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11 November 2016

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
Product Removal 471818- SynReam Flexible shaft

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

Attention: OR/Risk Management

Synthes GmbH is initiating a medical device removal (recall) of the SynReam Flexible shaft, which are part of the SynReam medullary reaming system. This notification affects the items listed below.

Product Subject to this Removal:

Part Description	Part Number(s)	Lot Numbers
SynReam Flexible Shaft	352.040	9946822, 9947895, 9956527, L084498
Flexible Shaft Ø 7.0mm, long	352.044	9916436, 9916503, 9916508, L000158, L000160, L000573, L000603, L000604, L000605, L000607, L000632, L009405, L030364, L044313, L082974

Reason for the Recall:

Synthes has determined there is a potential the affected lots of the SynReam Flexible Shaft (352.040 and 352.044) may have been manufactured with a non-symmetric hexagonal coupling which may result in the reamer shaft not fitting into the reamer heads.

The SynReam Flexible shafts are intended for use as an optional reaming step in intramedullary nailing systems.

Potential Patient Impact:

In the event that the Flexible Shaft cannot be assembled with the Reamer Head, surgical delay may occur if another device is not available in the surgical suite.

Actions to be taken:
Our records show that your facility has received one or more of the product(s) subject to this product removal. **Please take the following actions:**

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. Complete the attached verification Section (page 3 of this notification) Please include your Facility Name and Address, Account number, name of person completing form, title, email address, telephone number and signature in the spaces provided:
    a. Send a copy of the completed Verification Section to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
    b. If the Verification Form 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 in page three (3) 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.

We apologize for any inconvenience that this product removal (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

[redacted]

Senior Quality Assurance Manager,
Product Safety and Performance

Cc:

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MEDICAL DEVICE FIELD SAFETY NOTIFICATION-
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Verification Section

Affected Product:

Part Description	Part Number(s)	Lot Numbers
SynReam Flexible Shaft	352.040	9946822, 9947895, 9956527, L084498
Flexible Shaft Ø 7.0mm, long	352.044	9916436, 9916503, 9916508, L000158, L000160, L000573, L000603, L000604, L000605, L000607, L000632, L009405, L030364, L044313, L082974

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

RETURNED DEVICES (including quantity):

_____

____ We acknowledge receipt of this information, but do not have any affected 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:	

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.