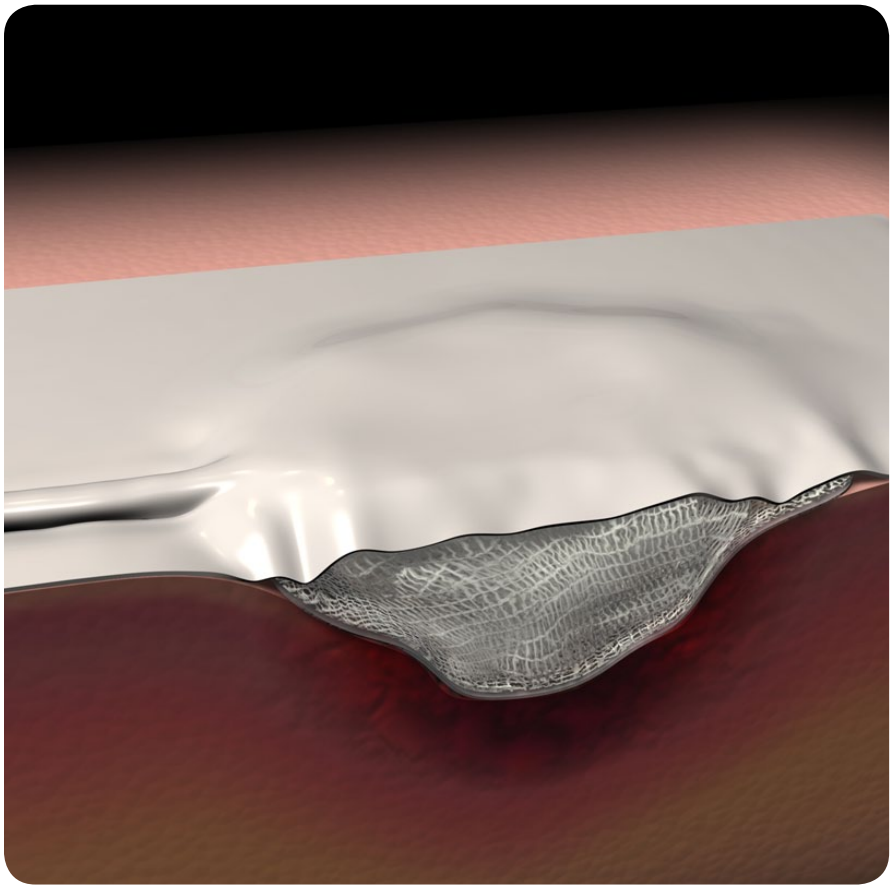
Negative Pressure Wound Devices Draw FDA Notice, Advice

The Food and Drug Administration (FDA) has notified health professionals, and advised patients, about rare but serious complications—including deaths—from the use of negative pressure wound therapy (NPWT).

Negative pressure wound therapy devices can help in the healing and closure of wounds. They create negative pressure (a vacuum) at well-sealed wound sites that can help remove fluids and infectious materials and draws wound edges together.

FDA issued a notification to health professionals and advice for patients regarding the complications with NPWT on Nov. 13, 2009.

In the notifications, the agency alerted the public and health professionals that serious complications, especially bleeding and infection, have been reported in some patients using NPWT devices. These complications can occur wherever NPWT is used, including hospitals, long-term care facilities, and at home.



Phototake

This illustration shows a sealed wound that has been prepared to undergo negative pressure wound therapy (NPWT). The tubing seen to the left is set to be connected to a vacuum device to apply negative pressure.

Most deaths occurred at home or in long-term care facilities. Bleeding was the most serious complication, occurring in all six deaths and in 17 of the injuries.

Reports of Injuries, Deaths

Over the past two years, FDA has received six death and 77 injury reports associated with NPWT devices. Most deaths occurred at home or in long-term care facilities. Bleeding was the most serious complication, occurring in all six deaths and in 17 of the injuries.

According to these reports, extensive bleeding has occurred in patients

- with blood vessel grafts in the leg
- with breastbone or groin wounds
- receiving medication for blood clots
- during removal of dressings attached to the tissues

The reports also included cases of infections from original open infected wounds worsening due to pieces of dressing that remained in the wound, and of injury from foam dressing pieces and foam sticking to tissues or clinging to wounds. Most of these patients required surgery, additional hospitalization, and antibiotics.

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

FDA Recommendations

The reports of the adverse events led FDA to issue recommendations for patients using negative pressure wound therapy. If it is determined that you are a candidate for using NPWT at home, you should do the following:

- Receive adequate training from a health professional (for example, your doctor, a nurse, or a home health care provider) so that you understand how to use your NPWT device. Demonstrate to your trainer that you know how to use the device properly.
- Find out how long you should expect to use the device.
- Understand the possible complications that may be associated with using the device. Know the warning signs so you can recognize complications early. Watch especially for bleeding, which can be life-threatening. If you see signs of bleeding, seek medical assistance immediately.
- Before using NPWT at home, ask your health professional what to do if complications do occur. Find out
  - who to contact
  - how to recognize bleeding and serious infection
  - how to recognize if your wound condition is worsening.
- Get NPWT patient instructions (labeling) from your doctor, home health care provider, NPWT distributor, or the manufacturer's Web site. Keep these instructions where you can easily find them.
- Let your health professional know if you do not feel capable of managing the NPWT device at home. He or she might recommend that you be assisted by an appropriate caregiver.
- Ask your health professional whether you need to stop taking aspirin or any other medications that affect bleeding or blood clotting, and what the associated risk is of stopping or avoiding such medicines.

Health professionals and consumers may report adverse reactions related to negative pressure wound therapy to FDA's MedWatch Adverse Event Reporting program online, by regular mail, fax or phone.

- Online at *www.accessdata.fda.gov/scripts/medwatch/*
- Regular Mail: Use FDA postage paid form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 800-FDA-0178
- Phone: 800-FDA-1088

This article appears on FDA's Consumer Updates page (*www.fda.gov/ForConsumers/ConsumerUpdates*), which features the latest on all FDA-regulated products.

For More Information

Advice for Patients: Serious Complications with Negative Pressure Wound Therapy Devices
www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm190476.htm

FDA Preliminary Public Health Notification: Serious Complications Associated with Negative Pressure Wound Therapy Systems
www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm190658.htm