

**URGENT NOTICE:**  
**MEDICAL DEVICE FIELD SAFETY NOTIFICATION**  
**- Product Removal R2014032\_2**  
**RIA system - incorrect shelf life**

*Please distribute this information to appropriate personnel at your facility.*

Dear Sir/Madam,

Part Description, Part and Lot Numbers

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

Synthes GmbH is initiating a medical device removal (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 Patient Impact:**

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:**

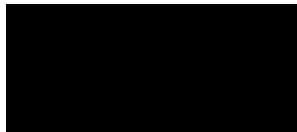
1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business 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 apologize for any inconvenience that this product 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.

Yours Sincerely,



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Lee, Ching Hwee  
Associate Manager, Regulatory Affairs

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**Affected Product:**

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

Please check (✓) accordingly:

- ☐ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.
- ☐ We located the identified product in stock; returned quantity is documented below:

| Product Code | (Serial/Lot Number) | Quantity (Number in "Eaches") |
|--------------|---------------------|-------------------------------|
|              |                     |                               |
|              |                     |                               |

**Please sign, date and stamp below.** Your signature provides confirmation that you have received and understood this notification.

\_\_\_\_\_  
Customer Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature & Date

\_\_\_\_\_  
Stamp (*Stamp shall bear facility name*)

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.