California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medline Industries, LP – Northfield Recalls Medline General Surgery Tray

Recall Date	Product Description	Recalling Firm	Recall Reason
8/27/25	The Medline General Surgery Tray is customized to meet requirements of the hospitals and health care professionals utilizing them. The kit is provided sterile, single-use and includes a range of components dependent upon the specific procedure. These kits will be assembled using Medline and other manufacturer\x19s medical device components and drug components in some cases. Customers specify the kit contents, quantity, and placement of individual items in the kit.	MEDLINE INDUSTRIES, LP - Northfield	Affected kits contain recalled Stryker Color Cuff Sterile Disposable Tourniquet Cuffs. Stryker Instruments initiated this recall due to a potential manufacturing defect in which the flange may detach from the bladder at the welded connection point. This detachment compromises the cuff's ability to maintain adequate air pressure, potentially resulting in tourniquet failure and increased risk of patient hemorrhaging.

Recall Class	Product Identification	Distribution	Affected Dates
II	1. SKU DYNJ69405B UDI 10198459281655 (ea) 40198459281656 (case) Kit lots: 25DMG402 25FMB391	403 Units in California 1. UDI: 10198459281655 144 units	July 2025

	2. SKU DYNJ89705 UDI 10198459282133 (ea) 40198459282134 (case) Kit lot: 25CMH791; 3. SKU DYNJ9682800V UDI 10195327257248 (ea) 40195327257249 (case) Kit lots: 24EDA813 24FDA466 24GDA325 24IDB396 24JDB676	2. UDI: 10198459282133 55 units 3. UDI: 10195327257248 204 units	

For additional information, please visit the FDA Website.