



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Fresenius Medical Care Holdings Recalls 10 mL Syringe Luer Lock Needle for Potential Blood Backfill Leakage and Foreign Material

Recall Date	Product Description	Recalling Firm	Recall Reason
10/18/2023	10ml Syringe Luer Lock W/Out Needle Part Number 15-R010-0, 100 per box, 12 boxes to a case	FRESENIUS MEDICAL CARE HOLDINGS, INC. Waltham, Massachusetts	There is a potential for blood backfill leakage and foreign material.
10/18/2023	10ml Syringe Luer Lock W/Needle Part Number 15-10ML-0, 100 per box, 12 boxes per case	FRESENIUS MEDICAL CARE HOLDINGS, INC. Waltham, Massachusetts	There is a potential for blood backfill leakage and foreign material.

Recall Class	Product Identification	Distribution	Affected Dates
I	10ml Syringe Luer Lock W/Out Needle UDI-DI: 16945060501122; All Lots	124773 Units Nationwide	8 August 2023 and prior
I	10ml Syringe Luer Lock W/Needle UDI-DI: 16945060500125; All Lots	124773 Units Nationwide	8 August 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)

