Johnson&Johnson MedTech

DePuy Synthes

Date: 27 March 2024

URGENT FIELD SAFETY NOTICE (REMOVAL)
Cortex Screw Stardrive® Full Lot Product Mix (2 lots)

Subject Product:

Part Number	Description	Lot Numbers	EU GTIN
401.766TS	Cortex Screw Stardrive® Ø 2.4mm, L 16mm, Sterile	795P024	07612334104458
04.200.018TS	Cortex Screw Stardrive® Ø 3.5mm, L 18 mm, Sterile	777P906	07612334176325

Dear Valued Customer,

Synthes GmbH has initiated a field safety action (removal) of two lots of Cortex Screw Stardrive® listed in the table above. Also, see Attachment 1 for sample labels to aid in product identification. Plate and screw implants are intended for temporary fixation, correction, or stabilization of bones in various anatomical regions.

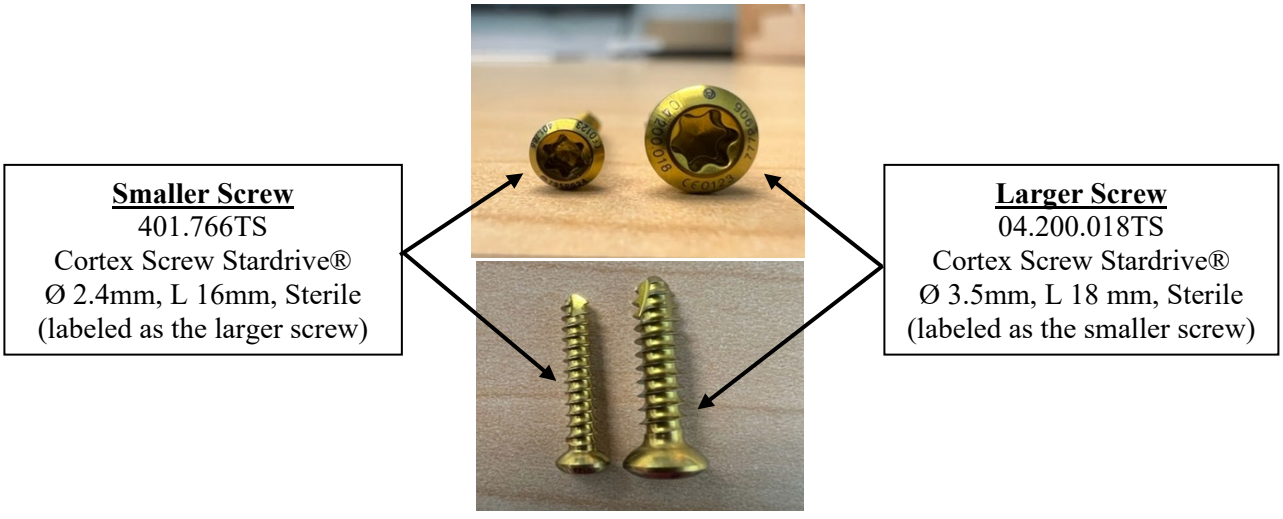
Our records show that you, or your facility, received one or more units of the product listed above. Please carefully review this notice for the steps that you should take to respond to this field safety action (removal).

Reason for the Field Safety Notice (Removal):
A product labeling mix has occurred between the two (2) subject lots of screws listed in the table above. This resulted in incorrect labels being applied to each subject lot. See figures 1 and 2 for a description of the mix.

Figure 1 – Labeling Mix Description

Incorrect Product Description on Label			Actual Product in Sterile Package	
401.766TS	Cortex Screw Stardrive® Ø 2.4mm, L 16mm, Sterile	→	04.200.018TS	Cortex Screw Stardrive® Ø 3.5mm, L 18 mm, Sterile
04.200.018TS	Cortex Screw Stardrive® Ø 3.5mm, L 18 mm, Sterile	→	401.766TS	Cortex Screw Stardrive® Ø 2.4mm, L 16mm, Sterile

Figure 2 – Side-by-side comparison of the two mixed lots of screws



Potential Patient Impact:
It is likely that the user will notice the discrepancy between the packaging label description and the actual product contained inside. The potential patient harms associated with this issue are as follows:

- If the wrong screw size is detected intraoperatively, surgical delay may occur.
- If the wrong screw is not detected intraoperatively and attempt is made to insert it, bone damage may occur.

Health care providers who have used the subject product on patients should continue to follow those patients pursuant to their standard of care for those procedures.

Please Take the Following Steps:

1. Examine your inventory immediately to determine if you have the subject products and quarantine them immediately. DO NOT USE THE SUBJECT PRODUCTS.

