

Provider Newsflash June 17, 2021

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 of the Alaris Infusion Pump Module Model 8100 Bezel, Product Number TIPA-8100-4410, Lot number 20200608 distributed from January 15, 2021 to March 14, 2021 that where purchased and/or installed by Infusion Pump Repair for service and repair of Alaris infusion pump modules. The bezel components may crack or separate leading to inaccurate delivery of fluids to patients which could cause serious patient harm.

What do I need to do?

- Please review the following recall notice:
- <u>https://www.fda.gov/medical-devices/medical-device-recalls/infusion-pump-repair-recalls-alaris-infusion-pump-module-8100-bezel-due-possible-cracked-or?utm_medium=email&utm_source=govdelivery</u>
- 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.