

To the ATTENTION of: Operating Room Manager

06 November 2014

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Number	Lot Number	Description
03.617.914	8496070	Drill Bit Ø 2.0mm drilling depth 14mm, 3-flute, for Quick Coupling

Dear Valued Customer,

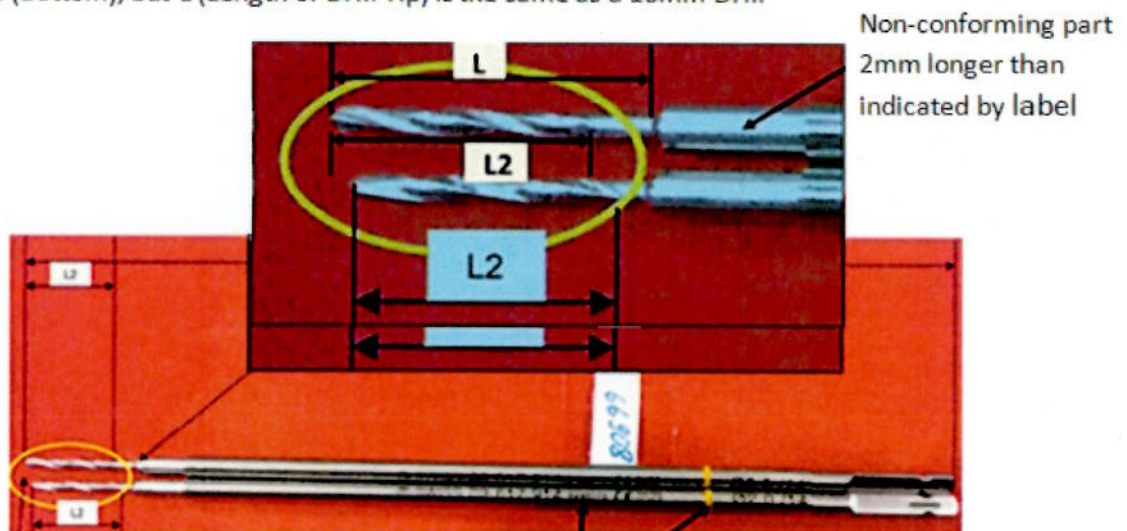
Synthes GmbH is issuing a medical device recall related to the above mentioned lot of Drill Bit Ø 2.0mm drilling depth 14mm, 3-flute, for Quick Coupling.

Our records indicate that you may have inventory or loan sets that are subject to this product recall and we kindly request you review the information below and complete the Verification Section at the end of this letter.

Description of the problem:

It was discovered that a product of the above mentioned lot of 2.0 mm Drill Bits with 14mm Stop/Zero-P had been manufactured with a tip that was 16mm. This 16mm component was then incorrectly packaged, labeled, and distributed as a 14mm drill bit.

L2 (flute length) for non-conforming part (top) is the same as that of a 14mm Drill (Bottom), but L (Length of Drill Tip) is the same as a 16mm Drill



Potential hazard:

If the non-conforming drill bit passed unrecognized into the operation room and to the surgeon for use, the longer than intended drill bit could potentially penetrate the posterior wall of the vertebral body. This could potentially result in minor bone, soft tissue or disc damage or, in a worst-case scenario, damage to the spinal cord, meninges, or nerves with the potential for permanent injury. If a dural tear occurred intraoperatively, the necessary repair might lead to a significant lengthening of the surgery.

To date, there have been no reports of patient injury related to this issue.

Requested Immediate Customer actions:

1. Immediately identify and quarantine all unused product listed below 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 organization within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days. Credit or replacement will be provided based on product availability.
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. Keep a copy of this notice with the affected product.

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

We apologize 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 DePuy Synthes sales consultant.

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Synthes GmbH

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06. November 2014

NOTICE: MEDICAL DEVICE REMOVAL R20131589**Verification Section**

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- 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: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____