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20 April 2015

URGENT NOTICE:
Field Safety Notification – FSN2014-217R
Connecting Screw for Insertion of DHS Blade

Please distribute this information to the appropriate personnel at your facility

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers	
Connecting Screw for Insertion of DHS Blade	03.224.007	2161305	8037035
		2243635	8117808
		2260851	7799873
		2260851-I	2557362
		2260851-L	2561953
		2290278	2630618
		2290282	2684005
		2290283	2733243
		2512219	2762808
		2513675	2800137
		2523116	

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part and Lot Number of the Connecting Screw for insertion of DHS Blade

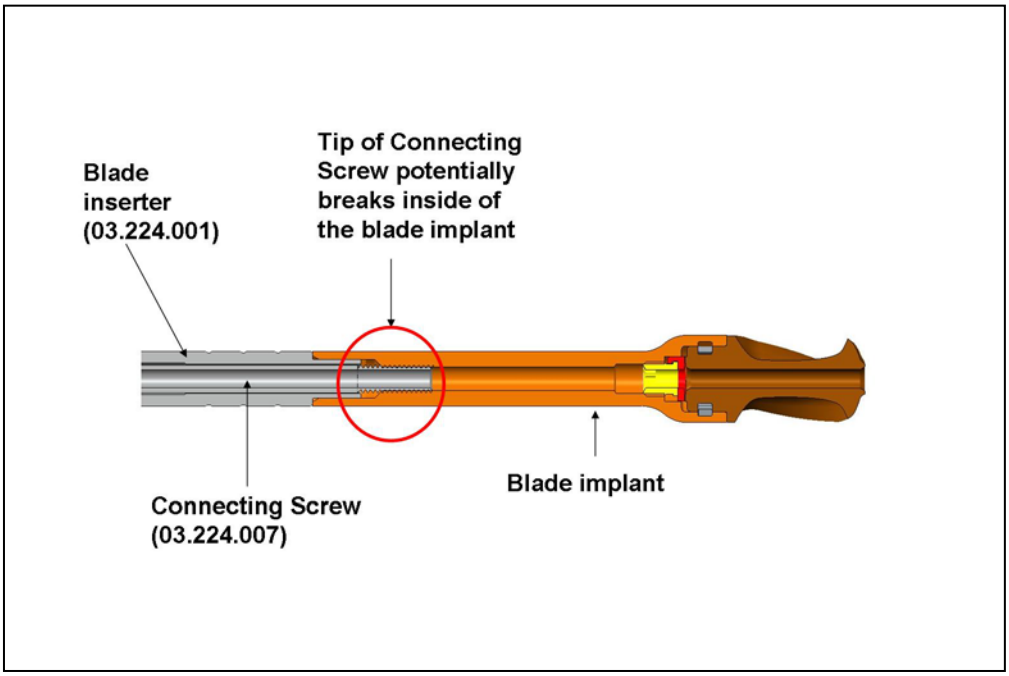
The connection screw for insertion of DHS Blade is used to insert the DHS Blade implant during surgery. Indications for use include all combinations of DHS Blade and DHS Plates. Without the DHS connecting screw the DHS Blade implants cannot be implanted.

Our records indicate that you may have a connecting screw in your inventory that is impacted by this Recall.

Reason for the Recall

Complaints of insertion screw breaking inside the blade implant during insertion. When the DHS Blade Connecting Screw breaks inside the implant, it blocks the locking mechanism that is important for rotational stability (ensuring the bone fragments maintain anatomical reduction). See Image below.

Return Receipt Requested



Cross-sectional view for DHS Blade insertion assembly

Potential Hazards and Risk Mitigation Measures:

In the event that the tip of the Connecting Screw breaks intra-operatively, the implant locking mechanism (for rotational stability) cannot be secured.

The following Potential harms may occur under the following circumstances:

1) If the fragment is retrieved with no need to replace the implant, this can lead to prolongation of surgical operating time. The use of the Screw Extraction instrument 309.521 or OPERACE 80018 is recommended to retrieve the broken tip of the Connecting Screw.

2) If the fragment cannot be retrieved, rotational stability is compromised and the blade needs to be replaced or additional lag screws implanted. This may lead to possible prolongation of surgical operating time, bone damage and subsequent interventions. If the patient cannot be treated with replacement of implants or additional lag screws, the patient may require a total hip arthroplasty.

3) If the fragment cannot be retrieved and remains in the DHS Blade in the patient, this could lead to adverse tissue reaction because the Connecting Screw is made of implant grade stainless steel.

Return Receipt Requested

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 on page 4-5 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.

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.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this 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
Professional Affairs Executive

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URGENT NOTICE:
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Verification Section

Please distribute this information to the appropriate personnel at your facility

Part Description / Part Number:

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		2512219	2762808
		2513675	2800137
		2523116	

☐ We acknowledge receipt of this information and have located the identified product in stock; returned quantity is documented below:

No.	Lot Number	Quantity

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

Return Receipt Requested

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.

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.