

SPINE SAFETY ALERT:

Information for Healthcare Professionals: Heparin Sodium Injection: Recall of Multi-dose And Single-dose Vials

According to MedWatch, Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection, and their heparin lock flush solutions. According to the Baxter International Inc. press release dated February 28, 2008, the company initially recalled nine lots of heparin sodium injection multi-dose vials on January 17, 2008 as a precautionary measure due to a higher than usual number of reports of adverse patient reactions involving the product and suspended production earlier this month.

Given the widespread use of this blood thinner and the impact a product shortage would have on operating rooms, dialysis centers and other critical care areas, the FDA and Baxter concluded that removing additional lots and doses of Baxter's heparin from the market earlier would have created more risk to patients requiring heparin therapy than the increased potential for experiencing an adverse reaction. Accordingly, the FDA and Baxter decided not to recall all Baxter heparin vial products at that time. The FDA has now concluded that there is sufficient capacity on the part of other suppliers that Baxter's recall will not jeopardize access to this drug, and has told Baxter that the company can now proceed with recalling its remaining heparin sodium injection and heparin flush products.

Although the vast majority of the reports of adverse reactions have been associated with the multi-dose products, Baxter is taking the precautionary step of recalling all remaining heparin sodium injection and heparin flush products that are currently on the market. In addition to the previously recalled lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials, Baxter's recall will now include the remaining lots of those products and heparin sodium injection 5000 units/mL 10mL multi-dose vials, heparin sodium injection 10,000 units/mL 4mL multi-dose vials, heparin sodium injection 1000 USP units/mL, 5000 USP units/mL, and 10,000 USP units/mL single-dose vials, and all HEP-LOCK and HEP-LOCK U/P, 10 USP units/mL and 100 USP units/mL vials, both preserved and preservative-free.

This recall does not involve Baxter's heparin pre-mix IV solutions in bags: heparin sodium in 5% dextrose injection and heparin sodium in 0.9% sodium chloride injection.

Nearly all reported adverse reactions have occurred in three specific areas of product use – renal dialysis, invasive cardiovascular procedures and apheresis procedures. Reported adverse patient reactions have included: stomach pain or discomfort, nausea, vomiting, diarrhea, decreased or low blood pressure, chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath,

the feeling of a strong or rapid heartbeat, drug ineffectiveness, burning sensation, redness or paleness of skin, abnormal sensation of the skin, mouth or lips, flushing, increased sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, throat swelling, thirst, bleeding tendencies and difficulty opening the mouth. **Some of these reactions, particularly profound and refractory hypotension, may be severe or life-threatening.**

Customers have been instructed to **discontinue use and segregate the recalled product** from the rest of their inventory. Customers should then contact Baxter to arrange for return and replacement product. Customers with recalled product purchased indirectly should contact their wholesaler or distributor for return and replacement product. Customers with questions may contact the Center for One Baxter at 1-800-4-BAXTER (1-800-422-9837). Representatives will be available twenty-four hours a day, seven days a week.

Read the complete 2008 MedWatch Safety Summary including a link to the FDA Public Health Advisory, Q & A Document, News Release, along with the Baxter Press Release and Public Health Update regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj2>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.