

Provider Newsflash November 2023

FDA Recall – Nurse Assist, LLC

Purpose of this communication:

• We are writing to inform you that the FDA has issued notice of a voluntary recall by Nurse Assist, LLC of their 0.9% sodium chloride irrigation USP and sterile water for irrigation USP distributed with multiple brand names between November 1, 2021 and September 18, 2023 due to the potential for a lack of sterility assurance. The recalled products include the following which may be packaged inside kits:

Product	Size
I DIORIGO IRRIGATION	100 mL bottles, 250 mL bottles, 500 mL bottles, 1000mL bottles, 3.1oz spray can, 7.1oz spray can, 3mL syringes, 5mL syringes, and 10mL syringes
Sterile Water for Irrigation USP	100 mL bottles, 250 mL bottles, 500 mL bottles, 1000mL bottles, 120 mL cups, 10mL syringes, and 30mL syringes

What do I need to do?

- Please review the following recall notice: <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/nurse-assist-llc-issues-recall-09-sodium-chloride-irrigation-usp-and-sterile-water-irrigation-usp?utm_medium=email&utm_source=govdelivery</u>
- Notify impacted patients and facilitate the 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.