

FDA Advice for Patients: Serious Complications with Negative Pressure Wound Therapy Devices

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Negative pressure wound therapy (NPWT) patients and/or their caregivers

Background

NPWT helps various types of open wounds heal by creating a negative pressure (vacuum) at a well-sealed wound site. The vacuum helps remove fluids and infectious materials and draw wound edges together.

Patient concerns

The use of NPWT devices has helped healing and closure of wounds in many patients. Although rare, serious complications, especially bleeding and infection, have been reported in some patients using the devices. FDA has received six death and 77 injury reports associated with NPWT devices over the past two years. Bleeding was the most serious complication, occurring in all six deaths and in 17 of the injuries. These complications can occur in hospitals, long-term care facilities, and at home. FDA wants to alert you to the possibility of complications and provide recommendations to reduce your risk.

Recommendations for patients using NPWT

If your doctor has determined that you are a good candidate for using NPWT at home, you should:

- Receive adequate training from your doctor, nurse, or home healthcare provider so that you understand how to use your NPWT device. Demonstrate to your trainer how to use NPWT to make sure you are doing it properly.
- Understand the possible complications that may be associated with using your NPWT device. Watch especially for bleeding, which can be life-threatening. If you see signs of bleeding, seek medical assistance immediately.
- Get NPWT patient instructions (labeling) from your doctor, home healthcare provider, NPWT distributor, or the manufacturer's website. Keep these instructions where you can easily find them.
- Talk to your doctor if you do not feel capable of managing the NPWT device at home. He or she might recommend that you have help from an appropriate caregiver.

Reports received by FDA

In the past two years, FDA received six death and 77 injury reports associated with NPWT devices. Most deaths occurred at home or in a long-term care facility. Bleeding was the most serious complication, with reports of bleeding associated with six deaths and 17 injuries. Extensive bleeding occurred in patients with blood vessel grafts in the leg, breastbone and groin

wounds, those receiving medication for blood clots, and during removal of dressings attached to the tissues. Patients with bleeding required emergency room visits and/or hospitalization and were treated with surgery and blood transfusions.

Of the 83 reports to FDA, 27 reports indicated worsening infection from original open infected wounds or from pieces of dressing that remained in the wound, and 32 reports noted injury from foam dressing pieces and foam sticking to tissues or clinging to the wound. Most of these patients required surgery, additional hospitalization, and antibiotics.

FDA is addressing these problems with NPWT devices and will continue monitoring adverse events associated with these products.

Questions to ask your healthcare provider

Before using NPWT at home, consider asking the following questions:

- Am I using the NPWT device correctly?
- How long should I expect to use the NPWT device?
- What serious complications might occur in my situation?
- What should I do if any of those complications occur?
 - Whom do I contact?
 - How do I recognize bleeding?
 - How do I recognize serious infection?
 - How do I recognize if my wound condition is worsening?
- Do I need to stop taking aspirin or any other medicines that affect my bleeding system or platelet function? What's the risk associated with stopping or avoiding such medicines?
- Can you provide me with patient instructions or tell me where I can find them?

Reporting adverse reactions

Consumers may report adverse reactions related to negative pressure wound therapy to FDA's MedWatch Adverse Event Reporting Program online, by phone, FAX or mail.

- Online: MedWatch: [The FDA Safety Information and Adverse Event Reporting Program](#)
- Phone: 1-800-332-1088
- FAX: 1-800-FDA-0178
- Mail: use [postage-paid FDA form 3500](#) mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

For more information

See FDA's [Preliminary Public Health Notification: Serious Complications Associated with Negative Pressure Wound Therapy Systems](#).