

Date: 18 November 2020

URGENT FIELD SAFETY NOTICE:
RIA 2 (all lots)

Products Subject to this Field Safety Notice:

Part Number	Part Description	Lot	UDI
See Attachment 1	See Attachment 1	See Attachment 1	See Attachment 1

PLEASE DISTRIBUTE THIS INFORMATION TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

Dear Valued Customer,

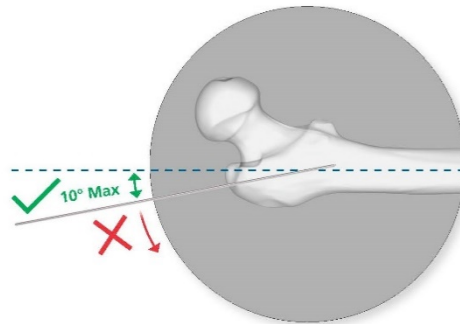
NOTIFICATION ONLY: We at Synthes GmbH are committed to deliver the best quality product and customer experience by continuously monitoring the performance of our products to help deliver patient safety and compliance.

Synthes GmbH is issuing a safety notification of the RIA 2 (Reamer Irrigator Aspirator) that is intended for use in adults and adolescents (12-21 years) for reaming of the medullary canal for preparation of internal fixation, harvesting of bone and bone marrow, and/or clearing of debris.

Reason for Field Safety Notification:

This field safety notification is advising physicians of the following supplemental information regarding the surgical approach of standard IM nail reaming as referred to in the surgical technique guide.

- Open the medullary canal and conduct reaming by following AO reaming techniques for IM nailing and maintain a guide wire entry angle of less than 10° from the axis of the canal.



PRECAUTION:

If the guide wire entry angle is greater than 10° from the axis of the canal, there is a risk that bowing of the reaming rod will result in:

- Eccentric reaming of the far cortex
- Damage to the reamer head connection, resulting in metal fragments in the canal

NOTE:

- For an antegrade femoral approach, if possible, adduct the limb/hip to facilitate access to entry

- point. For greater trochanter entry point, target >2cm distal to the lesser trochanter¹.
- For an antegrade tibial approach, the knee will need to be flexed to 90-110° for entry site access. Insert the guide wire aiming down the tibial crest, and thus the center of the medullary canal².

1. Paulo Barbosa and Clifford Turen. (2012). AO teaching video: Femur—Shaft fracture 32-B2 Intramedullary nailing with the Expert Lateral Femoral Nail (LFN). Retrieved from: <https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/femoral-shaft/simple-oblique-middle-1-3-fractures/antegrade-nailing#antegrade-nailing-approaches>

2. Matthias Hansen, Dankward Höntzsch. (2006). AO teaching video: Tibia Fractures - Intramedullary Nailing with the Expert Tibial Nail (with reaming). Retrieved from: <https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/tibial-shaft/simple-fracture-transverse/intramedullary-nailing#patient-preparation-and-approach>

Potential Clinical and Patient Impact:

The investigation identified the following potential harms should breakage occur, and any fragment be retained:

- Adverse Tissue Reaction may occur.
- Soft Tissue Damage may occur if the surgeon opts to enlarge the entry site or open the fracture site to retrieve the fragments.
- Bone Damage may occur if surgeon opts to retrieve the fragments it may be necessary to window or remove bone to access the retained fragments.

Synthes GmbH is not recommending any post-operative changes or surgical revision in the absence of symptoms in patients on whom these instruments may have already been used.

Actions to Take:

Our records show that your facility has received products that are subject to this field safety notification.

Please take the following actions:

- Forward this notice to anyone in your facility that needs to be informed.
- If any of the subject product has been forwarded to another facility, contact that facility.
- Keep a copy of this notice with the subject product.
- Identify and discard any current Printed Surgical Technique.
- To get the updated version visit our website: <https://www.jnjmedicaldevices.com/en-EMEA/product/ria-2-system-reamer-irrigator-aspirator>
- Review, complete, sign, and return the attached reply form on page 4 of this letter to your local sales organization in accordance with the directions on the form within 5-business days of receipt of this notification.
- Should you have any inquiries please do not hesitate to contact your sales consultant
- This letter is for notification only, no product needs to be returned.

In Synthes GmbH, we aim to keep people well at every age and every stage of life. Our primary goal is user and patient safety by providing high quality products. We apologize for any inconvenience that this Field Safety Notification may create and appreciate your cooperation with our request.

Thank you for your attention and cooperation.

Synthes GmbH

Attachment 1 - Products Subject to this Field Safety Notice:

Part Code	Description	Lot	GTIN (OUS)
03.404.016S	Reamer Head for RIA 2 ø 10.0mm, sterile	All	07612334142382
03.404.017S	Reamer Head for RIA 2 ø 10.5mm, sterile	All	07612334142399
03.404.018S	Reamer Head for RIA 2 ø 11.0mm, sterile	All	07612334142405
03.404.019S	Reamer Head for RIA 2 ø 11.5mm, sterile	All	07612334142412
03.404.020S	Reamer Head for RIA 2 ø 12.0mm, sterile	All	07612334142429
03.404.021S	Reamer Head for RIA 2 ø 12.5mm, sterile	All	07612334142436
03.404.022S	Reamer Head for RIA 2 ø 13.0mm, sterile	All	07612334142443
03.404.023S	Reamer Head for RIA 2 ø 13.5mm, sterile	All	07612334142450
03.404.024S	Reamer Head for RIA 2 ø 14.0mm, sterile	All	07612334142467
03.404.025S	Reamer Head for RIA 2 ø 14.5mm, sterile	All	07612334142474
03.404.026S	Reamer Head for RIA 2 ø 15.0mm, sterile	All	07612334142481
03.404.027S	Reamer Head for RIA 2 ø 15.5mm, sterile	All	07612334142498
03.404.028S	Reamer Head for RIA 2 ø 16.0mm, sterile	All	07612334142504
03.404.029S	Reamer Head for RIA 2 ø 16.5mm, sterile	All	07612334142511
03.404.030S	Reamer Head for RIA 2 ø 17.0mm, sterile	All	07612334142528
03.404.031S	Reamer Head for RIA 2 ø 17.5mm, sterile	All	07612334142535
03.404.032S	Reamer Head for RIA 2 ø 18.0mm, sterile	All	07612334142542

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Customer Reply Form

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Please complete this Customer Reply Form **within 5 business days upon receipt of the notification** and return to your local DePuy Synthes sales organization. Complete/return this form even if affected product is no longer in your inventory.

I have read and understand the notification

Your Name:		Facility/Business Name:	
Signed*:		Date:	
Facility/Business Address, City:			
Account Number:			
J&J Sales Rep (as applicable):			
Date the notification was received:			
Email Address:		Telephone Number:	
<i>*Your signature provides confirmation that you have received and understood this notification.</i>			
Your comments are always welcome:			