ICU Medical Issues a Voluntary Nationwide Recall of Aminosyn II 15%, An Amino Acid Injection, Sulfite Free IV Solution Due to the Presence of Particulate Matter

ICU Medical Inc. is voluntarily recalling one lot (2,112 units) of Aminosyn II, 15%, An Amino Acid Injection, Sulfite Free intravenous (IV) solution to the hospital/user level due to the presence of visible particulate matter identified as fibers, hair, and proteinaceous material along with other particles. ICU Medical became aware of this issue while inspecting retain samples as part of routine process.

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 or illness related to this recall.

Aminosyn II, Sulfite-Free, (an amino acid injection) infused with dextrose by peripheral vein infusion is indicated as a source of nitrogen in the nutritional support of patients with adequate stores of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated, is undesirable, or inadequate. Aminosyn II can be administered peripherally with dilute (5 to 10%) dextrose solution and I.V. fat emulsion as a source of nutritional support. This form of nutritional support can help to preserve protein and reduce the breakdown of organic or inorganic materials, such as proteins, sugars, fatty acids, etc. in stress conditions where oral intake is inadequate. Aminosyn II is also indicated for central vein infusion to prevent or reverse excreting more nitrogen than is being taken in in patients where the intestinal tract, by the oral, surgical opening into the stomach for the introduction of food or surgical procedure for a feeding tube routes cannot or should not be used and gastrointestinal absorption of protein is impaired. Product was distributed nationwide both by ICU Medical direct to customers and through medical distributors. The product is for human use only.

ICU Medical acquired this product from Hospira, a Pfizer company; therefore, the affected product contains a Hospira NDC number and a Hospira label. The affected product lot, manufactured in the U.S. by ICU Medical in November 2020, is listed below:

NDC Number / Catalog Number	**Product Description**	**Lot Number**	**Expiration Date**	**Configuration**	**Manufacture Date**	**Distribution Dates**
NDC: 0409-7171-17 Catalog Number: 07171-17	Aminosyn® II 15% An Amino Acid Injection, Sulfite-Free	4989094	01-Apr-2022	Pharmacy Bulk Package 2-liter Flexible Container	November 2020	January 2021 – March 2021

ICU Medical is notifying its distributors and customers of this recall by letter and is arranging for the return of all recalled products.

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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 1-844-654-7780 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
- 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.

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