State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Velano Vascular recalls PIVO Blood Collection Device for Incomplete sealing causing Breach in Sterile Barrier

Recall Date	Product Description	Recalling Firm	Recall Reason
11/10/2021	**PIVO Blood Collection Device 20G** REF: 202-0005	**Velano Vascular** San Francisco, California	Incomplete sealing of blood collection device unit packages may produce a breach in the sterile barrier enclosing the product. This could lead to microbial contamination of the device prior to use. The health effects range from no clinical effect up to bloodstream infection.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI: 00850984007027. Lots: 070621-02, 062221-01, 061021-02, 052721-03, 051421-02	2600 Units within California	November 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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