

*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.*

This is to inform you the B. Braun Medical, Inc. (BBMI) is issuing a pharmaceutical recall for product R5201-01, 0.9% NaCl IRR PIC 500 mL, due to the potential for particulate matter (PM) within the solution. 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 & Drug Administration.

During manufacturing, PM was detected in lots of R5201-01, 0.9% NaCl IRR 500 mL. The particles were further examined and determined to be High-Density Polyethylene (HDPE) and occurred due to cap chute misalignment. Once the source of PM was identified, it was determined that one (1) distributed lot of product R5201-01, 0.9% NaCl IRR PIC 500mL (Lot J4K936) that had passed inspection and release criteria may potentially be impacted.

To date, there have been no customer complaints received and there have been no reports of death or serious injury associated with this issue. If PM is identified in the solution, a delay in the procedure could occur while replacement product is obtained. If the PM is not detected, it could enter the surgical site leading to mild localized infection, significant infection, foreign body reaction, sepsis, or another life-threatening infection. These could result in invasive treatment, hospitalization, or patient death. During urological procedures, there is a potential for catheter blockage and/or particles entering the bladder which could cause irritation to the mucosa and the potential for the formation of the local granuloma.

PRODUCT: 0.9% NaCl IRR PIC 500 mL

NDC NUMBER: 0264-2201-01

LOT NUMBER: J4K936

PRODUCT CATALOG NUMBER: R5201-01

EXPIRATION DATE: 07/31/2027