detect the length discrepancy in a worst case scenario.

For screws with longer length discrepancy, in case the user did not detect the length discrepancy and complete the screw insertion, there is a potential it would be detected with intraoperative X-ray when the user checks the implant position. The user will then exchange the screw and a marginal surgical delay will result. In a worst scenario, if the user completed the surgery without detecting the nonconforming screw, there is a potential the longer screw may cause surrounding tissue irritation or damage. In this situation the patient will be symptomatic requiring treatment. Non-surgical treatment may not be effective and the disease could progress requiring revision surgery or reoperation. If treated in time, no permanent impairment is expected.

If a screw with shorter length were inserted there is the potential that the screw may not reach the target depth. It is important to note that these cortex screws are inserted in a bicortical fashion. If a cortex screw is not inserted to an adequate depth there is the potential that this could be detected with intraoperative X-ray; a surgeon may opt to exchange the screw and a marginal surgical delay could result. However, if the screw is not exchanged there is the potential for the screw to loosen or back out of the plate during the recovery period. A screw that loosens during the postoperative recovery period would be detectable upon follow-up visits with X-ray. Device loosening may require additional medical intervention to preclude permanent damage.

Customer immediate actions:

1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.
7. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

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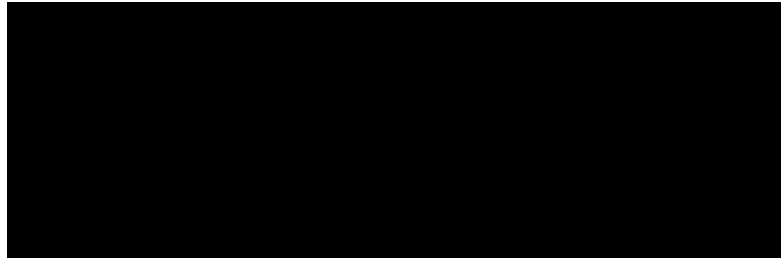
We apologise for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Synthes GmbH



Field Action Manager



VP Quality Mgmt Systems & Sy Quality OPS

Cc:

NOTICE: MEDICAL DEVICE RECALL R20131591

Cortex Screw Ø 4.5 mm, self-tapping, length 44 or 46 mm, SSt

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:

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____