

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:**

**Heparin: Change in Reference Standard –**

**The change will result in 10% reduction in the potency of the heparin marketed in the U.S.**

According to MedWatch, FDA notified healthcare professionals and patients of a change to heparin, effective October 1, 2009, which will include a new reference standard and test method used to determine the potency of the drug and be able to detect impurities that may be present in heparin. The change, which will also harmonize the USP unit dose with the WHO International Standard unit dose, will result in approximately a 10% reduction in the potency of the heparin marketed in the United States.

This may have clinical significance in some situations, such as when heparin is administered as a bolus intravenous dose and an immediate anticoagulant effect is clinically important. Healthcare providers should be aware of the decrease in heparin potency as they monitor the anticoagulant effect of the drug; more heparin may be required to achieve and maintain the desired level of anticoagulation in some patients.

There will be simultaneous availability of heparin manufactured to meet the “old” and “new” USP monograph, with potential differences in potency. Products using the new “USP unit” potency definition are anticipated to be available on or after October 8. FDA is working with the manufacturers of heparin to ensure that an appropriate identifier is placed on heparin made under the new USP monograph. Most manufacturers will place an “N” next to the lot number. FDA is also working with the heparin manufacturers to study the impact of this variation in potency and will make the results available when the studies have concluded.

Read the complete MedWatch 2009 Safety summary, including links to the Public Health Alert and Information for Patients, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm184687.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.