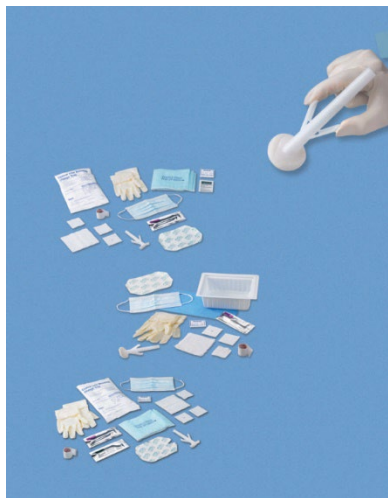


Busse Hospital Disposables Issues Nationwide Recall of Kits/Trays Containing Sterile Water Based Products Under Recall by Nurse Assist



Dressing Change Trays



Tracheostomy Care Tray

FOR IMMEDIATE RELEASE: December 19, 2023

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On November 21, 2023, Busse Hospital Disposables initiated a nationwide recall of medical device kits and trays containing (1) Nurse Assist part 6240, Stericare 100ML Sterile Saline Bottle. This is the only saline contained in the trays/kits. Busse initiated this recall 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, due to potential lack of sterility assurance, which could result in a nonsterile product. In populations most at risk, such as patients who are immunocompromised, there is a possibility that the use of the affected product could potentially result in severe or life-threatening adverse events.

All distributors who are affected have been identified and notified through recall letters. The devices that have been shipped to your facility and identified as affected may be destroyed following instructions on [recall letter](#). The recalled Busse kits/trays were manufactured and distributed to medical device distributors from July 2022 to November 2023.

The following products, which contain Nurse Assist Part#6240, Stericare 100ML Sterile Saline Bottle have been recalled:

Catalog Number	Product Description	Lot Number
800	Tracheostomy Care Tray – Sterile – Latex Free UDI: (01)00849233010000	2210099
		2210135
		2210337
		2210377
		2310181
		2310233

		2310291
1443	Dressing Change Tray – Sterile – Latex Free UDI: (01)00849233010727	2210077
		2210112
		2310275
		2310331
9251R1	Tracheostomy Care Set – Sterile – Latex Free UDI: (01)00849233011069	2210087
		2210165
		2310361

Products can be identified by locating the information above on their respective labeling – see reference below.

To date, Busse has not received any reports of serious injuries or deaths associated with this recall. Busse has notified both the FDA and affected distributors of the recall through direct communications. We remain committed to ensuring the safety and well-being of our customers.

Customers with any questions may contact Busse Hospital Disposables via telephone at 800-645-6526 Monday through Friday between the hours of 8am and 4pm (est) or via email at NurseAssistRecall@busseinc.com.

Customers may also contact Nurse Assist, LLC via telephone at 800-649-6800 Monday through Friday between the hours of 8am and 430pm (cst) or via e-mail at productremovalinfo@nurseassist.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

