

## B. Braun Medical – Recall of Acetic Acid Irrigation

- On December 15, 2017, [B. Braun Medical announced](#) a voluntary, user-level recall of one lot of 0.25% [acetic acid irrigation](#) because some bottles may contain white particulate matter. This particulate matter was identified as polyethylene, which is consistent with the material used to manufacture the container cap.
- The recalled lot was distributed between 11/02/2017 and 12/05/2017:

Product Name	NDC #	Lot # (Expiration Date)
0.25% acetic acid irrigation, 500 mL plastic irrigation container	0264-2304-10	J7N965 (10/31/2020)

- Acetic acid irrigation is indicated as a constant or intermittent bladder rinse to help prevent the growth and proliferation of susceptible urinary pathogens (especially ammonia-forming bacteria) in the management of patients who require prolonged placement of an indwelling urethral catheter. It also may be used for periodic irrigation of an indwelling catheter to help maintain patency by reducing the formation of calcium encrustations.
- B. Braun Medical determined that the potential impact of the presence of particulate matter in the acetic acid irrigation has the potential to occlude urinary catheters with small lumen, which would require catheter replacement.
  - Particles that enter the bladder during irrigation treatment may cause irritation of the mucosa and potentially result in the formation of local granuloma.
- Anyone with recalled product should stop use and distribution, quarantine the product and contact B. Braun Medical for return information.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using the recalled acetic acid irrigation.
- For general questions regarding this recall and return information, contact B. Braun Medical at **1-800-227-2862**. For clinical questions regarding this recall, contact B. Braun Medical Affairs Department at **1-800-854-6851**.