California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Boston Scientific Corporation WATCHMAN TruSeal Access

Recall Date	Product Description	Recalling Firm	Recall Reason
8/29/25	WATCHMAN TruSeal Access System DBL, US, Material Number (UPN) M635TU70020; intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.	Boston Scientific Corporation	Boston Scientific has identified a higher likelihood of air embolism events when procedures are performed without positive pressure-controlled ventilation. According to published literature and clinical data, in percutaneous procedures requiring transseptal access to the left atrium when conscious or deep sedation is used, patients have an approximately three-times higher risk (U.S. study) of negative left atrium pressure and air ingress. This risk is especially prevalent in patients with pre-existing low left atrial pressure, hypovolemia, and partial upper airway collapse.
8/29/25	WATCHMAN FXD Curve Access System Dbl, US, Material Number (UPN) M635TU80020; intended to provide vascular and transseptal access for the family of	Boston Scientific Corporation	Boston Scientific has identified a higher likelihood of air embolism events when procedures are

	WATCHMAN FLX LAAC Devices with Delivery Systems.		performed without positive pressure-controlled ventilation. According to published literature and clinical data, in percutaneous procedures requiring transseptal access to the left atrium when conscious or deep sedation is used, patients have an approximately three-times higher risk (U.S. study) of negative left atrium pressure and air ingress. This risk is especially prevalent in patients with pre-existing low left atrial pressure, hypovolemia, and partial upper airway collapse.
8/29/25	WATCHMAN TruSeal Access System SGL, US, Material Number (UPN) M635TU70010; intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.	Boston Scientific Corporation	Boston Scientific has identified a higher likelihood of air embolism events when procedures are performed without positive pressure-controlled ventilation. According to published literature and clinical data, in percutaneous procedures requiring transseptal access to the left atrium when conscious or deep sedation is used, patients have an approximately three-times higher risk (U.S. study) of negative left atrium pressure and air ingress. This risk

			is especially prevalent in patients with pre-existing low left atrial pressure, hypovolemia, and partial upper airway collapse.

Recall Class	Product Identification	Distribution	Affected Dates
I	GTIN 08714729965718, ALL NON-EXPIRED BATCHES	340185 units Worldwide	July 2025 and prior.
I	GTIN 00191506013813, ALL NON-EXPIRED BATCHES	340185 units Worldwide	July 2025 and prior.
I	GTIN 08714729965701, ALL NON-EXPIRED BATCHES	340185 units Worldwide	July 2025 and prior.

For additional information, please visit the FDA Website for M635TU70020, M635TU80020, M635TU70010.