carecentrix

Provider Newsflash
August 2023

FDA Recall – Baxter Healthcare Corporation

Purpose of this communication:

- We are writing to inform you that the FDA has issued a Class 1 recall of Baxter Healthcare Corporation's SIGMA Spectrum Infusion Pumps with Master Drug Library (Version 8) and Spectrum IQ Infusion Systems with Dose IQ Safety Software (Version 9) due to increased reports of false alarms for upstream occlusion after software upgrades to version v8.01.01 and v9.02.01 respectively. The recalled product codes are 35700BAX2 and 3570009 distributed from September 29, 2015 to May 2, 2023. False upstream occlusion alarms cause interrupted or delayed therapy which may cause serious adverse health consequences.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/baxter-healthcare-corporation-recalls-sigma-spectrum-infusion-pumps-master-drug-library-and-spectrum?utm_medium=email&utm_source=govdelivery
- 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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