MEDICAL DEVICE RECALL – R2014028R

Socket, Hexagonal Ø 4.0mm/11.0mm

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

Synthes GmbH is initiating a voluntary medical device recall of the following Part and Lot Numbers of the DePuy Synthes Hexagonal Socket, Ø 4.0mm/11.0mm. The Socket is a cannulated instrument used to insert the end caps in the following nail systems: Proximal Femoral Nail Anti-rotation (PFNA), PFNA-II, and the Antegrade Femoral Nail (AFN).

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

REASON FOR THE RECALL

There is a potential for the Socket-hex tip to break into fragments during use if too much force is applied.

POTENTIAL HAZARD

Breakage of the hex tip may result in surgical delay and an adverse tissue reaction.

As the affected item has been reported to break intra-operatively, there is potential for surgical delay while the fragments are retrieved. Consequently, surgical delay may occur while a replacement instrument or alternative device is located to insert the end cap. In addition, an adverse tissue reaction may possibly occur if any stainless steel fragments from the Socket are not retrieved from the patient.

PRODUCTS AFFECTED

This field safety notice involves the following product:

Product Code	Product Description	Affected lots
356.714	Socket, hexagonal Ø 4.0mm/11.0mm, cannulated	All lots

PRODUCT REPLACEMENT

The affected socket can be replaced with the Cannulated Screwdriver 6.5/7.3mm (part number 314.050), which has the same 4.0mm hexagonal drive as the recalled socket. As alternative for the Hex drive End Caps, the use of Stardrive End Caps can be considered. Please contact your local DePuy Synthes sales consultant for further details.

Significant supply issues may occur due to the expected high demand for the replacement screwdriver. Therefore the placement of end caps for the PFNA / PFNA-II and AFN according to the technique may not be possible until the replacement is available.

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NOTE: The Cannulated Screwdriver (part number 314.050) and the Socket (part number 356.714) are not indicated for the removal of the end cap.

ACTIONS REQUIRED FROM YOU

1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected product will not be used.

2. Review, complete, sign and return the attached Customer Acknowledgement Form to your DePuy Synthes sales representative or fax it to 6720 0750 within 5 business days of receipt of this notification.

3. To return affected product in your inventory, contact your DePuy Synthes sales representative or call our customer service. Attach a photocopy of the Customer Acknowledgement Form with the products. Johnson & Johnson Medical Singapore will issue credit for returned products, if applicable.

4. Forward this Field Safety Notice to anyone in your facility that needs to be informed.

5. If any of the affected products have been forwarded to another facility, contact that facility and arrange for the return.

6. Maintain awareness of this notice until all affected products have been returned to Johnson & Johnson Medical Singapore.

7. Keep a copy of this notice.

8. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

We apologize for the inconvenience 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 representatives.

Thank you for your cooperation and patience.

Yours sincerely,

[redacted]

Lee Ching Hwee

Senior Regulatory Affairs Executive

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