

SPINE SAFETY WARNING:

**Information for Healthcare Professionals:  
Gadolinium-based Contrast Agents:  
Class Labeling Change - Risk of Nephrogenic Systemic Fibrosis**

**AUDIENCE:** Radiology, Nephrology, Dermatology

**ISSUE:** FDA is requiring changes in the professional labeling for gadolinium-based contrast agents (GBCAs) to minimize the risk of nephrogenic systemic fibrosis (NSF), a rare, but serious, condition associated with the use of GBCAs in certain patients with kidney dysfunction. NSF has not been reported in patients with normal kidney function. Patients at greatest risk for developing NSF after receiving GBCAs are those with impaired elimination of the drug, including patients with acute kidney injury or chronic, severe kidney disease.

**BACKGROUND:** GBCAs are intravenous drugs used in diagnostic imaging procedures to enhance the quality of magnetic resonance imaging or magnetic resonance angiography.

**RECOMMENDATION:** Healthcare professionals should screen patients prior to administration of a GBCA to identify those with acute kidney injury or chronic, severe, kidney disease. See the Drug Safety Communication for the complete list of recommendations to healthcare professionals and patients.

Healthcare professionals and patients 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: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) 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

Read the MedWatch safety alert, including a link to the Drug Safety Communication, at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm225375.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.