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DePuy Synthes

To the ATTENTION of:
Operating Room Manager

8 December 2014

URGENT MEDICAL DEVICE PRODUCT RECALL - R2014032
RIA system - incorrect shelf life

Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
DePuy Synthes Trauma RIA (Reamer/Irrigator/Aspirator) system	Please refer to Attachment 1	

Dear Sir/Madam,

Synthes GmbH is initiating a recall of the above 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.

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.

Synthes GmbH

Pierre van Iwaarden
Field Action Manager

Markus Wien
Director Quality Assurance Operations

Cc:

DePuy Synthes

NOTICE: MEDICAL DEVICE PRODUCT RECALL - R2014032
RIA system - incorrect shelf life

Verification Section

Part Description	Part Number	Lot Numbers
Depuy Synthes Trauma RIA (Reamer/Irrigator/Aspirator) system	Please refer to Attachment 1	

☐ 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

DePuy Synthes

Attachment 1. Part Description, Part- and Lot Numbers

Part Description	Part Number	Lot Numbers
RIA Tube Assembly, for RIA Drive Shaft minimum length 360 mm, for No. 314.742, sterile	314.745S	2236937 2251445 2256899 2256900 2256901 2261784
Graft Filter for RIA, sterile	352.229S	2352843
RIA Tube Assembly, for RIA Drive Shaft minimum length 520 mm, for No. 314.743, sterile	314.746S	225144 225690 2236938 2251446 2256902 2256903 2256904 2256905 2256906 2256907 2261783
Locking Clip for RIA, sterile	352.260S	2353764 2516747 2537177 2542420 2570953 2580121 2595816 2601189 2615842 2628881 2633930 2658353 2671884
Seal for RIA Drive Shaft, sterile, pack of 2 units	351.718.02S	1611413 1611903 1611904 1611905 1620075 1633553 1655897 1655903 1655909

		1655910 1665972 1665973 1676234 1676236 1676238 1676239 1676241 1676242 1676243 1676250 1676251 1676252 1676253 1676254 1676255 1688712 1688713 1688714 1688715 1688716 1688717 1706479 1706480 1712361 1712362 1717190 1717191 1717192 1717193 1717200