

# **FDA Preliminary Public Health Notification\***

## **Serious Complications Associated with Negative Pressure Wound Therapy Systems**

**Date: November 13, 2009**

Dear Healthcare Practitioner:

This is to alert you to deaths and serious complications, especially bleeding and infection, associated with the use of Negative Pressure Wound Therapy (NPWT) systems, and to provide recommendations to reduce the risk. Although rare, these complications can occur wherever NPWT systems are used, including acute and long-term healthcare facilities and at home. FDA has received reports of six deaths and 77 injuries associated with NPWT systems over the past two years.

### **Recommendations**

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.

**Be vigilant for potentially life-threatening complications, such as bleeding, and be prepared to take prompt action if they occur.**

Obtain appropriate training prior to prescribing and using NPWT.

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, 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 written 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.

In addition, an [Advice for Patients](#) can be found on the FDA Consumer website.

### **Background on NPWT**

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. They are contraindicated in the presence of exposed anastomotic sites, exposed vasculature, exposed nerves, exposed organs, necrotic tissue with eschar present, untreated osteomyelitis, non-enteric and unexplored fistulas, and malignancy in the wound.

NPWT systems consist of the following components: an apparatus that generates vacuum and is capable of creating a negative pressure environment within a sealed wound; dressing materials used to pack the wound and seal it; a conduit for fluid removal from the wound bed; and a container/canister to collect waste materials that are removed from the wound bed via suction.

### **Reports received by FDA**

In the last two years, FDA received six death and 77 injury reports associated with NPWT systems. Most of the deaths reported to FDA occurred **at home or in a long-term care facility**. Bleeding was the most serious complication and was reported in six death and 17 injury reports. Extensive bleeding occurred in patients with vascular grafts (such as femoral and femoral-popliteal grafts), in sternal and groin wounds, in patients receiving anti-coagulant therapy, and during removal of dressings that adhered to or were imbedded in the tissues. Patients with bleeding required emergency room visits and/or hospitalization and were treated with surgical procedures and blood transfusions.

Twenty-seven reports indicated infection from original open infected wounds or from retention of dressing pieces in the wound. Retention of foam dressing pieces and foam adhering to tissues or imbedded in the wound were noted in 32 injury reports. The majority of these patients required surgical procedures for removal of the retained pieces, wound debridement, and treatment of wound dehiscence, as well as additional hospitalization and antibiotic therapy.

FDA will continue to monitor adverse events associated with these products, and will make available any new information that might affect their use.

### **Reporting adverse events**

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect a reportable adverse event associated with a NPWT system, you should follow the reporting procedure established by your facility. Prompt reporting of adverse events can help FDA to understand and communicate the risks associated with devices, and can help identify potential future problems with these products.

We also encourage you to report any medical device adverse events related to a NPWT system that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer or to MedWatch, the FDA's voluntary reporting program. This can be done online at <http://www.fda.gov/medwatch/report.htm>, by phone at 1-800-FDA-1088, by FAX at 1-800-FDA-0178; or by mailing FDA form 3500 (download from [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)) to MedWatch, 5600 Fishers Lane, Rockville, MD 20857-9787.

### **Getting more information**

If you have questions about this Notification, please contact FDA's Office of Surveillance and Biometrics by e-mail at [phann@fda.hhs.gov](mailto:phann@fda.hhs.gov) or by phone at 301-796-6640.

FDA Medical Device Public Health Notifications are available on the Internet. [\[\[LINK\]\]](#) You can also be notified through email each time a new Public Health Notification is added to our web page. To subscribe, visit: [http://service.govdelivery.com/service/subscribe.html?code=USFDA\\_39](http://service.govdelivery.com/service/subscribe.html?code=USFDA_39).

Sincerely yours,

Jeffrey E. Shuren, MD, JD  
Acting Director  
Center for Devices and Radiological Health  
Food and Drug Administration

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\*CDRH Preliminary Public Health Notifications are intended to quickly share device-related safety information with healthcare providers when the available information and our understanding of an issue are still evolving. We will revise them as new information merits and so encourage you to check this site for updates.

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**Table 1: NPWT is contraindicated for these wound types/conditions:**

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| <ul style="list-style-type: none"><li>• necrotic tissue with eschar present</li><li>• untreated osteomyelitis</li><li>• non-enteric and unexplored fistulas</li><li>• malignancy in the wound</li><li>• exposed vasculature</li><li>• exposed nerves</li><li>• exposed anastomotic site</li><li>• exposed organs</li></ul> |
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**Table 2: Patient risk factors/characteristics to consider before NPWT use:**

- patients at high risk for bleeding and hemorrhage
- patients on anticoagulants or platelet aggregation inhibitors
- patients with:
  - friable vessels and infected blood vessels
  - vascular anastomosis
  - infected wounds
  - osteomyelitis
  - exposed organs, vessels, nerves, tendon, and ligaments
  - sharp edges in the wound (i.e. bone fragments)
  - spinal cord injury (stimulation of sympathetic nervous system)
  - enteric fistulas
- patients requiring:
  - MRI
  - Hyperbaric chamber
  - Defibrillation
- patient size and weight
- use near vagus nerve (bradycardia)
- circumferential dressing application
- mode of therapy- intermittent versus continuous negative pressure