

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Dexamethasone Sodium Phosphate Injection, 4mg/mL, 30 mL Multiple Dose Vial:
Recall Due to Particulates in Product**

Source: FDA MedWatch

Audience: Health Care Providers, Risk Managers, Pharmacists

Issue: American Regent and FDA notified healthcare professionals of the nationwide recall of specific lots of Dexamethasone Sodium Phosphate Injection, USP 4 mg/mL, 30 mL Multiple Dose Vial because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates.

Background: This voluntary recall was initiated December 20, 2010 because some vials of these lots either contain particulates or have the potential to form particulates prior to their respective expiration dates. American Regent is undertaking this recall in consideration of the potential for safety issues if these lots of product are administered to patients.

Recommendation: The recalled lots are listed in the firm's press release below. Hospitals, infusion centers, clinics and other healthcare facilities should not use the drug product with these lot numbers for patient care and should immediately quarantine any product for return. As stated in the Dexamethasone Sodium Phosphate Injection, USP Product Package Insert, "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."

Read the complete 2010 MedWatch safety summary, including a link to the firm press release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm238104.htm>

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.