Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

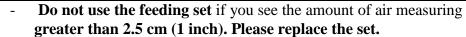
Safety Communication

رسالة سلامة

potential for air appearing in the enteral feed pump set tubing during setup

Device/ Product Description:	Kangaroo Enteral Feeding Pump Sets	
Affected Lot Number:	All product manufactured before Sep 3, 2020 with lot numbers 202580052 and below All lots before 21AXXXXXX** All lots before 20JXXXXXX** All lots before 21BXXXXXXX** All lots before 21AXXXXXXX* All lots before 21AXXXXXXX* All lots before 20LXXXXXXX* All lots before 21BXXXXXXXX* All lots before 21BXXXXXXXX* All lots before 21BXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	
Manufacturer:	Covidien, Cardinal Health LLC	
Problem:	The issue relates to air entry into the feed set tubing, which appears as air space in the tubing. 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.	
Recommendation /Actions:	 Make sure that this document is reached to the end-users. Follow the following steps to check the feed set: Press "Run" on the pump after installing and priming the feeding set. After 30 seconds, watch the tubing between the pump and the patient to check if the air getting into the line It is not a problem, to see a small amount of air in the feed tubing (approximately 1.3 cm [1/2 inch]) 	

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Do not use the feeding set if you see several air bubbles its total measure greater than 2.5 cm (1 inch). Please replace the set.



• Contact the authorized representative for any needed support.

For more information, Please click here.

If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:

NCMDR

Vigilance system

(19999) unified call center

Devices/Products photo:



Authorized	
Representative	
Details	

AR name:	International Medical Supplies Co.
Assigned Contact Person:	Ammar Abdullah Kaabi
Mobile/Phone:	011- 243 9384
Email:	akaabi@tibbiyah.com

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