



19 Jul 2016

URGENT: FIELD SAFETY NOTICE
Locking Screws Stardrive® Ø 2.4 mm,
Self-Tapping, Length 12 mm, Titanium-Alloy-Niobium Alloy
426750 – Product Removal

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Descriptions	Part Numbers	Lot Numbers	Picture	Diameter	Length	Color	Screw Tip
Locking Screw Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, TAN	412.812	9744302, 9946065, 9699702, 9746853		2.4mm	12mm	Green	Self-tapping
Locking Screw Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, TAN, Sterile	412.812S	9775771, 9724771		2.4mm	12mm	Green	Self-tapping

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Locking Screws Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, TAN which is a part of following systems:

- LCP Distal Radius System 2.4
- LCP Compact Hand 2.4
- LCP Compact Foot 2.4
- 2.4/2.7 mm Locking Tarsal Plates

Reason for the Recall

It was reported that the specified lots of the Locking Screws Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, TAN can break between the head and the shaft. This resulted from the neck feature being too close to the StarDrive feature leaving a thin wall between the neck and drive.

Potential Patient Impact:

In the event that the nonconforming screw should separate between the head and the shaft during insertion or removal, a surgical delay may occur as the surgeon attempts to remove the shaft or fragment from the bone. Patients with hard bone may be at a higher risk for breakage. Removal of fragments can result in bone damage. Additionally, a protruding fragment can lead to adverse tissue reaction or soft tissue irritation.

It is possible that a locking screw could have a partial separation, fracture, or a weakened area between the head and the shaft that may go unnoticed during insertion. It is anticipated that a partially broken or fractured device may be seen on X-ray; however, it is possible that it could go unnoticed and, should that occur, the patient may present at a later time with pain due to a broken or loosened device. In a worst case scenario, the patient may have a malunion / non-union which could either lead to revision surgery if healing has not occurred or removal of the device if healing has occurred. It is important to note that constructs typically have more than one size and/or type of screw which would decrease the risk of breakage in situ.

Customer immediate actions:

The Locking Screws Stardrive® Ø 2.4 mm, self-tapping, length 12 mm, TAN are too small to have a part or lot number etched on them. Therefore, we are asking you remove and return all unpackaged Locking Screws Stardrive ® Ø 2.4 mm, self-tapping, length 12 mm, TAN in your kits along with any screws still in the original packaging with the part number and lot number listed above.

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.

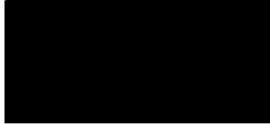
Please take the following actions:

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. Additionally, remove unpackaged Locking Screws Stardrive ® Ø 2.4 mm, self-tapping, length 12 mm, TAN in any affected kits.
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.

Yours Sincerely,





Lee, Ching Hwee
Associate Manager, Regulatory Affairs

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Please check (√) accordingly:

- We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.
- We located the identified product in stock; returned quantity is documented below:

Product Code	(Serial/Lot Number)	Quantity (Number in “Eaches”)

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

Customer Name

Title

Signature & Date

Stamp (*Stamp shall bear facility name*)

Please complete this Verification Section and return to your Deputy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.