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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

18 February 2014

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Description / Part Number

Part Number	Part Description	Lot Numbers
489.402	Cervical Spine Reconstruction Plate 3.5, 3 holes, hole spacing 8 mm, length 26 mm, Pure Titanium	All lots
489.403	Cervical Spine Reconstruction Plate 3.5, 3 holes, hole spacing 16 mm, length 42 mm, Pure Titanium	All lots
489.412	Cervical Spine Reconstruction Plate 3.5, 4 holes, hole spacing 16 mm, length 58 mm, Pure Titanium	All lots
489.413	Cervical Spine Reconstruction Plate 3.5, 5 holes, hole spacing 16 mm, length 74 mm, Pure Titanium	All lots
489.414	Cervical Spine Reconstruction Plate 3.5, 33 holes, hole spacing 8 mm, length 266 mm, Pure Titanium	All lots
489.415	Cervical Spine Reconstruction Plate 3.5, 2 holes, hole spacing 12 mm, length 22 mm, Pure Titanium	All lots
489.418	Cervical Spine Reconstruction Plate 3.5, 3 holes, hole spacing 12 mm, length 34 mm, Pure Titanium	All lots
489.423	Cervical Spine Reconstruction Plate 3.5, 4 holes, hole spacing 12 mm, length 46 mm, Pure Titanium	All lots
489.424	Cervical Spine Reconstruction Plate 3.5, 5 holes, hole spacing 12 mm, length 58 mm, Pure Titanium	All lots
489.425	Cervical Spine Reconstruction Plate 3.5, 22 holes, hole spacing 12 mm, length 262 mm, Pure Titanium	All lots

Dear Valued Customer,

Synthes GmbH is initiating a voluntary recall of the above mentioned articles and lots of the Cervical Spine Reconstruction Plates 3.5. Our records indicate that you may have inventory that is impacted by this recall.

Description of the problem:

The Synthes Cervical Spine Reconstruction Plate 3.5 set was released for sale as a Trauma product in 1996 with specific trauma indications and contraindicated for certain spine applications. In 1999 a module was released containing only a small offering of the Cervical Spine Reconstruction Plates 3.5. Upon review, it was determined that sales of the product contained in the Cervical Spine Reconstruction Plates 3.5 module have been made exclusively by Spine sales consultants indicating the plate.

Potential hazard:

The presence of a trauma plate that is being utilized or promoted for use in the cervical spine has the potential to cause harm to the patient, as it is not designed or tested for application in this clinical scenario/anatomic region. Because the device is not approved for use in the spine, the appropriate Instructions for Use would not be available to the surgeon.

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

E. Hartmann

Esther Hartmann
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

DePuy Synthes

NOTICE: MEDICAL DEVICE RECALL R20131560

Cervical Spine Reconstruction Plates 3.5

Verification Section

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489.412	Cervical Spine Reconstruction Plate 3.5, 4 holes, hole spacing 16 mm, length 58 mm, Pure Titanium	All lots
489.413	Cervical Spine Reconstruction Plate 3.5, 5 holes, hole spacing 16 mm, length 74 mm, Pure Titanium	All lots
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489.418	Cervical Spine Reconstruction Plate 3.5, 3 holes, hole spacing 12 mm, length 34 mm, Pure Titanium	All lots
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489.425	Cervical Spine Reconstruction Plate 3.5, 22 holes, hole spacing 12 mm, length 262 mm, Pure Titanium	All lots

☐ 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: _____

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