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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

12 October 2016

URGENT NOTICE:
FIELD SAFETY NOTICE-Product Removal – 453706
Sterile Reaming Rods for SynReam

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
SynReam Reaming Rod 2.5mm, L 650mm, sterile	351.709S	See Attachment 1

Dear Sir/Madam,

Synthes GmbH is initiating a product removal of unopened packages of the above mentioned Part and Lot Numbers for the Sterile Reaming Rods for SynReam.

The purpose of the reaming rod is:
1. To maintain anatomic alignment of the bone fragments along the medullary canal while providing guidance for the reamer head and flexible shaft assembly as it cuts its way through the medullary canal.
2. To maintain and strengthen the assembly connection between reaming head and the flexible shaft.

There are various intramedullary nailing indications where reaming of the medullary canal is required. In these indications, reaming and the use of the appropriate nail can achieve high stability for an early functional rehabilitation.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

Reason for the Recall:

The peel pouches for the above referenced reaming rods are delaminating. The surgical staff members may experience difficulty in opening the peel pouch potentially causing the sterile device to come in contact with a non-sterile layer of the pouch. DePuy Synthes is requesting correction of unopened affected products with one of the following two options:

Option 1:
Customers may choose to re-sterilize affected unopened products per the product Sterilization Instructions provided with the product's original packaging.

Option 2:
Customers may choose to return unopened affected devices for a replacement.

Potential hazard:

In the event there is difficulty in opening the sterile peel pouch a surgical delay may occur while a replacement part is located or while re-sterilization is performed. If surgery cannot be completed without the sterile part and no alternate is available, the procedure may need to be rescheduled.

If there is delamination of the peel pouches the layering and fragments may compromise the sterility of the part, which may place the patient at risk for infection. Infants, elderly, pregnant women, critically ill patients, and immunocompromised patients are at a greater risk of infection if a contaminated part is not detected prior to use and/or if the surgical procedure time is extended beyond what was expected.

Additionally, there may be adverse tissue reaction if particles from the delaminating peel pouch adhere to the part and subsequently contact the surgical site.

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected unopened products listed above in a manner that ensures the affected products will not be used.

2. As a correction to the potential for the sterile product to be compromised due to the difficulty in opening the package, all affected parts in inventory should be re-sterilized or returned to DePuy Synthes. The unopened product is to be re-sterilized per the product Sterilization Instructions contained within the Instructions For Use provided with the product. This information is also on the Synthes website (http://www.synthes.com/cleaning-sterilization). Note: These reaming rods are also offered for sale in non-sterile packaging.

3. Review, complete, sign and return the attached reply form on page 4 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.

4. For affected product that will not be re-sterilized, return the product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.

5. Forward this notice to anyone in your facility that needs to be informed.

6. If any of the affected products has been forwarded to another facility, contact that facility to arrange return.

7. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.

8. Keep a copy of this notice.

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.

DePuy Synthes

[redacted]

Cc:

DePuy Synthes
Companies of Johnson & Johnson

Account Name: _____

URGENT NOTICE:
FIELD SAFETY NOTICE-Product Removal – 453706
Sterile Reaming Rods for SynReam

Verification Section

Part Description, Part and Lot Numbers

Product Description	Part Number	Lot Numbers
SynReam Reaming Rod ø 2.5mm, L 650mm, sterile	351.709S	See Attachment 1

____ We have located the identified product in stock and will re-sterilize per pre-vacuum instructions in the IFU provided with the product. Affected quantity that will be re-sterilized is documented below.

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

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

RETURNED DEVICES OR RE-STERILIZED DEVICES (including quantity):

_____

_____

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

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.

DePuy Synthes
companies of Johnson & Johnson

Attachment 1. Part Description, Part- and Lot Numbers subject to this product removal

Part Description	Part Number	Lot Numbers	
SynReam Reaming Rod ø 2.5mm, L 650mm, sterile	351.709S	9913259	H060116
		9913260	H060115
		9963749	H040517
		9963751	H080081
		9963757	H080087
		9963747	H080082
		9963753	H080085
		9963752	H080083
		9963755	H080086
		9963756	H080088
		9963748	H080084
		H060114	H080089
		H040518	H105530