ICU Medical Issues a Voluntary Nationwide Recall of One Lot of 0.9% Sodium Chloride Injection Due to the Presence of Particulate Matter

July 28, 2017

LAKE FOREST, Ill., July 28, 2017 /PRNewswire/ -- ICU Medical, Inc. is voluntarily recalling one lot of 0.9% Sodium Chloride Injection, USP 1000 mL to the hospital/user level due to a confirmed customer complaint of particulate matter identified as stainless steel within a single flexible container.

Injection of particulate matter could potentially lead to limited adverse events such as allergic reactions, local irritation and inflammation in organs or tissues, or other serious adverse health consequences. Prior to administration, healthcare professionals, as instructed in the product labeling, should visually examine the product for particulate matter and discoloration and should discard if a defect is identified. The reported incident was identified prior to use, and there have been no reports of adverse events associated with this issue to date.

0.9% Sodium Chloride Injection, USP 1000 mL is an intravenous solution indicated for parenteral replenishment of fluid. The affected product lot was manufactured in the U.S. by Hospira, a Pfizer company, on February 1, 2016 and was distributed nationwide to Hospira customers between April 14, 2016 and February 2, 2017. The affected lot is:

NDC Number	Lot Number	Expiration Date	Configuration/Count
0409-7983-09	61-841-FW	January 01, 2018	1000mL Single Dose Flexible Container

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 1-800-441-4100 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.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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.

About ICU Medical, Inc.

ICU Medical, Inc. (Nasdaq: ICUI) is one of the world's leading pure-play infusion therapy companies with global operations and a wide-ranging product portfolio that includes IV solutions, IV smart pumps, dedicated and non-dedicated IV sets and needlefree connectors, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals. In addition, the company manufactures automated pharmacy IV compounding systems with workflow technology, closed systems transfer devices for hazardous IV drugs, and cardiac monitoring systems to optimize patient fluid levels. ICU Medical is headquartered in San Clemente, California. On February 3, 2017, ICU Medical completed the acquisition of the Hospira Infusion Systems business from Pfizer. More information about ICU Medical, Inc. can be found at www.icumed.com.

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