MEDWATCH **The FDA Safety Information and Adverse Event Reporting Program**

Audience: Acute and long-term healthcare facilities staff, consumers

[Posted 11/16/2009] FDA notified healthcare professionals of a Preliminary Public Health Notification describing deaths and serious complications associated with the use of Negative Pressure Wound Therapy (NPWT) systems. FDA has received reports of six deaths and 77 injuries associated with NPWT systems over the past two years.

NPWT systems are generally indicated for the management of wounds, burns, ulcers, flaps and grafts. They apply negative pressure to the wound in order to remove fluids, including wound exudates, irrigation fluids, and infectious materials. Healthcare professionals were advised to select patients for NPWT carefully, after reviewing the most recent device labeling and instructions. Patients should be monitored frequently in an appropriate care setting by a trained practitioner, and practitioners should be vigilant for potentially life-threatening complications, such as bleeding, and be prepared to take prompt action if they occur.

Read the MedWatch safety summary, including links to the FDA Preliminary Public Health Notification and FDA Advice to Patients, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm190704.htm