

Date: 26 March 2019

URGENT FIELD SAFETY NOTICE:
Femoral Neck System (FNS) Insert for Insertion Handle
1449426 – Product Removal

PLEASE DISTRIBUTE THIS INFORMATION TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS NOTICE

Dear Sir/Madam:

Synthes GmbH is initiating a product removal of the below part and lot numbers of Femoral Neck System (FNS) Inserts for Insertion Handle. These devices are intended for temporary fixation, correction, or stabilization of bones in the femoral neck.

Product Subject to this Removal:

Part Number	Part Description	Lot Numbers
03.168.009	Insert for Insertion Handle	170009-102, 170009-103, 170009-104, 170009-105, 170330-101, 170330-102, 170330-103

Reason for Recall:

Synthes GmbH has discovered the press fit of the insert components were not properly completed during manufacturing for the lots listed above. This may result in the drive head being loose or separating from the insert for the insertion handle. If this occurs intraoperatively the intra-operative compression step will not be able to be completed.

Potential Impacts:

There is a potential harm for surgical delay if the FNS procedure was not able to be completed. Additional harms may include bone damage and damage to surrounding structures if the procedure is changed and multiple screws or a hip screw fixation being used.

Actions to be taken:

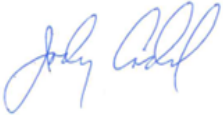
Our records show that your facility has received one or more of the products subject to this removal. Please take the following actions:

1. Immediately review your inventory to identify and quarantine the 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 the affected products within 30 business days. A credit note will be issued for the returned items or product will be replaced if readily available.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If the affected products have been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until the products have been returned.
7. Keep a copy of this notice.

This product removal has been reported to the local competent authority. 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.

DePuy Synthes



Jody Cadd
Product Safety Supervisor, Field Actions
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Business Phone: (610) 314-2106

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Verification Section

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___ We have located the identified product in stock; returned quantity is documented below.
 RETURNED DEVICES (Quantity): _____

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

CUSTOMER DETAILS	
Facility Name:	
Facility Address:	
Account Number:	
Reply Confirmation Completed by: (Please Print Name)	
Signature and Date: (REQUIRED FIELD)	
Title: (Please Print)	
Telephone Number: (Include Area Code and Extension)	
Email address:	
RA#: (IF applicable)	

The above acknowledges receipt of the subject Field Safety Notification, Product Removal in reference to the FNS Inserts.

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