State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Cordis US Recalls Angiogard Rx / Xp Emboli Capture Guidewire System For Potential Sheath Separation

Recall Date	Product Description	Recalling Firm	Recall Reason
5/17/2023	**Angioguard Rx / Xp Emboli Capture Guidewire System** REF 401814RMC, 501814RMC, 601814RMC, 701814RMC, 801814RMC, 603014MC, 501814REC, 401814RM, 501814RE, 601814RE, 701814RE, 601814RM, 501814RM, 801814RE	**CORDIS US CORP** Miami Lakes, Florida	There is a potential for separation of the ANGIOGUARD RX / XP delivery system and capture sheath which include but are not limited to situations of an intra-procedural delay, unplanned percutaneous or surgical intervention, or stroke; while a replacement device is prepared.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Angioguard Rx / Xp Emboli Capture Guidewire System** UDI/DI 20705032053508; Lot Numbers: 35262517, 35263334, 35264204, 35264222, 35265345. UDI/DI 20705032054802; Lot Numbers: 35264208, 35264212, 35265329, 35265654, 35265649, 35265667. UDI/DI 20705032056745; Lot Numbers: 35263328, 35264207, 35264213, 35264216, 35265393, 35265648, 35265659 UDI/DI 20705032056851; Lot Numbers: 35265661	4334 Units Nationwide	March 2023 and prior

	UDI/DI 20705032056943; Lot Numbers: 35265335, 35264202 UDI/DI 20705032056790; Lot Numbers: 35265492 UDI/DI 20705032054789; Lot Numbers: 35264223 UDI/DI 20705032053492; Lot Numbers: 35265339, 35265670 UDI/DI 20705032054772; Lot Numbers: 35264217, 35264226, 35265330, 35265344, 35265381, 35265641, 35265652, 35265655, 35264205, 35264210, 35264214, 35265340, 35265341, 35265394, 35265643 UDI/DI 20705032056714; Lot Numbers: 35264218, 35264224, 35264806, 35265342, 35265343, 35265382, 35265383, 35265646, 35265656, 35265658, 35264206, 35265645, 35265653 UDI/DI 20705032056820; Lot Numbers: 35264219, 35265391, 35265392, 35265399, 35265668, 35265660 UDI/DI 20705032056738; Lot Numbers: 35265658, 35264211, 35264225, 35265647 UDI/DI 20705032054796; Lot Numbers: 35265644 UDI/DI 20705032056929; Lot Numbers: 35267611		

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE