



November 16, 2023

Statement from Fresenius Medical Care Regarding Voluntary Recall of Sanxin Single Use Sterile Syringes

Fresenius Medical Care's top priority is to always provide safe, high-quality and life-sustaining acute and chronic dialysis therapy.

Fresenius Medical Care serves as the importer of Sanxin Syringes, manufactured by Jiangxi Sanxin Medtec Co. LTD. After learning of product complaints, Fresenius Medical Care made the decision to remove all lots of the affected part numbers from the marketplace. On August 8, 2023, the company sent a product recall notification to 1,699 customers in the United States with the information that the company is initiating a voluntary removal of all lots from three (3) part numbers of Sanxin Single Use Sterile Syringes, due to the potential for blood backfill leakage and foreign material.

The voluntary Sanxin Syringe recall classified and published by the Food and Drug Administration (FDA) applies to the following affected part numbers:

- 15-R010-0 – 10ML SYRINGE LUER LOCK W/OUT NEEDLE
- 15-10ML-0 – 10ML SYRINGE LUER LOCK W/NEEDLE
- 15-03ML-0 – 3ML Syringe Luer Lock with Needle 20GX1

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