State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Biosense Webster, Inc. Recalls Carto Vizigo Bi-Directional Guiding Sheath For Manufacturing Issue Of Combining Devices In Process Validation With Main Manufacturing Process

Recall Date	Product Description	Recalling Firm	Recall Reason
3/20/2024	**Carto Vizigo Bi-Directional Guiding Sheath** REF D128502 The CARTO VIZIGOTM Bi-Directional Guiding Sheath is designed to provide accessibility and maneuverability in the cardiac anatomy. The steerable sheath is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A side port with a three-way stopcock is provided for air or blood aspiration, and fluid infusion. The handle is equipped with a rotating collar to deflect the tip clockwise = 180¿ and counterclockwise = 180¿. The steerable sheath features distal vent holes to facilitate aspiration and minimize cavitation, and a radiopaque tip marker to allow fluoroscopic visualization. The sheath has electrodes on the outer surface to allow the sheath to interface with compatible CARTO" 3 Systems.	**BIOSENSE WEBSTER, INC.** Irvine, California	Due to a manufacturing issue, device under process validation phase were inadvertently mixed into the main manufacturing process.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Carto Vizigo Bi-Directional Guiding Sheath** Product No. D-1385-02 UDI-DI	65 Units in California	February, 2024 and prior

	code: 10846835016277 Lot Numbers: 60000282 60000282		

For additional information, please visit the FDA website

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