Synthes GmbH

Luzernstrasse 21 4528 Zuchwil Switzerland Tel. +41 32 720 40 60 Fax +41 32 720 40 61 http://www.depuysynthes.com/



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	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.

Page 1 of 5



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:



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

Page 3 of 5

d.

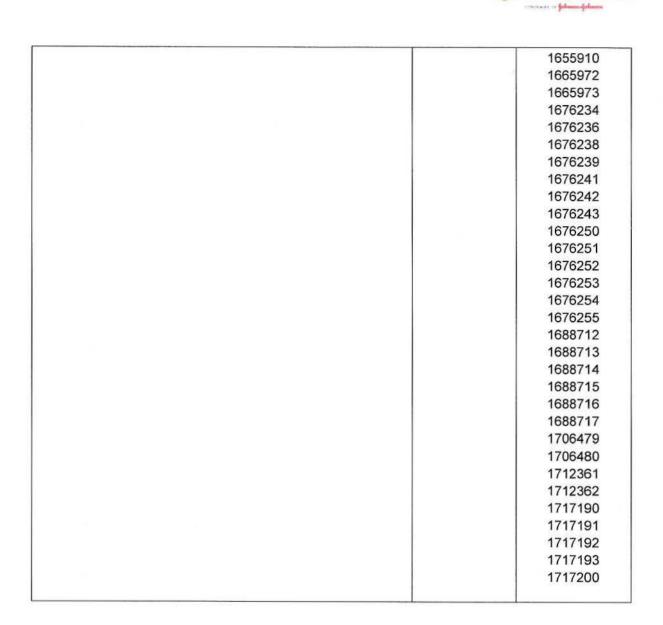


Attachment 1. Part Description, Part- and Lot Numbers

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
		2256900
		2261784
		2201704
Graft Filter for RIA, sterile	352.229S	2352843
RIA Tube Assembly, for RIA Drive Shaft minimum length 520 mm, for No. 314.743, sterile		225144
		225690
		2236938
		2251446
		2256902
	314.746S	2256903
		2256904
		2256905
		2256906
		2256907
		2261783
	352.260S	2353764
		2516747
		2537177
		2542420
		2570953
		2580121
Locking Olio for DIA starile		2595816
Locking Clip for RIA, sterile		2601189
		2615842
		2628881
		2633930
		2658353
		2671884
	351.718.02S	1611413
		1611903
Seal for RIA Drive Shaft, sterile, pack of 2 units		1611904
		1611905
		1620075
		1633553
		1655897
		1655903
		1655909

Page 4 of 5

1.



....

Page 5 of 5

() DePuy Synthes