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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

9 June 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – 413478
Cortex Screw Ø 2.7 mm, self-tapping

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
Cortex Screw Ø 2.7 mm, self-tapping, length 18 mm, Pure Titanium	402.818	9589442

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Number of the Cortex Screw Ø 2.7 mm, self-tapping. This part is indicated for use in multiple systems some of which include:

- VA-LCP Elbow Plating System
- VA-LCP Ankle Trauma System
- LCP Distal Tibia Plate System

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

Reason for the Recall:
The above mentioned part and lot number was manufactured out of specification with a screw head recess that is too deep, which may lead to the screw head loosening from the shaft of a Cortex Screw during explantation.

Potential hazard:

Surgical delay may occur if the nonconforming screw head recess is identified during implantation. If the screw is implanted and subsequent removal is attempted, the non-conformance may result in screw head loosening. Therefore, the potential for screw head loosening should be considered in the context of the individual patient when determining if explantation is appropriate.

If the screw head breaks off the shaft either during implantation or explantation, Surgical Delay could result. The Synthes Screw Extraction Set could be used to remove the embedded shaft.

In the event that fragments are retained, an adverse tissue reaction may possibly result despite the screw being implant grade and intended for permanent implantation.

Depending on the interventions needed to retrieve a retained screw shaft, bone damage could possibly occur.

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected 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 on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

3. Return any affected product as soon as possible, but 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 of the affected products 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. Keep a copy of this notice.

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

Thank you for your attention and cooperation.

DePuy Synthes

Anne Brisson

Anne Brisson
Senior Quality Assurance Manager,
Product Safety and Performance

Cc:

DePuy Synthes
COMPANIES OF Johnson & Johnson

Account Name: _____

URGENT NOTICE:
MEDICAL DEVICE RECALL – 413478
Cortex Screw Ø 2.7 mm, self-tapping

Verification Section

Part Description, Part- and Lot Numbers

Product Description	Part Number	Lot Numbers
Cortex Screw Ø 2.7 mm, self-tapping, length 18 mm, Pure Titanium	402.818	9589442

____ We have located the affected product in stock; returned quantity is documented below.

____ We acknowledge receipt of this information, but do not have any affected product in stock; returned quantity is zero.

RETURNED DEVICES (including quantity):

_____

_____

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page to your local DePuy Synthes sales organization.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.