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To the ATTENTION of:
Operating Room Manager

12 December 2016

URGENT NOTICE:
MEDICAL DEVICE FIELD SAFETY NOTIFICATION
-Product Removal R2014032_2
FOLLOW-UP NOTIFICATION: RIA system - incorrect shelf life
Additional Lot Numbers Identified

Dear Sir/Madam,

This is a follow-up notification to Synthes GmbH medical device removal (recall) issued on 8 December 2014. Specifically, additional lots of one part number of the DePuy Synthes Trauma RIA (Reamer/Irrigator/Aspirator) System were identified.

This expansion is initiating a medical device removal (recall) of the below mentioned products and lot numbers of the DePuy Synthes Trauma RIA (Reamer/Irrigator/Aspirator) System. 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.

Product Subject to this Removal:

Part Number	Part Description	Lot Numbers
314.746S	RIA Tube Assembly, for RIA Drive Shaft minimum length 520 mm, for No. 314.743, sterile	2251446-I, 2256902-I 2256903-I, 2256904-I 2256905-I, 2256906-I 2256907-I

Reason for the Recall:
It was discovered that the expiration date on the label for the referenced product is incorrect. Existing testing supports an expiration date of 2 years from manufacturing. The affected products on the market were labeled with an expiration date of 10 years. There is biocompatibility test data to support an expiration date 2 years only; biocompatibility testing was not completed for 10 years. There is no evidence that the devices would develop cytotoxicity after two years, but in the absence of supporting data a theoretical risk remains.

Potential hazard:
Leachates (liquefied constituents) from a non-biocompatible device may produce an Adverse Tissue Reaction. This is an undesired, excessive inflammatory response to foreign material (chemical, biological or physical) within the body. Medical or surgical treatment is optional and permanent impairment would not be expected. The possibility of this harm is deemed to be remote as the material used in the device has undergone and passed testing for integrity of packaging (both seal integrity and sterile barrier integrity) and biocompatibility, and is stable after sterilization for an expiration date of 2 years.

Customer immediate actions:

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 to your local DePuy Synthes sales organisation 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. DePuy Synthes is taking this action voluntarily.

We apologise for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

DePuy Synthes

Anne Brisson

Anne Brisson
Senior Quality Assurance Manager,
Product Safety and Performance

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Verification Section

Part Number	Part Description	Lot Numbers
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☐ We have located the identified product(s) in stock; returned quantity is documented below. We keep a copy of this letter for our records.

☐ We do not have any identified product in stock; returned quantity is zero. We keep a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

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