carecentrix

Provider Newsflash
December 2024

FDA Recall – Fresenius Kabi USA, LLC

Purpose of this communication:

- We are writing to inform you that Fresenius Kabi USA reports that a subset of pneumatic valves installed in some Ivenix LVPs have an increased chance of issuing a non-recoverable pump problem alarm. All devices with the affected valves, should be removed from use to be evaluated and returned to Fresenius Kabi's facility for repair. On December 5, 2024, Fresenius Kabi USA sent all affected customers a letter recommending the review of recalled Serial Numbers with removal of use of any impacted device until the affected LVPs are returned for pneumatic valve repair.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-infusion-pump-issue-fresenius-kabi-usa?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the LVP removal from use and repairs from the manufacturer, 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.