



URGENT: FIELD SAFETY NOTICE – FOLLOW UP

Event-2023-05782

Specific product codes and lots of:

- **Kangaroo Enteral Feeding Pump Sets- Air in line**

02 February 2024

Manufacturer SRN: US-MF-000017721

Dear Valued Customer,

Following on from our recent Field Safety Notice related to the potential for air appearing in the enteral feed pump set., Cardinal Health is issuing this follow up communication to inform you that we have completed our investigation and implemented appropriate corrective actions to ensure that manufacturing related issues are addressed.

Product Advisory Overview:	Cardinal Health has initiated a field safety corrective action for the following Kangaroo enteral feed pump sets.		
	Product Code	Product Description	Affected Lots
	666064	Joey 500ML Set FEED ONLY	All product manufactured from April, 2022 with lot numbers 22D to July 2023 to lot numbers 23G.
	666106	666106 Joey 1000ML Set FEED ONLY	
	777501	Joey ENPLUS Spike set FEED ONLY	
	777502	Joey Dual ENPLUS Spike Set FEED ONLY	
	777503	Joey ENPLUS 3 in 1 FEED ONLY	
777106	EPUMP 1000ML EZ Bag FEED ONLY		
*First two digits represent year of manufacture, the letter represents month of manufacture (A = January, B = February etc.) and X's represent a sequential number, FHX represents the manufacturing location.			
Usage Kangaroo Enteral Feed Pumps and sets are intended for use in patients with any condition requiring enteral feeding and/or enteral hydration. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to a patient's gastrointestinal system.			

Actions requested on your part:	<ol style="list-style-type: none"> 1) FOLLOW the steps described in Attachment A to assess and monitor for entry of air into the feed set. Discontinue use of the feeding set if you observe air in the line. Contact Cardinal Health to order replacement product. Retain a copy of this notice with the product. 2) COMMUNICATE with all personnel that utilize these feeding sets of the potential risk of air entering feeding set tubing. 3) NOTIFY any customers to whom you may have distributed or forwarded affected product about this field correction. 4) REVIEW, complete, sign and return the enclosed Acknowledgement Form by following the directions on the Form. 5) MAINTAIN awareness of this notice until all affected product has been utilized.
----------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Please report any product issues you encounter while using the products listed in the table above, Cardinal Health will ensure that all complaints are thoroughly investigated and addressed.

Furthermore, if you wish to request replacement product, please contact your Customer Service group representative, or local sales office.

We place high value on your feedback on any product concerns. Cardinal Health is committed to maintaining your confidence in the safety and quality of the products that we supply.

Respectfully yours,

Catherine Redmond

Catherine Redmond
Director Quality
Cardinal Health.