Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
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http://www.depuysynthes.com/

Date: 21 March 2018

URGENT FIELD SAFETY NOTICE:
FLEX ARM INSTRUMENT- REF. 1137529- 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 specified lots of Flex Arm instruments. The Synthes Flex Arm is a component of the Synthes Minimally Invasive Support System, which provides secure table mounting for minimally invasive spine surgery. Our records indicate that your facility may have devices in inventory that are included in the scope of this Recall.

Product Subject to this Removal:

Part Number	Part Description	Lot Numbers			
03.612.010	Flex Arm	9833185	9940637	H144265	H305886
		9866629	9982802	H212060	H347867
		9888308	H044106	H260544	H430221
		9914323	H072780	H260547	H430230

Reason for the Field Safety Notification:

Synthes GmbH has received complaint reports where the quick connect feature of the Flex Arm instrument was unable to secure the connection with the Flex Arm Adaptors, Insight Retractors, or other mating parts. The quick connect features of the above-mentioned lots of Flex Arm instruments may be impacted by this product issue.

Potential Patient Impact:

If the Flex Arm is unable to connect to a retractor or adaptor during surgery, there is a possibility of surgical delay to obtain an alternative instrument to complete the surgery. To date, surgical delay is the only adverse effect reported to DePuy Synthes for this issue.

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Actions to be taken:

Our records show that your facility has received one or more of the product(s) subject to this removal.

1. Immediately review your inventory to identify and quarantine all 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 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.

Appropriate National Competent Authorities will be advised of this field action. We apologize for any inconvenience that this product removal 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

[redacted]

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URGENT FIELD SAFETY NOTICE:
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Verification Section

Product Subject to this Removal:

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03.612.010	Flex Arm	9833185	9940637	H144265	H305886
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____ We have located the identified product in stock; returned quantity is documented below.

RETURNED DEVICES (Per part number including 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 product removal in reference to Recall 1137529.

Please complete and return this page to 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.