

14 Apr 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R20131571
Bending/Cutting Pliers with Nose, for LOCK Plates 2.0

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers
Bending/Cutting Pliers with Nose, for LOCK Plates 2.0	329.143	Please refer to Attachment 1

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the Bending/Cutting Pliers with Nose for LOCK Plates 2.0. The Bending/Cutting Pliers with Nose for LOCK Plates 2.0 is intended to be used for bending and/or cutting Compact 2.0 Mandible Locking Plates.

Our records indicate that you may have inventory, including loaner sets, which are impacted by this recall.

Reason for the Recall

The affected lots of the Bending/Cutting Pliers with Nose for LOCK Plates 2.0 have the potential for tip breakage while bending the extra-large Compact 2.0 Mandible Locking Plates (Part Numbers 447.412, 447.420, 447.422, 447.423, 447.424, 447.425, 447.426, 447.412S, 447.420S, 447.422S, 447.423S 447.424 S, 447.425 S and 447.426S) with the last hole feature of the instrument.

Potential Patient Impact:

If a nonconforming Bending/Cutting Pliers with Nose for LOCK Plates 2.0 is used and breaks while in the Operating Room, surgical delay may occur while alternate bending or cutting instruments are located.

To date, there have been no reports of adverse events related to this issue. Such reports are unlikely to occur as the Bending/Cutting Pliers with Nose for LOCK Plates 2.0 are not used in direct contact with the patient but rather on the plates before they are inserted.

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 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	(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 Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.

Attachment 1. Part Description, Part- and Lot Numbers subject to this recall

Part Description	Part Number	Lot Numbers	
Bending/Cutting Pliers with Nose, for LOCK Plates 2.0	329.143	117649	3690126
		117655	3713796
		118567	3774024
		118870	3808100
		119543	7508187
		119867	7535919
		120058	7671800
		120969	7687537
		121792	7695620
		126642	7736122
		126643	7759167
		129479	7768317
		1421494	7802342
		1462914	7841078
		2040260	7871724
		2053366	7882679
		2078194	7894228
		2093655	7944938
		2113844	8098561
		2137552	8170305
		3279314	8338225
		3307305	8359671
		3321734	8402580
		3340284	8422422
		3352331	8458573
		3352333	8499485
		3362459	8527650
		3450169	8549093
		3450688	8574032
		3660041	8604167