

FDA Recall – Medline Industries

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class 1 recall of Medline Kits and Trays. Medline Industries is recalling certain kits, trays, and packs in direct response to Nurse Assist LLC's, November 6, 2023, recall of 0.9% sodium chloride irrigation USP and sterile water for irrigation USP, over sterility concerns. These kits contain Nurse Assist saline solution that were recalled due to a lack of sterility. Using non-sterile saline for wound care could lead to severe, life-threatening infections, especially for those who are immunocompromised, undergoing surgery, or critically ill. This is the only saline used in these kits. The recall doesn't affect the integrity of the other kit components.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/medline-industries-recalls-certain-kits-and-trays-containing-sterile-water-based-products-under?utm_medium=email&utm_source=govdelivery
- 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.

Thank you in advance for your cooperation and continued partnership.