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9 July 2015

# URGENT NOTICE:
# MEDICAL DEVICE FIELD SAFETY NOTIFICATION - FSN2013664
# Reamer/Irrigator/Aspirator (RIA) Technique Guide

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

**Potentially Affected Product/Lot**

| Product Description | Part Numbers | Lot Numbers |
|---|---|---|
| RIA Drive Shaft, length 360 mm | 314.742 | All lots |
| RIA Drive Shaft, length 520 mm | 314.743 | |
| RIA Tube Assembly, for RIA Drive Shaft minimum length 360 mm, for No. 314.742, sterile | 314.745S | |
| RIA Tube Assembly, for RIA Drive Shaft minimum length 520 mm, for No. 314.743, sterile | 314.746S | |
| RIA Medullary Reamer Head Ø 12.0 mm, sterile | 352.250S | |
| RIA Medullary Reamer Head Ø 12.5 mm, sterile | 352.251S | |
| RIA Medullary Reamer Head Ø 13.0 mm, sterile | 352.252S | |
| RIA Medullary Reamer Head Ø 13.5 mm, sterile | 352.253S | |
| RIA Medullary Reamer Head Ø 14.0 mm, sterile | 352.254S | |
| RIA Medullary Reamer Head Ø 14.5 mm, sterile | 352.255S | |
| RIA Medullary Reamer Head Ø 15.0 mm, sterile | 352.256S | |
| RIA Medullary Reamer Head Ø 15.5 mm, sterile | 352.257S | |
| RIA Medullary Reamer Head Ø 16.0 mm, sterile | 352.258S | |
| RIA Medullary Reamer Head Ø 16.5 mm, sterile | 352.259S | |
| RIA Medullary Reamer Head Ø 17.0 mm, sterile | 352.261S | |
| RIA Medullary Reamer Head Ø 17.5 mm, sterile | 352.262S | |
| RIA Medullary Reamer Head Ø 18.0 mm, sterile | 352.263S | |
| RIA Medullary Reamer Head Ø 18.5 mm, sterile | 352.264S | |
| RIA Medullary Reamer Head Ø 19.0 mm, sterile | 352.265S | |

**Please note that this is a Medical Device Field Safety Notification only, it is not required to return the Synthes Reamer/Irrigator/Aspirator (RIA) system**

Dear Sir/Madam,

Synthes GmbH is initiating a Field Safety Notification for DePuy Synthes Reamer / Irrigator / Aspirator (RIA), which is intended for intramedullary reaming and bone harvesting:

- To clear the medullary canal of bone marrow and reaming debris
- To clear the medullary canal of infected bone tissue
- To effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis
- To harvest finely morselized autogenous bone and bone marrow for any surgical procedures that require bone graft in order to facilitate fusion and/or fill bone defects. These procedures include spinal fusion, joint arthrodesis, total joint replacement, fracture repair, nonunion, maxillofacial reconstruction, and tumor removal.

Our records indicate that you may have inventory that is impacted by this Field Safety Notification.

**Reason for the Field Safety Notification:**

Precautionary statements are being added to the "Reamer / Irrigator / Aspirator (RIA) Surgical Technique Guide". It was reported that the RIA Drive Shaft, Tube Assembly, and Reamer Head have the potential to break when **incorrectly assembled or used improperly as follows:**

- Failure to fully engage the reamer to shaft at assembly prior to surgery. Incorrect assembly creates a reduced reamer/shaft contact surface area, in which excess rotational forces could cause breakage
- Use of RIA drive shafts after the flats have become worn and rounded
- Use of any excess force beyond design limit
- Use with an incompatible Power Tool

**Potential Hazard:**

Improper assembly and use could cause the hex tips of the reamer shaft and the "fingers/prongs" of the reamer head to be in contact, and there is the potential of breakage thus resulting in device fragments. Upon identifying resulting fragments remaining in the medullary canal, a surgical delay may occur. Un-retrieved fragments may result in adverse tissue reaction.

In the event of the "fingers/prongs" of the reamer head and/or the hex portion of the reamer shaft breaking, the reamer head may begin to wobble in the bone and may also have the potential to damage the medullary canal, especially in a patient with poor bone quality or with complicated fractures. In this circumstance, the patient would likely experience pain.

**Implemented Measures:**

- The updated Surgical Technique Guide (036.000.553) DSEM/TRM/0615/0404 will contain a Precaution statement on pages 10, 11 and 12 (**Precaution: Improper assembly can result in product breakage which may lead to surgical delay, bone damage and/or adverse tissue damage**).

**Customer immediate actions:**

We ask that you review the information contained in this Field Safety Notification and complete the following actions:

1. Replace the current Surgical Technique Guide SE_157366 version AA dated 07/2008 with the updated Surgical Technique Guide (036.000.553) DSEM/TRM/0615/0404 as soon as it is available.
2. Discard outdated revisions of the Technique Guide.

3. Please contact your DePuy Synthes Sales Consultant if a hardcopy of a specific Technique guide is preferred.
4. Forward this Field Safety Notification to anyone in your facility that needs to be informed, especially those personnel that conduct the RIA system.
5. If the affected product or surgical technique guide have been forwarded to another facility, contact that facility and provide them with a copy of this Field Safety Notification.
6. Maintain awareness of this notice until all surgical technique guides have been exchanged.
7. If the Verification Form 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 page 4-5.
8. Review, complete, sign and return the attached reply form on page 4-5 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.
9. Maintain a copy of this notice.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this field safety notification 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,**

[redacted]

**Lee Ching Hwee**
**Professional Affairs Executive**

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**Verification Section**

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☐ We have received the updated Synthes Reamer/Irrigator/Aspirator (RIA) Surgical Technique Guide (PN 036.000.553, version DSEM/TRM/0615/0404) and will discard the previous versions (PN 036.000.553, version AA).

☐ We acknowledge receipt of this information but do not have the Synthes Reamer/Irrigator/Aspirator (RIA) Surgical Technique Guide at this facility.

**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.

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.