



URGENT: FIELD SAFETY NOTICE

Event-2023-05782

Specific product codes and lots of:

- **Kangaroo Enteral Feeding Pump Sets**

November 10, 2023

Manufacturer SRN: US-MF-000017721

Dear Valued Customer,

The purpose of this communication is to inform you that Cardinal Health is issuing a field safety corrective action for all product codes of Kangaroo Enteral Feed Pump Sets listed in the table below due to the potential for air appearing in the enteral feed pump set. This is not a product removal. You are not required to return the product.

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.			
<p>Usage</p> <p>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.</p>			

Why you are being contacted:	You are receiving this notice because our records indicate that you have purchased Cardinal Health Kangaroo Enteral Feed Pump sets in the past.
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Description of the problem:	<p><u>What is the issue?</u></p> <p>The issue relates to air entry into the feed set tubing.</p>
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*The image above is an example and air in the tubing may not be as pronounced as shown.

Why are we sending this Product Correction?

Air entry into the feed set tubing may potentially result in the following health consequences to the patient: vomiting, dehydration, hypoglycemia, weight change, electrolyte imbalance, abdominal pain, and abdominal distention.

What other actions is Cardinal Health taking?

Cardinal Health is implementing the appropriate corrective actions to ensure that the issue is corrected.

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. 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.
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Available Assistance:	If you have any questions regarding this field safety notice, please contact your local sales representative, or local sales office.
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Additional Information:	<u>Regulatory Notification</u> The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action.
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We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. 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 & Regulatory Affairs
Cardinal Health.