

FDA Recall

Purpose of this communication:

We are writing to inform you that effective immediately the FDA has issued notice of a voluntary recall by ICU Medical, Inc. of Aminosyn II, 15%, an Amino Acid Injection, Sulfite Free intravenous (IV) solution, lot #4989094, Expiration date April 1, 2022 distributed January, 2021 through March, 2021 due to the presence of particulate matter.

What do I need to do?

- Please review the following recall notice:
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/icu-medical-issues-voluntary-nationwide-recall-aminosyn-ii-15-amino-acid-injection-sulfite-free-iv?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.