

Human hair leads Hospira to recall IV solution

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Singapore: Biopharmaceutical manufacturer Hospira has initiated a voluntary recall of one lot of Aminosyn, an amino acid solution administered intravenously (IV), after a customer reported finding an "unknown foreign particle" in the injection port of the product.

Hospira has highlighted that the unknown foreign particle was human hair. The firm said in a statement that it did not receive any reports of adverse events associated with the contamination, and that a root cause investigation is underway.

Hospira also added that the potential for the hair to physically affect a patient would be "minimal". The firm said that a 0.22 micron air eliminating filter should be used in the administration of the product.

The company said, "In the event that the particulate was not observed, the particulate identified theoretically would not be able to pass through the intravenous catheter or an intravenous infusion. It is also unlikely that the particulate could block the infusion of solution into the patient."

The recall comes just months after Hospira announced that FDA inspectors had found its Irungattukottai, India manufacturing facility to have "significant violations" of current good manufacturing practices, resulting in a warning letter being sent to it on May 28, 2013.