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## Urgent Medical Device Correction

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March 4, 2021

Dear Valued Patient:

**You are receiving this letter because there is an urgent medical device correction with your Kangaroo Enteral Feed Pump Set.** *Cardinal Health* has released a Medical Device Product Correction due to the possibility of air entering the enteral feeding tubing set during set-up for all Kangaroo Enteral Feed Pump Sets.

**What is the issue and why is *Cardinal Health* issuing this correction?**

The issue relates to air entering the tubing of the feed set, which will look like air space in the tubing. Air entry into the feeding set tubing could result in the following adverse health outcomes: Vomiting, dehydration, hypoglycemia, abdominal pain, and abdominal distention.

If your bag is defective (follow the instructions on **Attachment A**, page 2, of this letter on how to check this) do not use it and call Chartwell right away at **1-800-755-4704, option 4** to receive a corrected feeding tube set.

**What do I need to do?**

1. You only need to replace the bags if you are experiencing a large volume of air (more than 1 inch) in the feed set tubing. A small amount of air (1/2 inch or less) is normal, and the feed set tubing can safely be used.
2. Contact Chartwell at **1-800-755-4704, option 4** if you are experiencing excessive air in the tubing that cannot be removed by priming the feed set tubing.
3. Visit <https://chartwellpa.com/> to view the possible affected lots and read the official letter from *Cardinal Health*.

Thank you for your prompt attention and cooperation with this matter. As always, please call Chartwell, **1-800-755-4704, option 4** if you have any questions or concerns.

Your Partner in Care,

The Chartwell Enteral Nutrition Team



**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.