DePuy Synthes
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com/

DePuy Synthes
COMPANIES OF Johnson&Johnson

To the ATTENTION of:
Operating room manager

21 February 2017

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

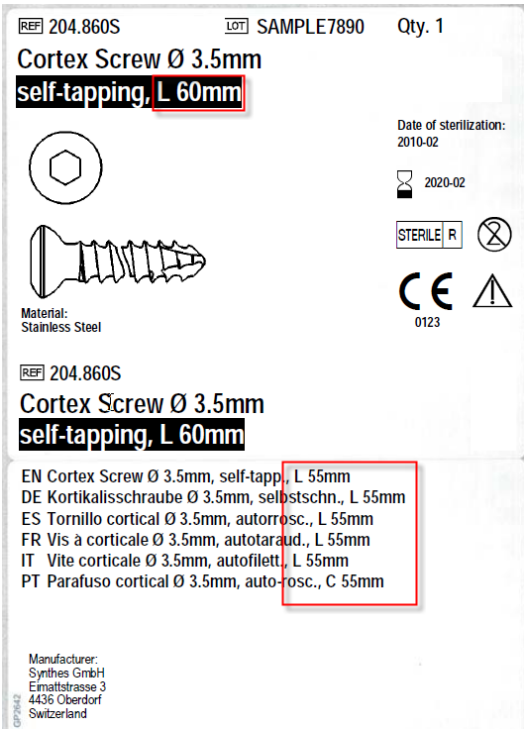
Part Number	Part Description	Lot Number
204.860S	Cortex Screw Ø 3.5 mm, self-tapping, length 60 mm, Stainless Steel, sterile	3323023; 3380392; 3461217; 3534940; 3546671; 3551641; 3556205; 3576436; 3597382; 3606629; 3651270; 3659534; 3671981; 3691141; 3724089; 3731582; 3754040; 3767354; 3775235; 3794411; 3803954; 3819982; 7513652; 7524510; 7559681; 7564120; 7575163; 7598196; 7623656; 7627325; 7659525; 7684763; 7758790; 7807744; 7855764; 7883557; 7933772; 7959158; 7988497; 8083716; 8123107; 8156523; 8220555; 8250627; 8302628; 8360810
204.920S	Cortex Screw Ø 3.5 mm, self-tapping, length 120 mm, Stainless Steel, sterile	3496752

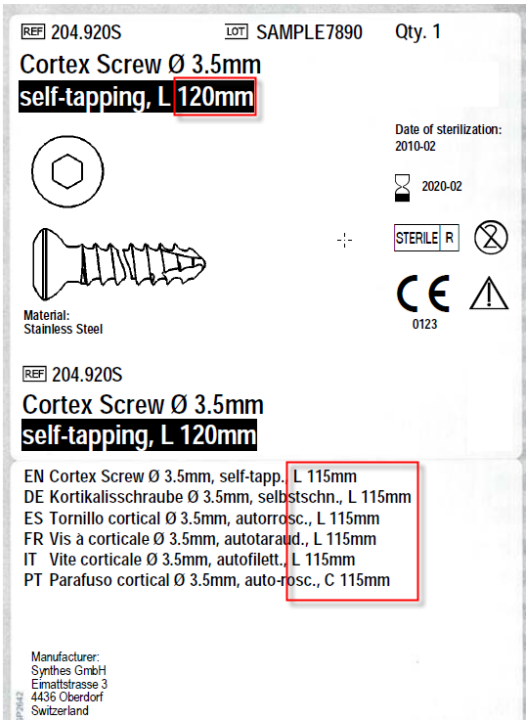
Dear Sir/Madam

Synthes is initiating a medical device removal regarding the above mentioned lots of the Cortex Screw Ø 3.5 mm, self-tapping, length XXX mm, Stainless Steel, sterile. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

204.860S: The length of the screw is erroneously indicated as 55mm in the six languages on the back of the box. In the English short text which is visible on the front of the box, on the sides, on the sterile inner blister and on the patient labels, the screw is correctly described as having a length of 60mm.





204.920S: The length of the screw is erroneously indicated as 115mm in the six languages on the back of the box. In the English short text which is visible on the front of the box, on the sides, on the sterile inner blister and on the patient labels, the screw is correctly described as having a length of 120mm.

Patient risk:
The use of an alternative product due to confusion caused by dissimilar labeling is likely in this case.

An exchange of the screw, due to implanting of a screw longer than anticipated and recognizing the condition during the index procedure is not likely to occur but must be considered a worst case scenario. This situation is only possible if the user utilize the foreign language text on the outer portion of the box as the only identifier

Re-operation, due to implanting of a screw longer than anticipated, not recognizing the condition during index procedure, and patient suffering pain or soft tissue irritation due to the presence of a screw that is longer than anticipated is also not likely to occur, but must be considered a worst case scenario. This situation is only possible if the user utilize the foreign language text on the outer portion of the box as the only identifier

Customer immediate actions:

1. Please remove and return the above mentioned articles / lots from your inventory immediately.

2. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

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

Thank you for your attention and cooperation.

Synthes GmbH

Claudia Allemann
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL

Cortex Screw Ø 3.5 mm, self-tapping, length XXX mm, Stainless Steel, sterile

204.860S, 204.920S

Verification Section

☐ 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:

_____

_____

_____

_____

_____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____