GROUPE FH ORTHO

DISTRIBUTOR SAFETY NOTIFICATION – *UPDATE*

FSN – RECALL OF LOTS

FSN no.: *CAPA 385*	**Date:** *12/05/2023*
Recipient:	To distributors
Type of action: *Field Safety Corrective Action – Recall of lot(s)*	

Dear Sir or Madam,

We hereby inform you that the FH ORTHO group, having notified the competent authorities, is voluntarily initiating the recall of the MDs listed below.

➢ Information about the products concerned:

Products: *BEPOD - Burr*	
References: - *256021 – BEPOD BROPHY BURR / MIS D6.0x15 mm (x5)* - *258156 - BEPOD PERCUTANEOUS CHEVRON BURR / MIS II D3.0x20mm (x5)* - *258157 - BEPOD PERCUTANEOUS CHEVRON BURR / MIS II D2.5x14mm (x5)* - *264425 - BEPOD PERCUTANEOUS CHEVRON BURR / MIS II D2.0x20mm (x5)* - *256016 – BEPOD WEDGE BURR / MIS D3.1x13mm (x5)* - *256017 – BEPOD WEDGE BURR / MIS D4.1x13mm (x5)* - *256018 - BEPOD STRAIGHT SHANNON BURR / MIS D2.0x12mm (x5)* - *256019 – BEPOD SHORT SHANNON BURR / MIS D2.0x8mm (x5)* - *256020 – BEPOD LONG SHANNON BURR / MIS D2.0x12mm (x5)* - *258152 – BEPOD EXTRA WIDE SHANNON BURR / MIS II D2.9x10mm (x5)* - *258153 – BEPOD INVERTED WEDGE BURR / MIS II D2.9x10mm (x5)* - *258154 – BEPOD WEDGE BURR / MIS II D4.1x13mm (x5)* - *258155 - BEPOD EXTRA SHORT SHANNON BURR / MIS II D2.0x6mm (x5)*	**Lots:** *All* *Except lots:* *- P00336 ref. 264425* *- P01351 ref. 256020*

➢ Description of the incident giving rise to the action:

The burrs are packaged in a sterile double pouch. During routine inspections, we observed that the sharp end of the burr had pierced the inner sterile barrier and thus came into direct contact with the film of the outer pouch. We also found a few samples whose outer sterile barrier was pieced.

➢ Potential associated risks:

A risk assessment has been carried out and has determined that there is a risk of losing product sterility.

➢ Immediate actions to be implemented:

Our records indicate that we have supplied you with products affected by this recall. We ask that you locate and cease to use all products. Please proceed as follows:

1- **Cease the distribution of any product identified in this notification.**
2- **Perform an inventory of your stocks, identify all affected products, and place them in distributor quarantine.**
3- **Identify all customers who have received affected products.**
4- **Circulate this information to all customers who use or order these products.**

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5- **Ask customers to identify affected products in their stocks and place them in quarantine.**
6- **Collect products that customers have placed in quarantine and place them in distributor quarantine.**
7- **Fill in the enclosed Acknowledgement of Receipt form and fax it to +33 3 89 81 84 26 or email it to vigilancedepartment@fhortho.com, even if you have no products in stock.**
8- **Upon receipt, our sales department will contact you to organise the return of the products and their replacement or issue of a credit note as soon as possible.**

➢ Contact persons for any information:

Our Medical Device Vigilance Correspondent, Mr. El Yazid ARIBI, and our Quality Department, remain at your disposal for any further information by email at vigilancedepartment@fhortho.com.

Please accept our apologies for the inconvenience caused by this action and thank you for your understanding and cooperation.

With our sincere regards,

Mr. El Yazid ARIBI

FH INDUSTRIE Medical Vigilance Correspondent

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DISTRIBUTOR RESPONSE FORM – CAPA 385 – 05/2023 – *UPDATE*

Please fill in this response form within 7 days and fax it back to us +33 3 89 81 84 26 or email it to vigilancedepartment@groupe-fh.fr.

I attest that:

- **I have received the FH ORTHO safety notification concerning the recall of BEPOD burrs,**
- **I have checked my stocks for the products concerned by this notification and I have implemented the immediate steps as requested,**
- **I have identified and informed the customers that had received the products concerned by this notification,**
- **I have received confirmation of receipt of this notification from these customers,**
- **I have submitted this declaration to the competent authority in my country, in application of current regulations.**

Check the appropriate response(s) and indicate the number of devices identified:

☐ We have identified the customers that had received the products concerned and we have informed them:

Customer name	Date of customer notification by the distributor	Date of implementation confirmation by the customer

☐ Further to placing the products in our stocks in quarantine and the recall of the products in our customers' stocks, we wish to return the following products:

Type	Reference	Lot	Quantity to return (please indicate boxes or individual pouches)
BEPOD BROPHY BURR / MIS D6.0x15 mm (x5)	256021		
BEPOD PERCUTANEOUS CHEVRON BURR / MIS II D3.0x20mm (x5)	258156		
BEPOD PERCUTANEOUS CHEVRON BURR / MIS II D2.5x14mm (x5)	258157		
BEPOD PERCUTANEOUS CHEVRON BURR / MIS II D2.0x20mm (x5)	264425		
BEPOD WEDGE BURR / MIS D3.1x13mm (x5)	256016		
BEPOD WEDGE BURR / MIS D4.1x13mm (x5)	256017		

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BEPOD STRAIGHT SHANNON BURR / MIS D2.0x12mm (x5)	256018		
BEPOD SHORT SHANNON BURR / MIS D2.0x8mm (x5)	256019		
BEPOD LONG SHANNON BURR / MIS D2.0x12mm (x5)	256020		
BEPOD EXTRA WIDE SHANNON BURR / MIS II D2.9x10mm (x5)	258152		
BEPOD INVERTED WEDGE BURR / MIS II D2.9x10mm (x5)	258153		
BEPOD WEDGE BURR / MIS II D4.1x13mm (x5)	258154		
BEPOD EXTRA SHORT SHANNON BURR / MIS II D2.0x6mm (x5)	258155		

☐ We have checked all of our storage areas and those of our customers and we do not have or no longer have products from these lots in stock.

Distributor:	**Name and position of the signer:**
Date:	**Signature:**

Upon receipt of this form, our sales department will contact you to organise the return of the products and their replacement as soon as possible.

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