Provider Newsflash
March 2024

FDA Recall – Vyaire Medical, Inc.

Purpose of this communication:

- We are writing to inform you that effective immediately, the FDA has issued a Class I recall notice of AirLife Manual Resuscitators manufactured by Vyaire Medical, Inc. in 2017 or earlier and products without a manufacturing date due to a manufacturing defect. Using the recalled resuscitators could result in patients not receiving enough ventilation. In some cases, patients may not receive any ventilation which may result in the patient's ability to properly exchange oxygen and carbon dioxide (hypoventilation) or experience a drop in blood oxygen (hypoxia) which can lead to serious injury or death.

What do I need to do?

- Please review the following recall notice: Vyaire Medical, Inc. Recalls AirLife Manual Resuscitators Due to Manufacturing Defect That Can Lead to Injury or Death | FDA
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.

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