

Date: 19 April 2023

**URGENT FIELD SAFETY NOTICE (REMOVAL)**  
**CEMVAC™ Revision Nozzles 6.5mm and 8.5mm (3 lots)**

**Subject Product:**

Model Number*	Description	Lot Number	GTIN
831230	CEMVAC Revision Nozzle 8.5mm	22030027	10603295302452
831231	CEMVAC Revision Nozzle 6.5mm	22030034 22050035	20603295434983

\*Reference Attachment A Instructions for Identifying Subject Product

**Dear Valued Customer,**

DePuy Ireland U.C. has initiated a field safety action (removal) of three (3) lots of CEMVAC Revision Nozzles listed in the table above. The CEMVAC Revision Nozzles are designed as an optional extension nozzle to be used with the CEMVAC Bone Cement System. These nozzles are designed to assist in the placement of bone cement into a long and/or narrow intermedullary canal.

Our records show that you, or your facility, received one or more units of the product lots listed above. Please carefully review this notice for the steps that you should take to respond to this field safety action (removal).

**Reason for the Field Safety Notice (Removal):**

Three (3) lots of CEMVAC Revision Nozzles are being removed because they were distributed prior to being sterilized.

**Potential Patient Impact:**

Use of the unsterile nozzle may result in infection, although it is expected that contamination on the device is low as a result of other cleaning processes. Health care providers who have used the subject products on patients should continue to follow those patients pursuant to their standard of care for those procedures.

To date, we have received no complaints related to this issue.

**Please Take the Following Steps:**

1. Examine your inventory immediately to determine if you have the subject products and quarantine them immediately. **DO NOT USE THE SUBJECT PRODUCTS.**
2. Contact your DePuy Synthes Sales Consultant or contact the customer support services at ([enter country contact](#)) [mailto:](#) to coordinate the return/credits of the subject products.
3. Review, complete, sign, and return the attached Business Response Form (page 3 of this letter) to ([enter country contact](#)) within three (3) business days of receipt of this notification. Please include in the email subject: FA 2248278 CEMVAC.
4. Please complete the attached Business Response Form even if you do not have the subject products on hand.
5. Forward this notice to anyone in your facility that needs to be informed (e.g., those who manage, transport, store, stock, or use the subject products).
6. If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
7. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This field safety notice (removal) has been reported to the relevant health authorities. If you have any questions, please contact your local DePuy Synthes Sales Consultant. For Medical Information request, please visit our website: <https://www.jnjmedicaldevices.com/mir>.

Sincerely,



Mona Rehmatullah  
Staff Quality Systems Recall Coordinator  
Email: [OneMD-Field-Actions@its.jnj.com](mailto:OneMD-Field-Actions@its.jnj.com)

### Attachment A: Instructions for Identifying Subject Product



Figure 1: Example Product

**URGENT FIELD SAFETY NOTICE (REMOVAL)**  
**CEMVAC™ Revision Nozzles 6.5mm and 8.5mm (3 lots)**

**Business Response Form**

**Subject Product:**

Model Number	Description	Lot Number	GTIN
831230	CEMVAC Revision Nozzle 8.5mm	22030027	10603295302452
831231	CEMVAC Revision Nozzle 6.5mm	22030034 22050035	20603295434983

- 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 Response Form (BRF) Form within 3 days after the receipt of this notification. Please return this form via email to at ([enter country contact](#)). Please include in the email subject: FA 2248278 CEMVAC

Your Name/Title:		Facility/Business Name:	
Signed*:		Date:	
Address:			
Account Number:			
Returned Authorization 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.			