ICU Medical, Inc. is voluntarily recalling one single lot of Lactated Ringer's Injection, USP, and one single lot of 0.9% Sodium Chloride Injection, USP. The products are being recalled to the hospital level due to the presence of particulate matter.

Administration of a drug product that contains particulate matter could result in adverse events ranging from inflammation at the site of injection to more serious events that could include the formation of a blood clot obstructing the flow of blood which could lead to end-organ damage or death. To date, ICU Medical, Inc. has not received reports of adverse events related to this recall.

The Lactated Ringer's Injection, USP and 0.9% Sodium Chloride Injection are indicated for parenteral replacement of extracellular losses of fluid and electrolytes, with or without minimal carbohydrate calories, as required by the clinical condition of the patient. Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient. Product was distributed nationwide both by ICU Medical direct to customers and through medical distributors.

The affected product lots, manufactured in the U.S. for ICU Medical by Hospira, a Pfizer company in late 2017 and early 2018, are listed below:

NDC Number	Product Description	Lot Number*	Expiration Date	Configuration	Manufacture Date	Distribution Dates
0409-7953-03	Lactated Ringer's Injection, USP	84-603-FW	01-Dec-2019	500 mL Flexible Container	December 2017	February 2018 – June 2018
0409-7983-25	0.9% Sodium Chloride Injection, USP	95-101-C6	01-May-2020	250 mL VisIVTM Container	November 2018	December 2018 – March 2019

ICU Medical is notifying its distributors and customers of this recall by letter and is arranging for the return of all recalled products. Hospitals/distributors that have product that is being recalled should stop use/further distribution and return to place of purchase.

Customers with questions regarding this recall can call ICU Medical at 1-844-6547780 Monday through Friday between the hours of 8 a.m. and 5 p.m. Central time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

1. Complete and submit the report Online
2. Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information
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