

16 March 2015

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014206
Cross-Link Clamp (pre-assembled)**

Please distribute this information to the appropriate personnel at your facility

Part Description, Part- and Lot Numbers

Part Descriptions	Part Numbers	Lot Numbers
Cross-Link Clamp for Rods Ø 6.0 mm, preassembled, Titanium Alloy (TAN), dark blue	498.813(S)	2780518
		2781527
		2780516
		2780511
		2780509
		2780507

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of pre-assembled Cross-Link Clamp. The pre-assembled Cross-Link Clamp is used with 6mm longitudinal and 3.5mm transverse rods to provide additional rotational stability to long posterior thoracolumbar constructs.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loaner set.

Reason for the Recall:

Due to an error in production, the above mentioned Part- and Lot Numbers of pre-assembled Cross-Link Clamp cannot be securely attached to 6mm longitudinal rods.

Potential hazard:

Potential for the clamp to not tighten appropriately may lead to surgical delay. If backup pre-assembled Cross-Link Clamp are available unsterile, they would require sterilization (4 minutes of sterilization time and 20 minutes for the dry time at minimum, plus time for the device to cool down¹).

At the point where there is no alternative device available to the surgeon for use, it is reasonable that the surgeon would close the surgical site and determine what additional postoperative care would be needed. In a worst case scenario, the patient may undergo re-operation for implantation of the transverse rod(s) with Cross-Link Clamp that was

¹ Important information (with Cleaning and Sterilization Instructions), © Synthes GmbH 2014, EN SE_023827 AJ 12/14 10100803.

unavailable during the initial surgery, if the surgeon deems this necessary for additional rotational stability of the construct. To date, there have been no reports of revision surgery related to this issue.

Customer immediate actions:

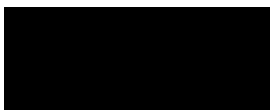
1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 2 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.
8. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

The applicable regulatory agencies are being notified.

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,



Cherie Yip
Regulatory Affairs Specialist

Account Name: _____

**URGENT NOTICE:
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Verification Section

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_____ We have located the identified product in stock; returned quantity is documented below.

_____ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

RETURNED DEVICES (including quantity):

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 DePuy Synthes representative or fax it to +65 6720 0750 within **(2) two business days** of receipt of the Field Safety Notice.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.