



URGENT: FIELD SAFETY NOTICE (Correction)

Event-2020-03389

Specific product codes and lots of:

- **Kangaroo Enteral Feeding Pump Sets**

March xx, 2021

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 tubing during set-up. The purpose of this communication is to advise you of this situation and to provide guidance to help address the issue prior to the availability of the corrected product. 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
	672055	Kangaroo™ ePump INT. 500ML Feed Only NS	All product manufactured before Sep 3, 2020 with lot numbers 202580052 and below
	673656	Kangaroo™ ePump INT. 1000ML Feed Only NS	
	673662	Kangaroo™ ePump INT. 1000ML Feed/Flush NS	
	773656	Kangaroo™ ePump DEHP Free 1000ML Feed Only	
	773662	Kangaroo™ ePump DEHP Free 1000ML Feed and Flush	
	775659	Kangaroo™ ePump ENPlus Spike Pump Set	
	776150*	Kangaroo™ ePump Burette Re-certification Burette 100ML*	
	666064	Kangaroo™ Joey 500mL Pump Set	All lots before 21AXXXXXX**
	668104	Kangaroo™ Joey 1000 mL Pump Set with 1000 mL Flush Bag	All lots before 20JXXXXXX**
	777056	Kangaroo™ ePump 100ML Burette	All lots before 20HXXXXXX**
	777064	Kangaroo™ ePump 500ml EZ Cap Set	All lots before 21BXXXXXX**
	777106	Kangaroo™ ePump 1000ml EZ Cap Set	All lots before 21BXXXXXX**
	777163	Kangaroo™ ePump 1600ml EZ Cap Set	All lots before 21AXXXXXX**
	777401	Kangaroo™ ePump™ ENPlus Spike Set	All lots before 21BXXXXXX**
	777402	Kangaroo™ ePump™ Dual ENPlus Spike Set	All lots before 20LXXXXXX**
	777403	Kangaroo™ ePump™ ENPlus 3 in 1 Pump Set	All lots before 21BXXXXXX**
	777405	Kangaroo™ ePump™ ENPlus Spike Feed Set with 1000 mL Flush Bag	All lots before 21BXXXXXX**
	777406	Kangaroo™ ePump™ ENPlus 3 in 1 Feed Set with 1000 mL Flush Bag	All lots before 21BXXXXXX**
	777407	Kangaroo™ ePump™ ENPlus Spike feed with vented Spike flush	All lots before 20KXXXXXX**
	777408	Kangaroo™ ePump™ ENPlus 3 in 1 Feed Set with Flush Bag	All lots before 21AXXXXXX**
	777501	Kangaroo™ Joey ENPlus Spike Pump Set	All lots before 21BXXXXXX**
	777502	Kangaroo™ Joey Dual ENPlus Spikes Pump Set	All lots before 20LXXXXXX**
	777503	Kangaroo™ Joey ENPlus 3 in 1 Pump Set	All lots before 21BXXXXXX**
	777505	Kangaroo™ Joey ENPlus Spike Pump Set with 1000 mL Flush Bag	All lots before 21BXXXXXX**


777506	Kangaroo™ Joey ENPlus 3 in 1 Pump Set with 1000mL Flush Bag	All lots before 20FXXXXXX**
777507	Kangaroo™ Joey ENPlus Spike Feed Set with Vented Spike Flush	All lots before 20AXXXXXX**
778104	Kangaroo™ 1000ml feed & 1000ml flush bag set	All lots before 21AXXXXXX**
778161	Kangaroo™ ePump 1600ml Feed and 1000ML Flush Bag Set	All lots before 21BXXXXXX**

*Although this product code is not used for feeding, the air in tubing issue may affect the recertification/calibration process and the same steps in Attachment A should be followed. Feeding pumps that have successfully passed recertification using this product code are still considered certified.

**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

Usage
Kangaroo Enteral Feed Pump sets are used for enteral feeding either as feed/flush pump sets or feed only pump sets.

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> The issue relates to air entry into the feed set tubing, which appears as air space in the tubing.</p>  <p>*The image above is an example and air in the tubing may not be as pronounced as shown.</p> <p><u>Why are we sending this Product Correction?</u> Air entry into the feed set tubing may potentially result in the following health consequences: vomiting, dehydration, hypoglycemia, abdominal pain, and abdominal distention in patients.</p> <p><u>What other actions is Cardinal Health taking?</u> Cardinal Health is implementing the appropriate corrective actions to ensure that the issue is corrected.</p>
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Actions requested on your part:	<ol style="list-style-type: none"> 1) FOLLOW the steps described in Attachment A (Air in Tubing Check Process) to check 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:**

Regulatory Notification

The applicable regulatory agencies are being notified that Cardinal Health is voluntarily taking this action.

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,



Moazzam Khan
Director, QRA Management



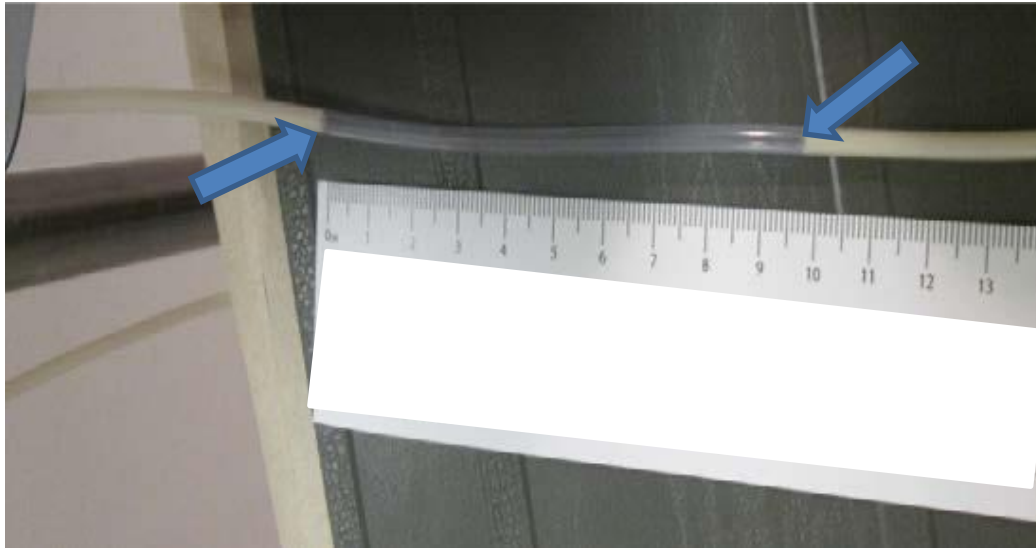
**Attachment A (Air in Kangaroo Enteral Feed Pump Sets
Tubing Check Process)**

To check the feed set for entry of air in the tubing (see the example below) follow the steps described below.

- Press “Run” on the pump after installing and priming the feeding set.
- After 30 seconds, observe the tubing between the pump and the patient to check for air being drawn into the line.
- It is not uncommon, and not a problem, to see a small amount of air in the feed tubing (approximately 1.3 cm [1/2 inch]) after the pump checks for any blockages.
- **Do not use the feeding set** if you see a single segment of air measuring **greater than 2.5 cm (1 inch)**.
- **Do not use the feeding set** if you see several air bubbles that cumulatively measure **greater than 2.5 cm (1 inch)**

NOTE:

The air in tubing event is found to be intermittent and is not observed in all lots. Thus, if a defective feeding set is identified, it does not necessarily mean that the entire lot is defective.



*This is an example and the air in the tubing may not be as pronounced as shown in the image.