

Date: December 17, 2020

URGENT FIELD SAFETY NOTICE:
OPTIONAL APEX HOLE ELIMINATOR (HE) USED WITH PINNACLE® CUP DEVICES

Product Subject to this Field Safety Notice:

Part Number	Part Description	GTIN	Lot Number
See Table 1	See Table 1	See Table 1	See Table 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 committed to delivering high quality products and superior customer experience by continuously monitoring the performance of its products for safety and compliance.

This voluntary Field Safety Notice is ONLY directed to users of the optional Apex Hole Eliminator (Apex HE) (Part Number 124603000) with certain PINNACLE® CUP devices in their procedures.

Our records show that your facility received one or more of the 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 (FSN):

There is a potential of an out of specification condition (oversized “minor diameter”) on certain PINNACLE® CUP devices. This defect is limited to lots that were manufactured on one specific machine tool in the manufacturing facility from July 2017 to November 2020.

This FSN is intended to advise physicians, who use the Apex HE, of the oversize condition of the hole in the cup, which could lead the Apex HE to thread through the shell of the cup without stopping (refer to **Figure 1**) or to protrude internally as a result of “cross-threading” (refer to **Figure 2**). This may occur if the Apex HE is manipulated or toggled while threading it through the hole of certain PINNACLE® CUP devices. If cross-threading occurs, physicians will not feel the positive stop of the Apex HE against the cup.

Cross-threading is believed to occur because of an oversize condition of the hole for the Apex HE in the cup, and it may lead to the following:

1. The Apex HE may pass through the shell of the cup without stopping; or

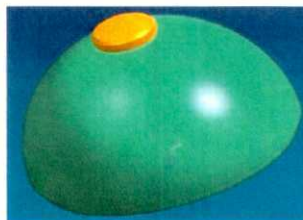


Figure 1: Apex HE thread through the cup

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2. The Apex HE may protrude internally as a result of cross-threading.

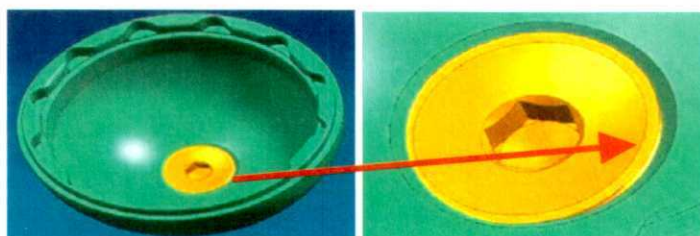


Figure 2: Apex HE angled, protruding internally in Pinnacle Cup

Physicians are advised to exercise care when threading the Apex HE to ensure that it is introduced perpendicular to the PINNACLE® CUP. If threaded properly, the Apex HE should engage normally with the cup as intended. It is only when the Apex HE is toggled or pushed off axis while threading that there is a potential for cross-threading.

Potential Patient Impact:

The possible clinical implications related to this issue include the following:

- Surgical Delay during retrieval or during replacement of the screw per surgeon's choice.
 - If the Apex HE passes through the cup or sits proud internally, the physician may choose to replace or retrieve it, potentially resulting in surgical delay.
- Poor Joint Mechanics and Pain
 - If the Apex HE sits proud internally as shown in Figure 2, the ceramic liner for the affected cup may fracture. Therefore, if not detected intraoperatively, the patient may experience poor joint mechanics and pain.
- Loosening of the Device:
 - If the Apex HE passes through the cup, it may come into contact with soft bone, possibly embedding itself within soft bone. If sclerotic bone is encountered, there may be a slight chance of push out force on the cup itself, potentially affecting fixation.

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. Carefully review the information contained in this Field Safety Notice.
2. Complete **all** fields of the attached 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.
3. Forward this notice to any personnel in your facility who need to be informed.
4. 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.
5. Post a copy of this notice in a visible area for awareness of this FSN.
6. **NO PRODUCT NEEDS TO BE RETURNED.**

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.

