B. Braun Medical – Recall of sodium chloride injection

- On June 17, 2025, B. Braun Medical announced a consumer-level recall of five lots of sodium chloride 0.9% injection due to the potential for fluid leakage.
    - There is potential for fluid leakage originating from pinholes in the same location of the bag. The size of the pinhole is small and therefore leakage only occurs when physical pressure is applied to the bag.
    - Other sodium chloride injection products that are not being recalled are available for patients to use.
- The recalled lots were distributed between October 2024 and December 2024.

Product Description	NDC#	Lot # (Expiration Date)
0.9% Sodium Chloride Injection in EXCEL IV Container, 500 mL	0264-7800-10	J4L260 (2/28/2027); J4L261 (2/28/2027); J4L270 (2/28/2027); J4L271 (2/28/2027); J4L280 (2/28/2027)

- Sodium chloride injection is indicated for:
    - Use in adults and pediatric patients as sources of electrolytes and water for hydration
    - Extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion
    - Use as a priming solution in hemodialysis procedures and may be used to initiate and terminate blood transfusions without hemolyzing red blood cells
    - Use as pharmaceutic aids and diluents for the infusion of compatible drug additives.
- Per B. Braun Medical, product leakage can result in solution on the floor/surfaces requiring cleanup, a potential for falls/slips and/or the potential delay of treatment while a new IV bag is obtained. If the bag contains hazardous medication, there is the potential for leakage of that medication with limited to significant exposure to hazardous drugs that may result in mild to severe injury to the patient, clinician or other. If the leakage is not evident, the contents of the container may be contaminated due to compromising the sterile barrier of the product, potentially resulting in bloodstream infection. In some patients, such as immunocompromised patients and neonates, a bloodstream infection is a life-threatening event.
- To date, there have been no reports of serious injury or death associated with this issue.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- For any questions regarding this recall, contact BBMI's Recalls Department by phone at **1-844-903-6417**.