

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Merit Medical Systems Inc. Recalls PC (Pericardiocentesis Tray - Fluid Drainage Tray)

Recall Date	Product Description	Recalling Firm	Recall Reason
08/21/2024	<p>Various Merit Medical convenience kits that contain recalled Jiangsu Shenli Medical Production Co. Ltd. syringes.</p> <p>The Pericardiocentesis Kit is intended to withdraw fluid from the pericardial sac (membrane surrounding the heart) to evaluate the fluid for diagnostic purposes or to remove excess fluid causing compression of the heart.</p>	Merit Medical Systems Inc. South Jordan, UT	Medical convenience kits contain plastic syringes affected by the FDA Safety Alert issued on March 19, 2024. Leaks, breakage, and/ other quality issues have been identified that may pose a risk to patient health.

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog Number/UDI-DI: PC101/B/00884450015278, PC201/B/00884450015285, PC801/00884450054017, PC801/A/00884450727911, PC802/00884450052297, PC802/A/00884450727928	7394 units in California	August 2024 and prior.

For additional information, please visit the [FDA Website](https://www.fda.gov).