Cardinal Health
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CardinalHealth

Urgent Medical Device Correction

Kangaroo Enteral Feed Pumping Sets

March 1, 2021

Dear Valued Customer,

Cardinal Health is initiating a Medical Device Product Correction to advise you of the potential for air appearing in the enteral feed pumping set tubing during set-up. The purpose of this communication is to advise you of this situation and to provide steps to help address the issue prior to the availability of the corrected product.

Product Correction 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 (lot 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	
716154	Kangaroo™ ePump 100ML Burette Sterile	
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	
772055	Kangaroo™ ePump DEHP Free 500ML Feed Only	
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*	

*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.

Usage

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

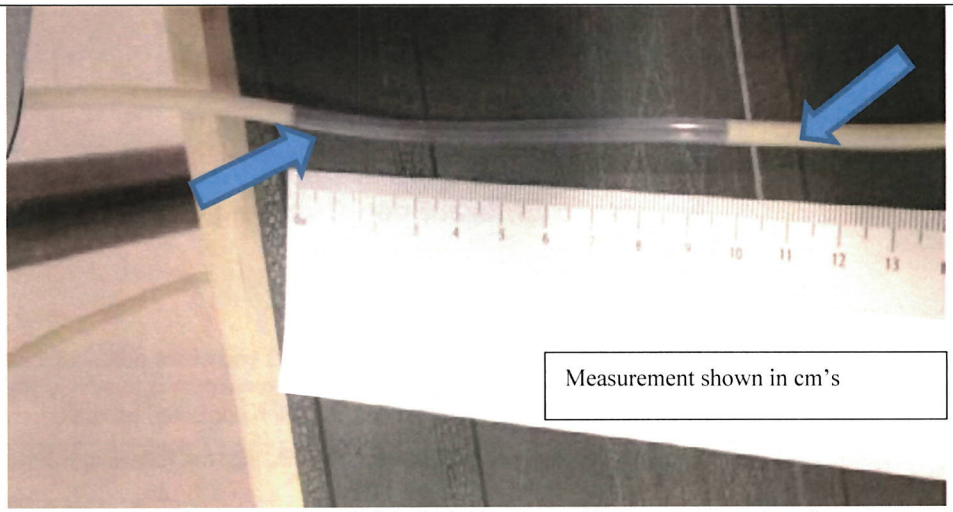
Why you are being contacted:

You are receiving this letter because our records indicate that you have purchased Cardinal Health Kangaroo Enteral Feed Pump sets in the past.

Description of the problem:

What is the issue?

The issue relates to air entry into the feed set tubing, which appears as air space in the tubing.



*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 feeding set tubing could 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:	1) **FOLLOW the** steps described in Attachment A (Air in Tubing Check Process) to check the feed set. 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/forwarded affected product to or will send the product on to about this product correction notice and share a copy of this notice and Attachment A. 4) **POST** a copy of this notification in your storeroom where the product is stored 5) **RETURN** the enclosed acknowledgment form via fax to 614-652-9648 or email to **gmb-fieldcorrectiveaction@cardinalhealth.com**, whether or not you have affected product.
Available Assistance:	Please contact the Customer Service group for any questions related to this action or to return defective product: • Hospital—800-964-5227 • Federal Government—800-444-1166 • Distributor—800-635-6021 • All other customers—888-444-5440 For questions related to the notification and/or acknowledgement form that are not adequately addressed in this letter, please contact the market action team at: GMB-FieldCorrectiveAction@cardinalhealth.com or call 800-292-9332.
Additional Information:	**Adverse Events Reporting Process** Cardinal Health has notified the U.S. Food & Drug Administration that we are taking this action. In the event you have experienced quality problems or adverse events related to the products listed above, send an email to: GMB-PRComplaints@cardinalhealth.com. The FDA can be contacted to report any adverse events experienced with these products: • Online @ http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or email) or call FDA 1-800-332-1088. **Regulatory Notification** The FDA and other applicable regulatory bodies have been notified and are aware 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