Date: February 17, 2023

URGENT FIELD SAFETY NOTICE (REMOVAL)

Limited manufacturing lots of:
Attune Revision Limb Preservation System (LPS) Tibial Inserts
Attune Posterior (PS) Fixed Bearing (FB) Tibial Inserts

Products Subject to this Removal:

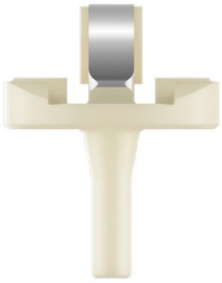
Part Number	Part Description	Batch/Lot	Quantity	GTIN
151760212	ATTUNE REV LPS INSERT XSM 12MM	JP9016	7	10603295490968
151640507	ATTUNE PS FB TIB INSERT SZ5 7MM	JN6613	12	10603295490968

Dear Valued Customer,

DePuy Synthes is issuing a medical device recall (removal) of the part and lot numbers listed in the above table. These Inserts are components of Total Knee Arthroplasty and are individually packaged and supplied sterile.

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

Reason for the Medical Device Recall (Removal):
The subject product lots are being recalled because they received a higher than specified irradiation dose. This exceeds the validated range for exposure to gamma radiation of these devices and may result in changes to the implant material properties. The figures below depict the products subject to this medical device recall (removal).



Attune Revision LPS Tibial Insert

Attune PS FB Tibial Insert

Potential Patient Impact:
To date, we have received only one complaint related to this issue regarding difficulty opening the packaging, and no adverse events have been reported.

We do not anticipate harms associated with the issue from typical patient activity; however, there is the potential for poor joint mechanics if the implant fractured due to a sudden impact.

Health care providers who have treated patients using the products subject to this removal should continue to follow those patients pursuant to the health care provider's standard of care and may consider more frequent follow-up depending on the activity level and needs of an individual patient. For questions, or to consult with an in-house DePuy Synthes physician on this issue, please reach out to your sales consultant for assistance.

Please take the Following Steps:

- Examine your inventory immediately to determine if you have the subject products and quarantine the subject products. **DO NOT USE THE SUBJECT PRODUCTS**.
- Contact your **DePuy Synthes Sales Consultant** to coordinate the return/credits of the subject products.
- Review, complete, sign, and return the attached business response form (page 3 of this letter) to your local DePuy Synthes Sales Representative.
- Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the devices subject to this action).
- If any of the subject device has been forwarded to another facility, contact the facility and provide them with this notice.
- Contact your Product Support Team at [Insert country specific information here] for additional support as needed.

This field safety notice has been reported to the local competent authority.

We apologize for any inconvenience that this notification may cause and appreciate your cooperation with our request.

Thank you for your prompt attention and cooperation in this matter.

Sincerely,

Senior Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

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☐ The subject product has been located. A copy of this notice is being retained and I have read and understood the notification. RETURNED Quantity:_____

☐ None of the subject product is available for return. A copy of this notice is being retained and I have read and understood the notification.

Please complete this Business Reply Form (BRF) within 3 days after you have been notified and return this form via email to [Insert country specific information here].

Your Name/Title:	Facility/Business Name:
Signed*:	Date:
Address:	
Account Number:	
J&J Sales Rep (as applicable):	
Email Address:	Telephone Number:
Comments (if any):	
**Your signature provides confirmation that you have received and understood this notification.*	