Date: February 18, 2021

URGENT FIELD SAFETY NOTICE (REMOVAL) - UPDATED: PINNACLE® CUP DEVICES (Specific Lots Only)

Product Subject to this Field Safety Notice:

Part Number	Part Description	GTIN	Lot Number
See Attachment 1	See Attachment 1	See Attachment 1	See Attachment 1

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

Dear Valued Customer,

DePuy (Ireland) UC is providing an update to the Field Safety Notice (FSN) and this removal notification **replaces the FSN dated December 17, 2020.**

Our records show that your facility received one or more of the affected PINNACLE® CUP devices that were manufactured from July 2017 to November 2020. The PINNACLE® CUP devices are part of the PINNACLE Hip Solution for the anatomic reconstruction of the hip joint, which promotes prosthetic joint load and function.

Reason for Field Safety Notice (Removal):

There is a potential of an out of specification condition (oversized "minor diameter of Apex Hole thread") on the PINNACLE® CUP devices listed in Attachment 1. This defect is limited to those lots that were manufactured on one specific machine tool in the manufacturing facility from July 2017 to November 2020. The defect is only of clinical relevance if an Apex Hole Eliminator (HE) (Part Number 124603000) is used in surgery with the PINNACLE® CUP. The use of an Apex HE with an affected PINNACLE® CUP may lead to the Apex HE threading through the shell of the cup without stopping or protruding internally as a result of "cross-threading". If cross threading occurs and the Apex HE sits proud internally, the ceramic liner may be affected. This issue has not been reported and the probability for this to occur is considered extremely rare.

Updated Instructions: Following further discussions with the EU Coordinating Competent Health Authority, we are advising physicians not to use the affected PINNACLE® CUP devices (listed in Attachment 1) remaining in their inventory.

Potential Patient Impact:

When using the affected PINNACLE® CUP devices with the optional APEX HE, the possible clinical implications related to this issue, if not detected intraoperatively, include the following: surgical delay during retrieval or during replacement of the screw per surgeon's choice, poor joint mechanics, loosening of the device and pain.

At the present time the only customer complaints we have received have reported surgical delay.

Patient Communication:

Physicians who have treated patients using Apex HE with the affected PINNACLE® CUP devices (see Table 1) should continue to follow up on those patients post-operatively according to the physician's standard of care.

Please Take the Following Actions:

1. Examine your inventory immediately to determine if you have the affected PINNACLE® CUP devices and quarantine the product.
2. Contact your DePuy Synthes Sales Consultant to coordinate the return of any affected devices or call customer service following the typical returns process in order to acquire a return number prior to shipping product.
3. Complete **all** fields of the attached updated Business Response Form. Please make sure to include your facility name and address, account number, name of person completing the form, title, email address, telephone number and signature in the spaces provided.
4. Forward this notice to any personnel in your facility who need to be informed.
5. If any of the affected products have been forwarded to another facility, contact that facility and provide a copy of this FSN to the relevant personnel.
6. Post a copy of this updated notice in a visible area for awareness of this FSN.

This Field Safety Notice has been reported to the local competent authority.

Contact Information:

In DePuy Synthes we have aimed 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. If you have any questions, please contact your Sales Consultant.

Thank you for your attention and cooperation.

Mona Rehmatullah
Senior Recall Coordinator
OneMD-Field-Actions@its.jnj.com
Business Phone: (561) 494-3036

Attachment 1:

Please see the attached embedded file with list of affected part number and lot combination.

1896433 - Affected Part Lot Numbers fo

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Business Response Form

Part Number	Part Description	GTIN	Lot Number
See Attachment 1	See Attachment 1	See Attachment 1	See Attachment 1

Please complete this Customer Acknowledgement Form **within 3 business days upon receipt of the notification** and email/fax this form to Name of the Franchise/Third Party [enter contact details/info].

☐ **The impacted devices have been located. A copy of this letter is being retained and I have read and understood the notification. RETURNED Quantity: _____**

☐ **No impacted devices are available for return. A copy of this letter is being retained and I have read and understood the notification.**

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