



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Scientia Vascular Recalls Plato 17 Microcatheter For Potential Embolic Event, Small Vessel Occlusion And Chronic Inflammation

Recall Date	Product Description	Recalling Firm	Recall Reason
3/22/2023	Plato 17 Microcatheter Straight Tip, PL17-160-000 ; 45 degree Tip, PL17-160-045; 90 degree Tip, PL17-160-090	SCIENTIA VASCULAR, INC. West Valley City, Utah	Microcatheters for embolic coil and diagnostic agent introduction to peripheral /neuro vasculature, due to manufacturing non-conformance, and due to flush, guidewire insertion and manipulation prior to placement, may have loose particles within catheter lumens that may be introduced to patients, which could cause embolic event, small vessel occlusion, and subacute to chronic inflammatory response.

Recall Class	Product Identification	Distribution	Affected Dates
II	Plato 17 Microcatheter All lots, REF/UDI-DI/Lot(Expiration): PL17-160-000/00818075010455/ 900164(8/31/2022), 900165(8/31/2022), 900172(8/31/2022), 900177(9/30/2022), 900180(9/30/2022), 900186(10/31/2022), 900187(10/31/2022),	48 Units in California	August 2022 to March 2023

	<p>900188(10/31/2022), 900193(10/31/2022), 900196(12/31/2022), 900199(12/31/2022), 900202(12/31/2022), 900221(2/28/2023), 900222(2/28/2023), 900225(2/28/2023), 900226(3/31/2023), 20441(11/30/2023), 20476(11/30/2023), 20650(12/31/2023); PL17-160- 045/00818075010462/900167(8 /31/2022), 900168(8/31/2022), 900169(8/31/2022), 900174(8/31/2022), 900175(8/31/2022), 900179(9/30/2022), 900181(9/30/2022), 900183(10/31/2022), 900185(10/31/2022), 900205(1/31/2023), 900206(1/31/2023), 900210(1/31/2023), 900211(1/31/2023), 900215(1/31/2023), 900220(1/31/2023), 900219(1/31/2023), 900217(2/28/2023), 900223(2/28/2023), 900224(2/28/2023); PL17-160- 090/00818075010479/900170(8 /31/2022), 900171(8/31/2022), 900178(9/30/2022), 900182(9/30/2022), 900192(11/30/2022), 900195(11/30/2022), 900209(1/31/2023), 900228(3/31/2023)</p>		
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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