Provider Newsflash
September 2024

FDA Recall – Baxter Healthcare Corporation

Purpose of this communication:

- We are writing to inform you that effective immediately, the FDA has issued a Class I recall of Baxter Healthcare Corporation's Volara System Single Patient Use Circuits (codes M08473 and M08474) and Blue Ventilator Adapter Assembly (code M07937) due to reports that the handset plug within these components may disconnect from the nebulizer port on the blue ventilator adapter. When using the Volara System in line with a ventilator and without a nebulizer connected to the blue ventilator adapter, the handset plug is required for proper operation and gas flow. If the plug is disconnected, the ventilator may not provide enough ventilation to the patient which may cause serious adverse health consequences.

What do I need to do?

- Please review the following recall notice: Lung Therapy Component Recall: Baxter Healthcare Corporation Recalls Certain Volara System Single-Patient Use Circuits and Blue Ventilator Adapter Assemblies Due to Disconnection Risk That May Prevent Proper Ventilation | FDA
- Notify impacted patients and facilitate the 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.