

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: FDA Communication: Update on Serious Complications Associated with Negative Wound Pressure Therapy Systems

SOURCE: FDA MedWatch

AUDIENCE: Health Care Providers, Patients, Caregivers

ISSUE: On Nov. 13, 2009, the FDA issued a [Preliminary Public Health Notification](#) and [Advice for Patients](#) on serious complications, especially bleeding and infection, from the use of NPWT systems. Although rare, these complications can occur wherever NPWT systems are used, including hospitals, long-term health care facilities, and at home. The FDA has issued an update with information about its activities to date involving NPWT, as well as to provide new recommendations and information about pediatric use.

RECOMMENDATIONS FOR HEALTH CARE PROVIDERS:

- Select patients for NPWT carefully, after reviewing the most recent device labeling and instructions. Know that:
 - NPWT systems are contraindicated for certain [wound types](#) (Table 1), and
 - Patient [risk factors](#) (Table 2) must be thoroughly considered before use.
- Assure that the patient is monitored frequently in an appropriate care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient's condition, including the wound status, wound location and co-morbidities. Ensure consistent wound care management by following the patient's care plan.
- **Be vigilant for potentially life-threatening complications, such as bleeding, and be prepared to take prompt action if they occur.**
- Be aware of complications associated with dressing changes such as infection and bleeding, which can be associated with retained dressing pieces, adherence of new tissue to retained dressing pieces, or removal of tissue during dressing changes.
- To help minimize the risk of retained dressing pieces:
 - Keep track of the number of dressing pieces placed in the wound.
 - Do not cut the dressing directly over the wound in order to avoid dressing fragments or debris falling into the wound area while cutting.
- Obtain appropriate training about prescribing, using and discontinuing NPWT.
- Resume NPWT as soon as possible after transitioning a patient to the home or another care facility so the wound stays moist.
- If the patient is determined a proper candidate for using the NPWT system at home:

- Instruct the patient and/or caregiver about how to use the system, potential complications and their signs/symptoms, and what to do if complications occur.
- Request that the patient and/or caregiver demonstrate use of the system (such as familiarity with safety alarms), and document his/her proficiency.
- Assure that the patient and/or caregiver understands the warnings associated with NPWT system use.
- Provide the patient with a printed copy of the patient labeling from the NPWT system manufacturer, if available. Encourage the patient to keep these materials and instructions for use readily accessible.

Additional information including a summary of the problem/scope, FDA activities relative to the NPWT safety issues, and recommendations for patients and caregivers is available at:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm244211.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.