

## SPINE SAFETY CAUTIONARY NOTICE:

### **Information for Healthcare Professionals: Drug Safety Labeling Changes - Tisseel (fibrin sealant)**

According to MedWatch, FDA notified healthcare professionals that the WARNINGS, PRECAUTIONS and ADVERSE REACTIONS text for Tisseel (fibrin sealant) has been updated. The following sentences have been added to the labeling:

## **WARNINGS and PRECAUTIONS**

### ***Application Precautions***

- Air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. This event appears to be related to the use of the spray device at higher than recommended pressures and in close proximity to the tissue surface.
- When applying Tisseel using a spray device, be sure to use the pressure within the pressure range recommended by the spray device manufacturer. In the absence of a specific recommendation avoid using pressure above 20-25 psi. Do not spray closer than the distance recommended by the spray device manufacturer. In the absence of a specific recommendation avoid spraying closer than 10-15 cm from the surface of the tissue. When spraying Tisseel, changes in blood pressure, pulse, oxygen saturation and end tidal CO<sub>2</sub> should be monitored because of the possibility of occurrence of air or gas embolism.

## **ADVERSE REACTIONS**

### **Post Marketing**

- Air embolism associated with misapplication of fibrin sealant using the spray device, Class Effect: A post marketing fatality was reported in association with the use of another fibrin sealant when applied using a spray device. The case involved an attempt to stop active bleeding by applying the fibrin sealant using a spray device attached to a wall unit at a higher than recommended pressure for the spray device. In addition, the spray head was placed at a distance from the bleeding site that was closer than the recommended distance guidelines for the application of the sealant. The patient suffered a fatal air embolism.

Read the complete summary of MedWatch safety labeling changes at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm212129.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.