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DePuy Synthes
COMPANIES OF Johnson & Johnson

**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 |

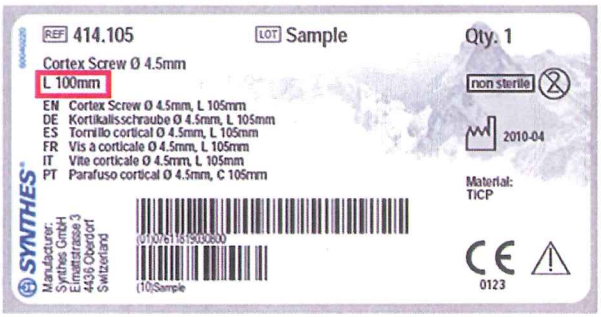


**Figure 1 – Incorrect Label for Part 414.105**

**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.

Synthes GmbH

on behalf of Pierre van Iwaarden

Pierre van Iwaarden
Field Action Manager

on behalf of Charles Goldberg

Charles Goldberg
Worldwide Director Complaint Management

Cc:

DePuy Synthes
COMPANIES OF Johnson & Johnson

Account Name: _____

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# 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.