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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

18 June 2014

URGENT MEDICAL DEVICE PRODUCT REMOVAL: MatrixRIB™ Fixation System (T-Plate 2.0mm, I-Plate 2.0mm and 2.0mm straight)

Part Description / Part Number

Part Number	Part Description	Lot numbers
04.501.098	MatrixRIB T-Plate 2.0 mm, 7 holes	all lots
04.501.098S	MatrixRIB T-Plate 2.0 mm, 7 holes, sterile	all lots
04.501.099	MatrixRIB I-Plate 2.0 mm, 11 holes	all lots
04.501.099S	MatrixRIB I-Plate 2.0 mm, 11 holes, sterile	all lots
04.501.100	MatrixRIB-Plate 2.0 mm, straight, 10 holes	all lots
04.501.100S	MatrixRIB-Plate 2.0 mm, straight, 10 holes, sterile	all lots

Dear Valued Customer,

Synthes GmbH is initiating a voluntary product removal of the above mentioned articles and lots. Our records indicate that you may have inventory that is impacted by this removal.

Description of the problem:

There is the potential that the MatrixRIB T-Plates 2.0 mm may break intraoperatively during contouring. These plates are new plates which are currently part of a Market Preference Evaluation (MPE) for the MatrixRIB Chest Wall Deformity and Reconstruction System, you agreed to participate in.

Please note: The MatrixRIB-Plate, straight, 24 holes (04.501.096, 04.501.096S) and MatrixRIB-Plate, straight, 30 holes (04.501.097, 04.501.097S) are not affected by this recall.

Potential hazard:

A moderate surgical delay may result from breakage of the plate secondary to bending when using the combination bending pliers in the undercut area.

Application device failure could occur in the postoperative period as higher stresses are placed on the plate through activities of daily living particularly prior to union of the bone. These additional stresses placed on a plate with a crack, could result in device loosening or breakage of the implant.

Mitigation Steps for Patients with MatrixRIB T-Plates 2.0mm currently implanted

Patients should be closely followed during the bone healing process to mitigate the risk of plate breakage.

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.

Thank you for your attention and cooperation.

Synthes GmbH

[redacted]

Field Action Manager

Director Quality Assurance Operations

Cc:

[redacted]