ICU Medical – Recall of Aminosyn® II injection

- On September 7, 2021, ICU Medical announced a voluntary, user level recall of one lot of Aminosyn II (an amino acid injection, sulfite-free) 15% because of 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.

- ICU Medical acquired this product from Hospira, a Pfizer company; therefore, the affected product contains a Hospira NDC number and a Hospira label. It was distributed nationwide by ICU Medical from January 2021 through March 2021:

Product Description	NDC #	Lot# (Expiration Date)
Aminosyn II 15% (an amino acid injection, sulfite-free) 2-liter flexible container	0409-7171-17	4989094 (4/1/2022)

- Aminosyn II 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 is also indicated for central vein infusion to prevent or reverse negative nitrogen balance in patients where the alimentary tract, by the oral, gastrostomy or jejunostomy route cannot or should not be used and gastrointestinal absorption of protein is impaired.

- 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 has not received reports of any adverse events or identifiable safety concerns attributed to the recalled lot.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled Aminosyn II injection.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

- Contact ICU Medical at **1-844-654-7780** for further information regarding this recall.