carecentrix

Provider Newsflash March 6, 2020

FDA RECALL

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a Class 1 recall by Becton Dickinson (BD) CareFusion 303, Inc. of all lots of the following Alaris System Infusion Pump Modules due to software and system errors:

- BD Alaris™ System PC Unit Model 8000, software versions 9.5 and prior
- BD Alaris™ System PC Unit Model 8015, software versions 9.33 and prior, and software version 12.1.0
- BD Alaris™ Pump Module Model 8100, software versions 9.33 and prior, and software version 12.1.0.
- Alaris™ Syringe Module Model 8110, software versions 9.33 and prior, and software version 12.1.0
- Alaris™ PCA Module Model 8120, software versions 9.33 and prior, and software version 12.1.0

Distribution Dates: Alaris PC units with software version 9.33 and older - July 2004 to October 31, 2019; Alaris PC units with software version 12.1.0 December 18, 2019 to January 23, 2020

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/medical-devices/medical-device-recalls/becton-dickinson-bd-carefusion-303-inc-recalls-alaris-system-infusion-pumps-due-software-and-system?utm_campaign=2020-03-06%20Alaris%20Infusion%20Pumps%20Recalled%20Due%20to%20Software%20Errors%20and%20Use%20Errors&utm_medium=email&utm_source=Eloqua
- 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 for your prompt attention and cooperation in this matter.