

PRODUCT DISRUPTION BRIEF

Irrigation solutions and sterile water (reviewed November 1)

Distributors of Nurse Assist water-based medical products and manufacturers of kits and trays that contain Nurse Assist recalled products are initiating voluntary recalls; ICU Medical supply interruptions for irrigation solutions packages in Semi-Rigid Bottles (SRB) continue.

See additional mitigation information [here](#).

ICU Update 8/27/24

ICU Medical is still in-process of transitioning suppliers for our Semi-Rigid Bottles (SRB) for Irrigation solutions. Enclosed is the latest update we have for both our interim and long-term SRB suppliers.

- ICU is committed to continuing to provide an unlimited supply and access to Irrigation solutions in both SteriCare SRB and ICU Medical bag presentations
- ICU's Interim SRB supplier has communicated to ICU Medical a late '24 projected availability for their enhanced SteriCare bottle design, which will incorporate a 38 mm neck size and tamper evident break-band design (i.e. Lift N' Peel elimination) for their 500 mL Sodium Chloride and Sterile Water Irrigation solution presentations
- ICU is continuing to work with their long-term SRB supplier, who is currently performing key milestone testing that will establish a more precise commercial launch date. We will provide updates upon testing completion in the coming months.

Current conditions

In direct response to the [Nurse Assist, LLC recall](#) on November 6, 2023, distributors of Nurse Assist water-based medical products and manufacturers of kits and trays that contain Nurse Assist recalled products are initiating voluntary recalls per [the FDA communication](#) on February 28.

The list of additional recalls and affected products is listed [here](#). Vizient is actively reaching out to suppliers to determine the scope of the impact, and additional mitigation strategies to assist providers. More information will be forthcoming.

The FDA is [warning health care providers](#), and health care facilities not to use recalled saline (0.9% sodium chloride) and sterile water medical products manufactured by Nurse Assist, LLC, and sold under various brands. Nurse Assist, LLC announced the recall of the following water-based medical products because the products may not be sterile:

- 0.9% Sodium Chloride Irrigation USP (100 mL bottles, 250 mL bottles, 500 mL bottles, 1000 mL 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, 1000 mL bottles, 120 mL cups, 10mL syringes, and 30mL syringes).

Water-based medical products that are nonsterile and potentially contaminated with bacteria could cause serious or life-threatening infections, including bloodstream, urinary tract, open wound/soft tissue, and respiratory infections. Patients who are elderly, critically ill, have weak immune systems (including newborn infants, pregnant women, and cancer patients) or have chronic diseases are particularly at risk of infection. However, other patients could also develop infections after they are exposed to contaminated water-based medical products.

To date, the FDA is not aware of reports of adverse events associated with the use of these recalled products.



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As the nation's largest member-driven health care performance improvement company, Vizient provides solutions and services that empower health care providers to deliver high-value care by aligning cost, quality and market performance. With analytics, advisory services and a robust sourcing portfolio, we help members improve patient outcomes and lower costs.

These products were sold under the following brands: Nurse Assist, Cardinal, Covidien, Halyard Owens Minor, Idexx, Mac Medical, McKesson, Medichoice Owens Minor, Medline, Sol, SteriCare, Trudell, and Vyaire. The recalled products may be available as individual units or may be included as part of a kit. Nurse Assist is not a Vizient-contracted supplier. Refer to the FDA communication for [recommendations for consumers, health care providers, and facilities](#). [recommendations for consumers, health care providers, and facilities](#).

Refer to the FDA communication for [recommendations for consumers, health care providers, and facilities](#) and a list of [affected products](#).

ICU Medical is experiencing supply interruptions for irrigation solutions packages in Semi-Rigid Bottles (SRB) resulting in intermittent product shortages on current products through Q1 2025. To help improve supply availability, they have identified SteriCare Solutions as an alternative source to distribute and distribute 0.9% Sodium Chloride Irrigation USP and Sterile Water for Irrigation USP solutions in 250 mL & 500 mL. ICU Medical plans to fully transition to the SteriCare irrigation solutions packaged in SRB by Q1 2025. SteriCare's USP solutions have been cleared by the FDA as medical device(s) and will not have a NDC number.

During this transition, ICU Medical is asking customers to continue ordering current SRB products as normal as they will continue to service committed customers on 100% direct committed basis with their current Irrigation solutions portfolio based on inventory availability throughout Q1 2025.

Related additional recalls as of February 28, 2024

Recalling Firm	Description	Additional Information
Cardinal Health	Covidien and Cardinal Health brand urology and operating room-specific kits and trays that contain 0.9% sodium chloride irrigation USP and sterile water for irrigation USP supplied by Nurse Assist	Cardinal Health Issues Medical Device Recall for Nurse Assist Products Contained Within Kits/Trays Affected Covidien and Cardinal Health brand codes and lot numbers
Busse Hospital Disposals	Medical device kits and trays, such as, tracheostomy care trays, tracheostomy care sets, and dressing change trays, containing 1 Nurse Assist part 6240, Stericore 100ML Sterile Saline Bottle.	Busse Hospital Disposables Issues Nationwide Recall of Kits/Trays Containing Sterile Water Based Products Under Recall by Nurse Assist
ROi CPS LLC	Regard Operative Lap P&S Surgical trays or kits which contain irrigation solution component recalled by Nurse Assist.	ROi CPS, LLC Recalls Regard Operative Lap P&S Surgical Kit Due to Possible Lack of Sterility FDA; Affected Products UDI and lot numbers
Windstone Medical Packaging dba Aligned Medical Solutions	Convenience kits, such as low extremity packs, ocular packs, and closure kits which contain the recalled Nurse Assist Sterile Saline, brand Name - Medline Medical part # DYND40540 110ML Sterile Saline Cup or Nurse Assist Sterile Saline Brand Name - McKesson Medical part # 560284 100ML Sterile Saline Bottle.	Windstone Medical Packaging dba Aligned Medical Solutions Issues Nationwide Recall of Nurse Assist Sterile Saline Placed Into the Following Kits; AMS10833 Local Lower Extremity Pack I, AMS12947 In House Ocular Pack, AMS12947A In House Ocular Pack and AMS13043 Closure Kit
Maquet Cardiovascular, LLC	Express chest drains, models 4000-100N and 4050-100N, disposable systems prepackaged with 30 mL syringe filled with water-based products recalled by Nurse Assist.	Maquet Cardiovascular, LLC Recalls Atrium Express Dry Suction Dry Seal Chest Drain Containing Sterile Water Based Products Under Recall by Nurse Assist
Avanos Medical, Inc	MIC* Gastric – Jejunal Feeding Tube Kits. These kits include Nurse Assist supplied syringes, pre-filled with sterile water, essential for inflating the retention balloon of the feeding tube.	Avanos Medical, Inc. Announces Voluntary Recall in Response to Nurse Assist, LLC Sterile Water Medical Products Recall

Mitigation

ICU Medical has a **limited supply** of un-affected SteriCare 0.9% Sodium Chloride Irrigation USP in Plastic Pour Bottles along with immediate availability of Sodium Chloride and Sterile Water Irrigation Bags.

Vizient has identified Baxter and B Braun as the only alternative options for saline (0.9% sodium chloride) and sterile water medical products and both suppliers are currently on protective allocation. Work with your local representatives to determine allocation allowances and alternative SKUs.

Becton Dickinson is the only alternative supplier for prefilled syringes.

Vizient will continue to work with our supplier partners and clinical teams to determine if additional options are available during this disruption. More information will be forthcoming.

Additional resources

[Supply assurance webpage](#); [Vizient Newsroom](#)



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