

URGENT: FIELD SAFETY NOTICE (Correction)

Event-2020-03389 - UPDATE

Specific product codes and lots of:

- **Kangaroo Enteral Feeding Pump Sets**

March 29th 2021

Dear Valued Customer,

The purpose of this communication update is to inform you that additional product codes have been included in the scope of this field safety corrective action which Cardinal Health is conducting 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
	612054***	Kangaroo™ ePump INT. 500ML Feed Only ST	All product manufactured before Sep 3, 2020 with lot numbers 202580052 and below
	613650***	Kangaroo™ ePump INT. 1000ML Feed Only ST	
	614650***	Kangaroo™ ePump INT. Proximal Spike ST	
	672055	Kangaroo™ ePump INT. 500ML Feed Only NS	
	673656	Kangaroo™ ePump INT. 1000ML Feed Only NS	
	673662	Kangaroo™ ePump INT. 1000ML Feed/Flush NS	
	674655***	Kangaroo™ ePump INT. Proximal Spike NS	
	674668***	Kangaroo™ ePump Joey 500ML Feed/Flush DEHP Free	
	674669***	Kangaroo™ ePump INT. Proximal Spike and Flush NS	
	762055***	Kangaroo™ Joey 500ML Pump Set	
	763656***	Kangaroo™ Joey 1000ML Pump Set	
	763662***	Kangaroo™ Joey 1000ML Feed/Flush Set	
	765100***	Kangaroo™ Joey ENPlus Spike Feed and Flush 1000ML	
	765559***	Kangaroo™ Joey ENPlus Spike Set	
	773656	Kangaroo™ ePump DEHP Free 1000ML Feed Only	
	773662	Kangaroo™ ePump DEHP Free 1000ML Feed and Flush	
	775100***	Kangaroo™ ePump ENPlus Spike Feed and Flush Set 1000ML	
	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**	
666106***	Kangaroo™ Joey 1000mL Pump Set	All lots before 21AXXXXXX**	
668104	Kangaroo™ Joey 1000 mL Pump Set with 1000 mL Flush Bag	All lots before 20JXXXXXXX**	
777056	Kangaroo™ ePump 100ML Burette	All lots before 20HXXXXXXX**	

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

***Additional Product code included with this update

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:	<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.
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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: vomiting, dehydration, hypoglycemia, abdominal pain, and abdominal distention in patients.

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 (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:	<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,

