DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Date: 29 June 2022

URGENT: FIELD SAFETY NOTICE
ATTUNE™ MEASURED SIZING & ROTATION GUIDE INSTRUMENT

Product Subject to this Medical Device Correction

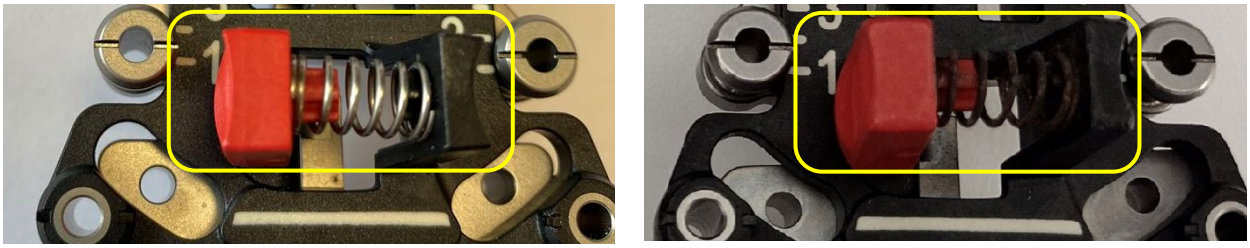
Part Number	Material Description	GTIN	Lots
254400525	ATTUNE™ Measured Sizing & Rotation Guide Instrument	10603295434061	AB4536235, AB4733296, AB4841493, AB4810808, AB4841495, AB4904565, AB4967214, AB5004557, AB5034303

Dear Valued Customer,

Please be advised that DePuy Ireland U.C. is initiating a medical device correction for nine (9) lots of the ATTUNE™ Measured Sizing & Rotation Guide Instrument (P/N 254400525) ("the subject product"). The subject product is intended to be utilized as part of the ATTUNE™ INTUITION™ Instrument Set to size the femur and align rotation of the bone cuts in preparation for the femoral implant. The table above lists the Part Number and Lot numbers of the subject product covered by this medical device correction.

Our records show that your facility received one or more units of the subject product. Please carefully review this notice for the steps that you should take to respond to this medical device correction.

Reason for the Medical Device Correction:
DePuy Ireland U.C. received communications from some customers indicating that the spring in the subject product had corroded. Upon further investigation, we discovered that nine (9) lots of the subject product had been manufactured with the incorrect grade of steel. As indicated by Figure 1, the incorrect steel spring material has the potential to oxidize, leading to corrosion. All nine (9) lots of the subject product, regardless of whether the spring has oxidized, are covered by this medical device correction. Note: The global complaint rate is 0.001%.



Correct Steel Spring | Incorrect Steel Spring (Oxidized)

Figure 1: Springs Comparison

Potential Patient Impact:
Patients that were treated with the subject device may experience the following:

- Surgical delay
- Osteolysis
- Poor Joint Mechanics
- Soft Tissue Irritation
- Pain

No adverse events have been reported to date for the subject product. Patients treated with the subject product should continue to be monitored pursuant to the health care provider's standard of care.

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Please take the Following Steps:

1. Examine your inventory immediately for the subject lots and quarantine the products.
2. To minimize disruption, replacement of the spring will be completed by your DePuy Synthes Sales Consultant. You will be contacted directly by a member of the Sales Team.
3. Familiarize yourself with the content of this letter and forward this notice to any personnel in your facility who need to be informed.
4. Review, complete, sign, and return the attached business response form (page 3 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.
5. *Complete the BRF even if you do not have any of the subject product in your current inventory*.
6. If any of the subject product has been forwarded to another facility, contact that facility, and provide a copy of this notice to the relevant personnel.
7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This medical device correction has been reported to the local competent authority. We apologize for any inconvenience that this recall may cause 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.

Sincerely,

Kimberly Long, Staff QS Action Coordinator
Email: OneMD-Field-Actions@its.jnj.com | Telephone: + 1 574-221-8156

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Co. Cork, Ireland

URGENT: FIELD SAFETY NOTICE
ATTUNE™ MEASURED SIZING & ROTATION GUIDE INSTRUMENT
Business Reply Form (BRF)

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Please complete this BRF **within three (3) business days upon receipt of this Notice** and email this form to [Enter Contact Info]. **IMPORTANT:** Complete the BRF even if you currently do not have any product in your inventory.

Note: Product is NOT being removed from the field and does not need to be returned.

☐ By signing this form, I am confirming that 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:
**Your signature provides confirmation that you have received and understood this notification.*	
Your comments are always welcome:	