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Baxter recalls dialysis solution

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Singapore: Baxter is voluntarily initiating a recall of two lots of DIANEAL Low Calcium Peritoneal Dialysis Solution with 2.5 percent Dextrose 5000mL (Ambu-Flex II) to the hospital/user level due to the presence of oxidized stainless steel, garment fiber, and PVC particulate matter identified during the manufacturing process.

Company informed that no adverse events or related product complaints have been associated with the recalled products, which were distributed to dialysis centers, facilities, distributors, and patients in United States.

Intraperitoneal administration of a product with particulate matter may cause local inflammation with foreign body reaction or result in adhesion formation. The particulate matter could potentially serve as a focal point for infection should any pre-existing peritonitis exist, and may lead to a fatal outcome.

DIANEAL is a peritoneal dialysis (PD) solution for use in chronic renal failure patients being maintained on peritoneal dialysis therapy. PD therapy is performed by using the body's peritoneal membrane as a filter, while special solution and osmotic pressure help remove extra fluids and clean the blood. This process takes the place of what healthy kidneys do for the body.