16 March 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2016010
VA-LCP Dorsal Distal Radius L-Plate 2.4, right angled and
VA-LCP Dorsal Distal Radius L-Plate 2.4, left angled

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
VA-LCP Dorsal Distal Radius L-Plate 2.4, right angled, shaft 5 holes, head 2 holes, length 51 mm, Pure Titanium	04.115.150	9678747
VA-LCP Dorsal Distal Radius L-Plate 2.4, left angled, shaft 5 holes, head 2 holes, length 51 mm, Pure Titanium	04.115.151	9678750

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part- and Lot Numbers of the VA-LCP Dorsal Distal Radius L-Plate 2.4. These implants are indicated for dorsally displaced fractures, extra-articular and intra-articular fractures with metaphyseal defect, open joint reconstruction, combination of distal radius with carpal and metacarpal fractures, and corrective osteotomies after distal radius malunion.

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

Reason for the Recall

A VA-LCP Dorsal Distal Radius L-Plate 2.4 may be etched with a part number that incorrectly identifies the angle. For example, a right-angled part may be etched with a left-angled part number or vice versa.

Potential Patient Impact:

Upon receipt of the non-sterile product the user may notice that the outside package label and the etching on the product match, however the 90 degree bend does not match the configuration within the tray/module. The user would not be able to place the implant into position within the tray/module without turning the implant over due to the 90 bend. No surgical delay is anticipated and it is highly likely the issue would be identified at this time.

Should the device make it into the operating room and the surgeon requests the part by anatomic configuration only, the plate can be used as intended. If the surgeon requests the

plate by part number, he/she would recognize that the plate configuration does not match the anatomy as anticipated (90 degree bend is incorrect). In this scenario a surgical delay may occur while a replacement plate (which is available sterile) is obtained.

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected 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,

[redacted]

Lee, Ching Hwee
Senior Regulatory Affairs Executive

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
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Business Reg No. 52836279L Company Reg No. 197402104W

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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.

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