

Northwest Community EMS System

System Memo: # 343

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Date: April 4, 2013

To: All System Members

From: Connie J. Mattera, MS, RN. EMT-P EMS Administrative Director

RECALLS of NS 0.9% IV Fluid Immediate action needed

Hospira, Inc. has issued a voluntary nationwide recall of one lot of 0.9% Sodium Chloride Injection, USP, 1000 mL, Flexible Container, NDC 0409-7983-09. This action is due to one confirmed customer report where brass particulate was identified in the container in the form of several small grey/brown particles.

Affected lot #:25-037-JT (the lot number may be followed by a -01 or -90)Expiration date:January 1, 2015

Distributed between January 2013 and March 2013 to wholesalers/distributors, hospitals and pharmacies

The brass particulate was identified as containing copper, zinc and lead. If administered, solution containing brass particulate may result in occlusion of small blood vessels. In a worst-case scenario, copper toxicity may potentially result in hemolysis and liver toxicity, including hepatic necrosis which may be fatal.

There was a second recall of NS issued a couple of weeks ago that we just learned about.

Affected lot #:23-511-FWExpiration date:November 1, 2014Distributed in February 2013

Reason: A case of NS was stolen from a shipping container and there is the potential that the uncontrolled stolen case could re-enter the supply chain.

ACTION NEEDED NOW:

- Check all inventory supplies of IV fluids for the affected lot numbers ASAP.
- If found, immediately remove those IV bags from inventory.
- Return them to your assigned System hospital for exchange. Notify the hospital EMSC/ED charge nurse that you are making the exchange so they can isolate the recalled product and return it to their pharmacies. Do not put the recalled IV bags back into the hospital EMS exchange supplies.

Healthcare professionals are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: <u>www.fda.gov/MedWatch/report.htm</u>
- <u>Download form</u> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178