

**To the ATTENTION of:
Operating room manager**

21 March 2017

URGENT MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number

Part Number	Part Description	Lot Number
314.560	Screwdriver Shaft, hexagonal, large, Ø 3.5 mm, length 165 mm, for Quick Coupling	7722501

Dear Madam / Dear Sir,

Synthes is initiating a medical device removal regarding the above mentioned article and lot number of the Screwdriver Shaft, hexagonal, large, Ø 3.5 mm, length 165 mm, for Quick Coupling. Our records indicate that you may have inventory that is impacted by this removal.

Description of problem:

Synthes received a complaint that the location slot for the screw holding sleeve was machined 3 mm out of position.

Patient risk:

The presence of a screw driver, 314.560, which is not manufactured to specification, may result in a surgical delay due to the non-conformance. Per the reported information, the screw sleeve retaining slot is 3 mm out of position. The combination of the non-conforming screwdriver and a retaining sleeve will result in a situation where the surgeon will have minor difficulty interfacing the screw with the driver and sleeve, but the surgeon should still be able to insert the screw. It is important to note that the surgeon may opt to utilize the screwdriver without the retaining sleeve. In addition, an alternative screwdriver is available in the graphic case. The resulting surgical delay is not anticipated to be clinically significant (<15 minutes) and no additional intervention is anticipated. The surgeon will be able to complete the index procedure.

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Customer immediate actions:

1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected product will not be used.
2. Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product 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 product listed below 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 Synthes GmbH.
7. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

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.

Yours sincerely,



Linn Kai Kiong

Head of Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments



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NOTICE: MEDICAL DEVICE REMOVAL R2013562

Verification Section

Part Number	Part Description	Lot Number
314.560	Screwdriver Shaft, hexagonal, large, Ø 3.5 mm, length 165 mm, for Quick Coupling	7722501

- ☐ 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:

Hospital name & Stamp: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____