

**To the ATTENTION of:  
Operating Room Manager**

9 April 2015

**URGENT NOTICE:  
MEDICAL DEVICE RECALL – R2014217  
Connecting Screw for Insertion of DHS Blade**

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers		
Connecting Screw for Insertion of DHS Blade	03.224.007	2161305	8037035	8037035
		2243635	8117808	8117808
		2260851	7799873	8296913
		2260851-I	2557362	8465206
		2260851-L	2561953	8487190
		2290278	2630618	8577396
		2290282	2684005	
		2290283	2733243	
		2512219	2762808	
		2513675	2800137	
		2523116	7799873	

Dear Sir/Madam,

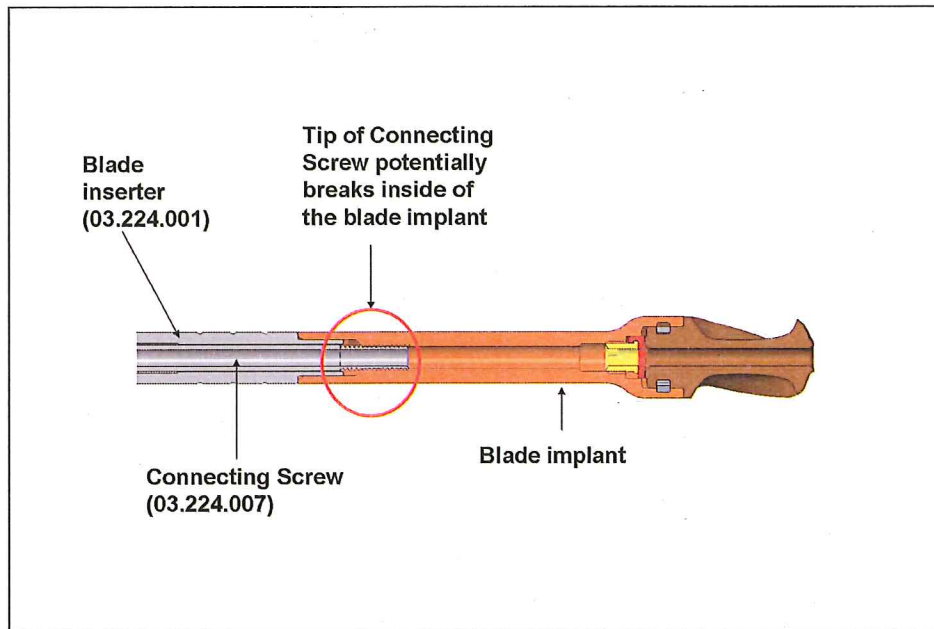
Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part and Lot Number of the Connecting Screw for insertion of DHS Blade

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.



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 intraoperatively, 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.

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 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.

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.

Synthes GmbH



Pierre van Iwaarden  
Field Action Manager



Charles Goldberg  
Worldwide Director Complaint Management

Cc:

Account Name: \_\_\_\_\_

**URGENT NOTICE:**  
**MEDICAL DEVICE RECALL – R2014217**  
**Connecting Screw for Insertion of DHS Blade**

**Verification Section**

Part Description / Part Number:

Product Description	Part Number	Lot Numbers		
Connecting Screw for Insertion of DHS Blade	03.224.007	2161305	8037035	8037035
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		2512219	2762808	
		2513675	2800137	
		2523116	7799873	

\_\_\_\_ 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: \_\_\_\_\_

RGA # (If applicable):

\_\_\_\_\_

**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.