

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Ketorolac Tromethamine Injection, USP 30 mg/mL; 1mL and 2mL Single Dose Vials
Recall**

According to MedWatch, American Regent and FDA notified healthcare professionals of a voluntary recall of all lots of Ketorolac Tromethamine Injection, USP 30 mg/mL, including NDC# 0517-0801-25 [30 mg/mL 1mL Single Dose Vial] and NDC# 0517-0902-25 [30 mg/mL 2mL Single Dose Vial (60 mg/2mL)]. There is a potential for particulate matter in conjunction with crystallization that may be present in the product, which may result in adverse events such as obstruction of blood vessels which can induce pulmonary emboli or thrombosis, activate platelets and/or neutrophils to induce anaphylactic reactions. Other adverse effects associated with the injection of particulate matter include foreign body granulomas, and local irritation at the injection site.

This recall does not include other concentrations of American Regent Ketorolac Tromethamine Injection. The product was distributed to wholesalers and distributors nationwide. Hospitals, surgicenters, clinics and other healthcare facilities should not use any American Regent Ketorolac Tromethamine Injection, USP Injection 30 mg/mL for patient care and should immediately quarantine any product for return.

Read the MedWatch safety summary, including a link to the firm press release, at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm187481.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.