Provider Newsflash
October 2024

FDA Recall – Zyno Medical

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued notice of a Class I recall by Zyno Medical of certain their Zyno Medical Z-800, Z-800F, Z-800W and Z-800 WF infusion pumps due to an air-in-line software defect that may allow a 1.0 mL air bubble to be passed on to the patient which may cause serious adverse health consequences including air entering the blood vessels (vascular air embolism), fast and irregular heartbeat (tachyarrhythmia), heart attack (myocardia infarction), stroke, seizure and death.

What do I need to do?

- Please review the following recall notice: Infusion Pump Recall: Zyno Medical Removes Z-800, Z-800F, Z-800W, and Z800WF Infusion Pumps due to an Air-in-Line Software Defect That May Allow Larger than Expected Air Bubbles to Enter Patients | 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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