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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

28 April 2014

URGENT VOLUNTARY MEDICAL DEVICE PRODUCT RECALL

Part Description	Part Numbers	Lot numbers
Shortcut for MatrixMANDIBLE™ Plates, thickness 1.5 to 2.8, with Rasp, required in pairs	03.503.057	8384952

Dear Valued Customer,

Synthes GmbH is initiating a voluntary recall of the above mentioned article and lot of the CMF Shortcut for MatrixMANDIBLE™ Plates, thickness 1.5 to 2.8, with Rasp, required in pairs (03.503.057). Our records indicate that you may have inventory that is impacted by this recall.

Description of the problem:
The face of the Shortcut for MatrixMANDIBLE™ Plates has the potential for discoloration/corroded material in the affected lot noted above.

Potential hazard:
Discoloration/corroded material on the Shortcut for MatrixMANDIBLE™ Plates has the potential to result in a surgical delay or an adverse tissue reaction.

Any discoloration or corroded material on this instrument would likely be visually detected in the preoperative period. However, if the discoloration was detected during the intraoperative period, surgical delay may occur. Slight delays are not likely to result in increased risk to the patient. However, if the Shortcut for MatrixMANDIBLE™ Plates is needed to cut a large plate (1.5mm, 2.0mm, 2.5mm, or 2.8mm thick), two cutters are required, and therefore the surgical delay may be extended if alternate cutting tools are not immediately available in the operative theater.

If any discoloration or corroded material on the surface of the Shortcut for MatrixMANDIBLE™ Plates is not discovered during surgery, use of the cutters may result in an adverse tissue reaction. Although the potential for an adverse tissue reaction does exist, it is not anticipated that this harm would occur.

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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 to your local DePuy 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 DePuy Synthes.

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 recall 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.

Synthes GmbH

Dr. med. Maga I. Behrens MDRA
Field Action Manager

Markus Wien
Director Quality Assurance Operations