DePuy (Ireland) UC

TABLE 1: Products Subject to this Field Safety Notice:

Part Number	Part Description	Lot Number	GTIN
121701048	PINNACLE 100 ACET CUP 48MM	All	10603295008538
121701050	PINNACLE 100 ACET CUP 50MM	All	10603295008545
121701052	PINNACLE 100 ACET CUP 52MM	All	10603295008552
121701054	PINNACLE 100 ACET CUP 54MM	All	10603295008569
121701056	PINNACLE 100 ACET CUP 56MM	All	10603295008576
121701058	PINNACLE 100 ACET CUP 58MM	All	10603295008583
121701060	PINNACLE 100 ACET CUP 60MM	All	10603295008590
121701062	PINNACLE 100 ACET CUP 62MM	All	10603295008606
121711048	PINNACLE 100 HA ACET CUP 48MM	All	10603295009047
121711050	PINNACLE 100 HA ACET CUP 50MM	All	10603295009054
121711052	PINNACLE 100 HA ACET CUP 52MM	All	10603295009061
121711054	PINNACLE 100 HA ACET CUP 54MM	All	10603295009078
121711056	PINNACLE 100 HA ACET CUP 56MM	All	10603295009085
121712048	PINN SECTOR HA ACET CUP 48MM	All	10603295009146
121712050	PINN SECTOR HA ACET CUP 50MM	All	10603295009153
121712052	PINN SECTOR HA ACET CUP 52MM	All	10603295009160
121712054	PINN SECTOR HA ACET CUP 54MM	All	10603295009177
121712056	PINN SECTOR HA ACET CUP 56MM	All	10603295009184
121722048	PINN.SECTOR ACET.CUP 48MM	All	10603295009801
121722050	PINN.SECTOR ACET.CUP 50MM	All	10603295009818
121722052	PINN.SECTOR ACET.CUP 52MM	All	10603295009825
121722054	PINN.SECTOR ACET.CUP 54MM	All	10603295009832
121722056	PINN.SECTOR ACET.CUP 56MM	All	10603295009849
121722058	PINN.SECTOR ACET.CUP 58MM	All	10603295009856
121722060	PINN.SECTOR ACET.CUP 60MM	All	10603295009863
121722062	PINN.SECTOR ACET.CUP 62MM	All	10603295009870
121731048	PINN 100 W/GRIPTION 48MM	All	10603295010180
121731050	PINN 100 W/GRIPTION 50MM	All	10603295010197
121731052	PINN 100 W/GRIPTION 52MM	All	10603295010203
121731054	PINN 100 W/GRIPTION 54MM	All	10603295010210
121731056	PINN 100 W/GRIPTION 56MM	All	10603295010227
121731058	PINN 100 W/GRIPTION 58MM	All	10603295010234
121731060	PINN 100 W/GRIPTION 60MM	All	10603295010241
121731062	PINN 100 W/GRIPTION 62MM	All	10603295010258
121732048	PINN SECTOR W/GRIPTION 48MM	All	10603295010289
121732050	PINN SECTOR W/GRIPTION 50MM	All	10603295010296
121732052	PINN SECTOR W/GRIPTION 52MM	All	10603295010302
121732054	PINN SECTOR W/GRIPTION 54MM	All	10603295010319
121732056	PINN SECTOR W/GRIPTION 56MM	All	10603295010326
121732058	PINN SECTOR W/GRIPTION 58MM	All	10603295010333
121732060	PINN SECTOR W/GRIPTION 60MM	All	10603295010340
121732062	PINN SECTOR W/GRIPTION 62MM	All	10603295010357
121732064	PINN SECTOR W/GRIPTION 64MM	All	10603295010364

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Business Response Form

Part Number	Part Description	GTIN	Lot Number
See Table 1	See Table 1	See Table 1	See Table 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 \[enter contact details/info\]](#).

I have read and understand the notification

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