California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

LeMaitre Vascular, Inc. Pruitt Occlusion Catheter, TufTex Over-the-Wire Embolectomy Catheter, and Pruitt Irrigation Occlusion Catheter

Recall Date	Product Description	Recalling Firm	Recall Reason
05/12/2025	Pruitt Occlusion Catheter. Catalog Numbers: 2103-36, 2103-46, 2103-56, E2103-36, E2103-46, E2103-56	LeMaitre Vascular, Inc.	During internal product testing, it was observed that some packages to have incomplete seals (sterile barrier).
05/12/2025	TufTex Over-the-Wire Embolectomy Catheter. All Catalog numbers: 1651-34, 1651-38, 1651-44, 1651-48, 1651-58, 1651-64, 1651-68, 1651-78, 1651-84, 1651-88, E1651-34, E1651-38, E1651-44, E1651-48, E1651-64, E1651-68, E1651-78, E1651-84, E1651-88, 1651-44J, 1651-48J, 1651-84J, 1651-88J.	LeMaitre Vascular, Inc.	During internal product testing, it was observed that some packages to have incomplete seals (sterile barrier).
05/12/2025	Pruitt Irrigation Occlusion Catheter. Catalog Numbers: 2102-09, E2102-09.	LeMaitre Vascular, Inc.	During internal product testing, it was observed that some packages to have incomplete seals (sterile barrier).

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 00840663101535, 00840663101542. Catalog Numbers: 2103-36, 2103-46, 2103-56, E2103-36, E2103-46, E2103-56. Lots not expired with the following prefix: POC, QPO, XPO.	362 units distributed in California	April 2025 and Prior

II	UDI-DI: 00840663100651, 00840663100668, 00840663100675, 00840663100682, 00840663100699, 00840663100705, 00840663100712, 00840663100729, 00840663107551, 00840663100736, 00840663100743, 00840663100750, 00840663100767, 00840663100774, 00840663100781, 00840663100798, 00840663100804, 00840663100811, 00840663100828, 00840663100835, 00840663107568, 00840663100842, 00840663100859, 00840663100866. Catalog numbers: 1651-34, 1651-38, 1651-44, 1651-48, 1651-68, 1651-78, 1651-84, 1651-88, E1651-34, E1651-38, E1651-44, E1651-48, E1651-64, E1651-68, E1651-78, E1651-84, E1651-88. Lots not expired with the following prefix: OTW, QOT, XOT, COT	5,804 units distributed in California	April 2025 and Prior
II	UDI-DI: 00840663101580, 00840663101559, 00840663101566, 00840663101597, 00840663101573, 00840663101603. Catalog Numbers: 2102-09, E2102-09. Lot not expired with the following prefix: PIO, QPI, XPI.	612 units distributed in California	April 2025 and Prior

For additional information, please visit this FDA Website Pruitt Occlusion Catheter, this FDA Website TufTex Over-the-Wire Embolectomy Catheter, and this FDA Website Pruitt Irrigation Occlusion Catheter.