2. Contact your DePuy Synthes Sales Consultant or contact the customer support services at (enter country contact) to coordinate the return/credits of the subject products.

3. Review, complete, sign, and return the attached Business Response Form (page 3 of this letter) to (enter country contact) within three (3) business days of receipt of this notification.

4. Please complete the attached Business Response Form even if you do not have the subject products on hand.

5. Forward this notice to anyone in your facility that needs to be informed (e.g., those who manage, transport, store, stock, or use the subject products).

6. If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.

7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This medical device product recall has been reported to the local competent authority. For a Medical Information request, please visit our website: https://www.jnjmedicaldevices.com/mir. Should you have any other inquiries please do not hesitate to contact your DePuy Synthes Sales Consultant.

Thank you for your attention and cooperation.

Sincerely,

KIMBERLY LONG

Digitally signed by KIMBERLY LONG
DN: c=US, o=JNJ, ou=Subscribers, cn=KIMBERLY LONG, 0.9.2342.19200300.100.1.1=169611
Reason: I attest to the accuracy and integrity of this document.
Date: 2024.03.27 07:39:31 -04'00'
Adobe Acrobat version: 2020.013.20064

Kimberly Long
Staff Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

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URGENT FIELD SAFETY NOTICE (REMOVAL)
Cortex Screw Stardrive® Full Lot Product Mix (2 lots)

Business Response Form

Subject Product:

Part Number	Description	Lot Numbers	EU GTIN	Returned Quantity
401.766TS	Cortex Screw Stardrive® Ø 2.4mm, L 16mm, Sterile	795P024	07612334104458	
04.200.018TS	Cortex Screw Stardrive® Ø 3.5mm, L 18 mm, Sterile	777P906	07612334176325	

☐ **The subject product has been located. A copy of this notice is being retained and I have read and understood the notification.**

☐ **None of the subject product is available for return. A copy of this notice is being retained and I have read and understood the notification.**

Please complete this Business Response Form (BRF) Form within three (3) days after the receipt of this notification. Please return this form via email to at (enter country contact).

Your Name/Title:	Facility/Business Name:
Signed*:	Date:
Address:	
Account Number:	
Returned Authorization Number	
J&J Sales Rep (as applicable):	
Email Address:	Telephone Number:
Comments (if any):	
**Your signature provides confirmation that you have received and understood this notification.*	

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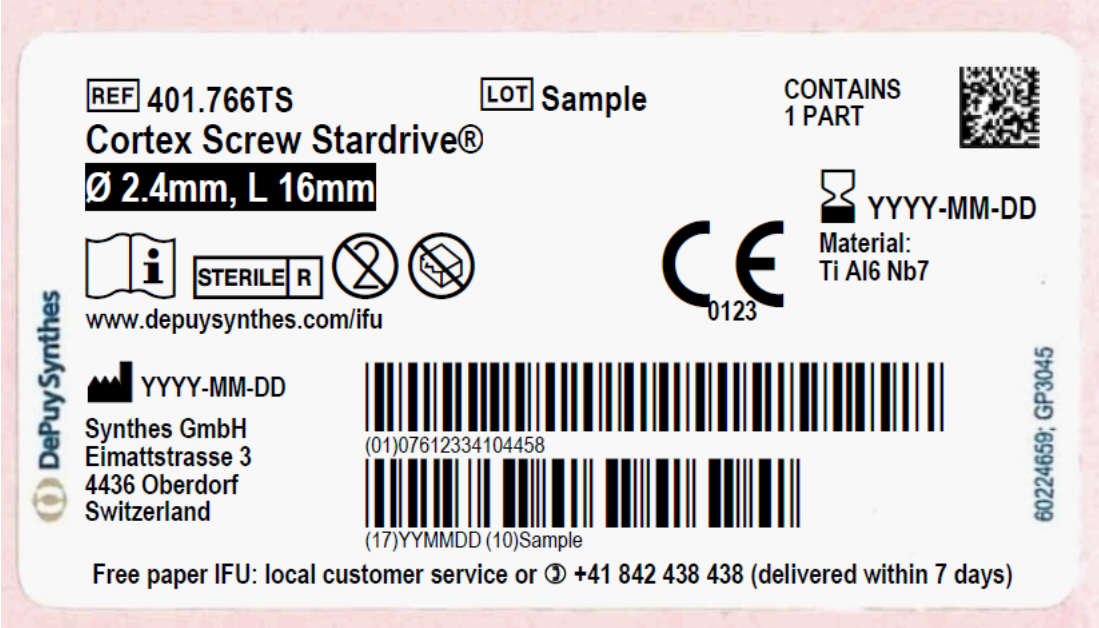
Attachment 1:

Sample Label for Part Number 401.766TS



Sample Label for Part Number 04.200.018TS