



## This is an official **DHEC Health Alert**

Distributed via Health Alert Network  
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### **Simulated IV Saline Solution Resulting in Adverse Events**

#### **Summary**

The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are investigating instances of the administration of simulated intravenous (IV) saline to patients. At least 40 patients in several states received infusions of Wallcur simulated IV saline solution, Practi-0.9% sodium chloride solution. The simulated IV saline solution is intended for training purposes only; it is not sterile and should not be injected in humans or animals. Most medical facilities involved in the investigation reported that they were unaware they were simulation products. Reported adverse events among patients receiving infusions include fever, chills, tremors, and headache. Multiple patients were hospitalized and there is one death associated with the use of these products, though it is not known if this death is directly related to the use of the product. Wallcur has initiated a voluntary recall. DHEC is sending this alert in case the product was sent to providers who have not yet been notified.

FDA, in partnership with CDC, has collected samples of Wallcur Practi 0.9% Sodium Chloride from clinics and distributors for testing to determine if the product may have caused the reported adverse events. FDA is working to determine how the products entered the supply chain and subsequently were administered to patients.

DHEC was notified of two outpatient facilities in South Carolina that received the product after ordering IV normal saline through their usual ordering mechanism. The product was sent without notice that it was not intended for administration to patients. Neither facility had administered the product to patients.

Clinicians and office staff should ensure IV solution simulation products are removed from any inventory of IV normal saline intended for clinical use to eliminate the possible infusion of simulated products into patients.

- Inspect all IV saline solution bags for any of the following labels: "Wallcur," "Practi-products," "For clinical simulation," or "Not for use in human or animal patients."
- If you either confirm or suspect you may have received products with these labels, separate the simulation products from any inventory intended for clinical use and contact your distributor for directions on how to return the products.
- If you have received Wallcur Practi-products in error, contact the distributor, or Wallcur, LLC of San Diego for return instructions.
- Assure office procedures are in place to include inspection of all future shipments of normal saline products to ensure they are for clinical use.

If you suspect that any Wallcur training IV products may have been administered to a patient, whether or not the incident has resulted in an adverse event:

- Evaluate all potentially exposed patients with new, or ongoing symptoms;
- Use appropriate treatment;
- Report suspected cases to your Regional Public Health Office as outlined below; and

- Report any adverse events following use of these products to FDA's MedWatch program online or at 1-800-332-1088.

FDA has been working with manufacturers to increase Sodium Chloride 0.9% Injection (IV normal saline) supply including the temporary distribution of additional IV normal saline from alternate sources Fresenius Kabi USA, Baxter Healthcare Corp., and B. Braun Medical Inc. See the FDA website for the available supply from manufacturers.

**Resources for Additional Information**

<http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm>

**DHEC contact information for reportable diseases and reporting requirements**

Reporting of **outbreaks or unusual disease** is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2015 List of Reportable Conditions available at:

<http://www.scdhec.gov/Library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

<b>Regional Public Health Offices – 2015</b>			
Mail or call reports to the Epidemiology Office in each Public Health Region			
<b>MAIL TO:</b>			
<b>Lowcountry</b> 4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051	<b>Midlands</b> 2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993	<b>Pee Dee</b> 145 E. Cheves Street Florence, SC 29506 Fax: (843) 661-4859	<b>Upstate</b> 200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373
<b>CALL TO:</b>			
<b>Lowcountry</b> <b>Berkeley, Charleston, Dorchester</b> Phone: (843) 953-0043 Nights/Weekends: (843) 441-1091  <b>Beaufort, Colleton, Hampton, Jasper</b> Phone: (843) 322-2453 Nights/Weekends: (843) 441-1091  <b>Allendale, Bamberg, Calhoun, Orangeburg</b> Phone: (803) 943-3878 Nights/Weekends: (843) 441-1091	<b>Midlands</b> <b>Kershaw, Lexington, Newberry, Richland</b> Phone: (803) 576-2749 Nights/Weekends: (888) 801-1046  <b>Chester, Fairfield, Lancaster, York</b> Phone: (803) 286-9948 Nights/Weekends: (888) 801-1046  <b>Aiken, Barnwell, Edgefield, Saluda</b> Phone: (803) 642-1618 Nights/Weekends: (888) 801-1046	<b>Pee Dee</b> <b>Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion</b> Phone: (843) 661-4830 Nights/Weekends: (888) 847-0902  <b>Clarendon, Lee, Sumter</b> Phone: (803) 773-5511 Nights/Weekends: (888) 847-0902  <b>Georgetown, Horry, Williamsburg</b> Phone: (843) 915-8804 Nights/Weekends: (888) 847-0902	<b>Upstate</b> <b>Anderson, Oconee</b> Phone: (864) 260-5801 Nights/Weekends: (866) 298-4442  <b>Abbeville, Greenwood, Laurens, McCormick</b> Phone: (864) 227-5947 Nights/Weekends: (866) 298-4442  <b>Cherokee, Greenville, Pickens, Spartanburg, Union</b> Phone: (864) 372-3133 Nights/Weekends: (866) 298-4442
<b>For information on reportable conditions, see</b> <a href="http://www.scdhec.gov/Health/FHPE/ReportDiseasesAdverseEvents/ReportableConditionsInSC/">http://www.scdhec.gov/Health/FHPE/ReportDiseasesAdverseEvents/ReportableConditionsInSC/</a>		<b>DHEC Bureau of Disease Control</b> <b>Division of Acute Disease Epidemiology</b> 2100 Bull St • Columbia, SC 29201 Phone: (803) 898-0861 • Fax: (803) 898-0897 Nights / Weekends: 1-888-847-0902	

Categories of Health Alert messages:

- Health Alert** Conveys the highest level of importance; warrants immediate action or attention.
- Health Advisory** Provides important information for a specific incident or situation; may not require immediate action.
- Health Update** Provides updated information regarding an incident or situation; unlikely to require immediate action.
- Info Service** Provides general information that is not necessarily considered to be of an emergent nature.