

FDA Recall – Fresenius Kabi USA, LLC

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has posted notice of a Class I recall by Fresenius Kabi USA, LLC of the Ivenix Infusion System (IIS), LVP Software due to multiple software anomalies that have the potential to result in serious patient harm or death. The recall is a correction that will take the form of a software update, not a product removal.

What do I need to do?

- Please review the following recall notice: [Fresenius Kabi Recalls Ivenix Infusion Pump LVP \(govdelivery.com\)](https://www.govdelivery.com)
- 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.