

**To the ATTENTION of:
Operating Room Manager**

26 May 2015

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014952R
Synthes Cortex Screw Ø 4.5 mm, Length 105 mm, Pure Titanium**

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
Cortex Screw Ø 4.5 mm, Length 105 mm, Pure Titanium	414.105	≤8990754

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the non-sterile Cortex Screw Diameter 4.5 mm, Length 105 mm, Pure Titanium. The cortex screw is used in the fixation of plate to the bone or fixation and/or compression of fracture fragments for osteosynthesis.

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:

Upon evaluation, it was discovered that certain lots of the non-sterile Cortex Screw Diameter 4.5 mm, Length 105 mm, Pure Titanium were labeled with the incorrect length as detailed below:

Part Number	Part Description	Correct Length	Length as Labeled
414.105	Cortex Screw Ø 4.5 mm, Length 105 mm, Pure Titanium	105 mm	100 mm



Figure 1 – Incorrect Label for Part 414.105

Potential hazard:

The nonconformance may result in surgical delay and may also cause damage to the structures surrounding the screw.

There is the potential that the product could enter the operative theater if the screw rack is stocked solely on the label without measuring the length of the screw. If the length discrepancy is identified after screw insertion, the user may replace it with a screw of the correct length leading to surgical delay while a replacement screw is procured. In addition, as the intent of the cortical screw is for bicortical fixation, the longer screw may possibly exit the bone and cause damage to the surrounding structures.

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 on page 4 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.



Pierre van Iwaarden
Field Action Manager



Charles Goldberg
Worldwide Director Complaint Management

Cc:

Account Name: _____

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014952R
Synthes Cortex Screw Diameter 4.5 mm, Length 105 mm, Pure Titanium

Verification Section

Part Description / Part Number:

Part Description	Part Number	Lot Numbers
Cortex Screw Ø 4.5 mm, Length 105 mm, Pure Titanium	414.105	≤8990754

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

____ We acknowledge receipt of this information, but do not have any identified 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 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.