B. Braun Medical – Withdrawal of heparin

- On December 18 2020, B. Braun Medical announced a voluntary, consumer-level withdrawal of several lots of heparin sodium in 5% dextrose injection because of ongoing changes that B. Braun is performing to ensure their heparin products meet certain potency requirements.

- Out of an abundance of caution, B. Braun is voluntarily withdrawing non-expired batches of heparin in dextrose injection products which were produced prior to implementation of manufacturing changes.

- To avoid potential market shortages, B. Braun is withdrawing heparin in dextrose products in two phases. This is the second phase of the withdrawal. The first phase was announced in July 2020. B. Braun is not anticipating any major potential for supply disruption.

- Clinical Services, through the Drug Safety Notification Program, did not identify any members that may be affected by the withdrawal by B. Braun Medical, thus mailings will not be conducted.

- The withdrawn products are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Heparin sodium 20,000 units per 500 mL in 5% dextrose injection	0264-9567-10	Refer to notice for list of withdrawn lots
Heparin sodium 25,000 units per 500 mL in 5% dextrose injection	0264-9577-10	
Heparin sodium 25,000 units per 250 mL in 5% dextrose injection	0264-9587-20	

- Heparin sodium is indicated for prophylaxis and treatment of venous thrombosis and pulmonary embolism; prophylaxis and treatment of thromboembolic complications associated with atrial fibrillation; treatment of acute and chronic consumption coagulopathies (disseminated intravascular coagulation); prevention of clotting in arterial and cardiac surgery; prophylaxis and treatment of peripheral arterial embolism; and anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures.

- Administration of low potency heparin may result in reduced anti-coagulant effects. The clinical impact of reduced heparin potency may range from mild requiring titration to effect, to serious and life-threatening in rare circumstances.

- To date, B. Braun has not received any reports of serious injury or death associated with low potency. The rate of reports of lack of effect/low potency associated with heparin in dextrose is 3.1 events per million units distributed.

- Patients who have the withdrawn heparin in dextrose injection should stop use and contact their physician or healthcare provider if they have experienced any problems that may be related to using the withdrawn heparin in dextrose injection.

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- Anyone with an existing inventory of the withdrawn product should stop use and distribution and quarantine the product immediately.

- Contact B. Braun Medical Affairs department at **1-800-854-6851** for further information regarding this withdrawal.

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