ICU Medical – Recall of 0.9% sodium chloride injection

- On July 28, 2017, the FDA announced a hospital/user-level recall of one lot of 0.9% sodium chloride injection due to a confirmed customer complaint of particulate matter identified as stainless steel within a single flexible container.

- The affected product lot was manufactured by Hospira, a Pfizer company, and distributed nationwide between April 14, 2016 and February 2, 2017.

Product Description	NDC #	Lot # (expiration date)
0.9% sodium chloride injection, 1000 mL single dose flexible container	0409-7983-09	61-841-FW (1/1/2018)

- Intravenous solutions containing sodium chloride are indicated for parenteral replenishment of fluid and sodium chloride as required by the clinical condition of the patient.

- 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.

- Anyone with an existing inventory of the recalled lots should stop use and distribution, and return all recalled product.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

- For questions about this recall, please contact ICU Medical at **1-800-441-4100**.