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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

31 July 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014028R
Socket, Hexagonal Ø 4.0mm/11.0mm

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers
Socket, hexagonal Ø 4.0/11.0 mm, cannulated	356.714	All Lots

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned 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.

Customer immediate actions:

1. Immediately identify and quarantine all 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.

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.

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.

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.

Synthes GmbH

Pierre van Iwaarden
Field Action Manager

Anne Brisson
Senior Quality Assurance Manager,
Product Safety and Performance

Cc:

Account Name: _____

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MEDICAL DEVICE RECALL – R2014028R
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Verification Section

Part Description / Part Number:

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Socket, hexagonal Ø 4.0/11.0 mm, cannulated	356.714	All Lots

____ We have located the identified product in stock; returned quantity is documented below.

____ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

RETURNED DEVICES (including quantity):

_____

_____

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page your local DePuy Synthes sales organization.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.