

## SPINE SAFETY ALERT:

### **Information for Healthcare Professionals: Medtronic Neuromodulation Implantable Infusion Pumps: Class I Recall - Reports of Inflammatory Mass Formations**

According to MedWatch, FDA and Medtronic notified healthcare professionals of the Class 1 recall of Medtronic Neuromodulation Implantable Infusion Pumps, implantable devices for administering drugs to a specific site in the body to treat pain, spasticity and cancer. The company updated the labeling for the devices to include current patient management and treatment recommendations. The company received reports of inflammatory mass formations at or near the distal tip of intrathecal catheters which infuse opioids, baclofen, or chemotherapy drugs into patients. On January 28, 2008, Medtronic sent a letter to doctors who implant these devices and/or provide care to patients with the implanted device. The letter described the problem, patient risks, patient management, recommendations and next steps. Medtronic's representatives will complete a reply card to document their communication with each doctor regarding this recall, as well as asking the doctors to sign and return a reply card.

Read the complete MedWatch safety summary, including links to the Recall Notice and the "Dear Healthcare Professional" letter, at:

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

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.