

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

The purpose of this is to inform you that B. Braun Medical Inc. (BBMI) is issuing a pharmaceutical recall for specific batches of S8506, STERILE WATER FOR INJECTION USP 3L, and R8206, 0.9% SODIUM CHLORIDE IRR, USP, 3L BAG, due to the potential for leakage at the port site.

The depth of this recall is to the hospital/healthcare facility level. This recall is being conducted with the knowledge of the United States Food and Drug Administration.

BBMI has identified through complaints that there is a potential for fluid leakage from the port due to port misalignment. To date, there have been no reports of serious injury or death associated with this issue. Product leakage can result in the potential delay of treatment while a new product is obtained and prepared. If the product leakage is no evident and the product contaminated with microorganisms, there is a potential for the final mixed product to be contaminated potentially resulting in a bloodstream infection leading to additional medical treatment. In some patients, a bloodstream infection could be a life-threatening event.

Product Catalog Number	NDC Number	Product Description	Expiration Date	Region Distributed	Lot Number	Distribution Range
S8506	0264-7385-60	STERILE WATER FOR INJECTION USP 3L	8/31/26	US	J3L519	10/31/23 - 3/11/24
					J3L528	10/2/23 - 3/13/24
S8506	0264-7385-60	STERILE WATER FOR INJECTION USP 3L	2/28/27	US	J4C522	4/2/24 - 9/30/24
					J4C523	4/3/24 - 4/11/25

R8206	0264- 7388- 60	0.9% SODIUM CHLORIDE IRR, USP, 3L BAG	2/28/27	US	J4C521 J4C516 J4C524	5/17/24- 9/6/24 3/27/24- 8/19/24 4/17/24- 12/17/24
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