



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Fresenius Medical Care Holdings Recalls 3 ML Syringe Luer Lock With Needle For Potential For Blood Backfill Leakage And Foreign Material**

Recall Date	Product Description	Recalling Firm	Recall Reason
10/18/2023	<b>3ML Syringe Luer Lock With Needle 20GX1</b> Part Number 15-03ML-0, 100 per box, 24 boxes per case	<b>FRESENIUS MEDICAL CARE HOLDINGS, INC.</b> Waltham, Massachusetts	There is a potential for blood backfill leakage and foreign material.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>3ML Syringe Luer Lock With Needle 20GX1</b> UDI-DI: 16945060500101; All Lots	124773 Units Nationwide	8 August 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

