California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Fresenius Kabi USA, LLC Recalls IVENIX INFUSION SYSTEM LVP Blood Products Administration Set

Recall Date	Product Description	Recalling Firm	Recall Reason
6/6/25	IVENIX INFUSION SYSTEM LVP Blood Products Administration Set, Dual-Inlet, Low-Sorbing, Y-Site, Mesh Filter, 15 mL. Intravascular Administration Set.	Fresenius Kabi USA, LLC	Mis-assembly error of Blood Products Administrations Sets where the 200-micron drip chamber filter may be incorrectly positioned and unable to filter out large blood particulates.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model No. SET-0014-20; UDI 20811505030034; Lot No. FA24K05015.	14,280 Units Nationwide	May 2025 and prior.

For additional information, please visit the FDA Website.