



Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Route 92 Medical Inc. Recalls Neurovascular System For Risk Of Distal Tip Separation

Recall Date	Product Description	Recalling Firm	Recall Reason
5/1/2024	Route 92 Medical Full Length 070 Access System, Ref 7002 Rxonly, SterileEO. Used for Introduction of interventional devices into the neurovasculature.	ROUTE 92 MEDICAL INC San Mateo, California	Their is the potential for distal tip separation at the proximal marker band of the delivery catheters
5/1/2024	Route 92 Medical, Full Length 070 Reperfusion System, Ref: 7001 Rxonly, SterileEO. Used for Introduction of interventional devices into the neurovasculature.	ROUTE 92 MEDICAL INC San Mateo, California	Their is the potential for distal tip separation at the proximal marker band of the delivery catheters
5/1/2024	Route 92 Medical, 070 Access System, Ref 1004 Rxonly , Sterile EO. Used for introduction of interventional devices into the neurovasculature.	ROUTE 92 MEDICAL INC San Mateo, California	Their is the potential for distal tip separation at the proximal marker band of the delivery catheters
5/1/2024	Route 92 Medical, Tenzing 7 Delivery Catheter, Ref 1005 Rx Only, Sterile EO. Used for introduction of interventional devices into the neurovasculature.	ROUTE 92 MEDICAL INC San Mateo, California	Their is the potential for distal tip separation at the proximal marker band of the delivery catheters
5/1/2024	Route 92 Medical 070 Reperfusion System, Ref 1003 Rxonly, SterileEO. Used for introduction of interventional devices into the neurovasculature and aspiration of thrombus in ischemic stroke patients.	ROUTE 92 MEDICAL INC San Mateo, California	Their is the potential for distal tip separation at the proximal marker band of the delivery catheters

Recall Class	Product Identification	Distribution	Affected Dates
I	Route 92 Medical Full Length 070 Access System, Ref 7002 UDI: 00853799007473/ Lot # 23051901	10 Units Worldwide	March, 2024 and prior
I	Route 92 Medical, Full Length 070 Reperfusion System, Ref: 7001 UDI: 00853799007497/ Lot # 223060102, 24010102, 23070501, 24010903, 23082802 24011606 , 23100404, 24012403 , 23110901	750 Units Worldwide	March, 2024 and prior
I	Route 92 Medical, 070 Access System, Ref 1004 UDI: 00853799007442/ Lot # 23061601 24010306, 23081802, 24011801, 23100601, 24020801, 23102601	117 Units Worldwide	March, 2024 and prior
I	Route 92 Medical, Tenzing 7 Delivery Catheter, Ref 1005 UDI: 00853799007534/ Lot # 23033001, 23073101, 23070305, 23081707	200 Units Worldwide	March, 2024 and prior
I	Route 92 Medical 070 Reperfusion System, Ref 1003 UDI: 00853799007169/ Lot # 23112702 and 23112901	19 Units Worldwide	March, 2024 and prior

For additional information, please visit the FDA website [REF 7002](#), [7001](#), [1004](#), [1005](#), [1003](#)

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