



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Arrow International Inc Recalls Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device: 7Fr, Due to Risk of Separation

Recall Date	Product Description	Recalling Firm	Recall Reason
11/24/2021	Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device : 7FR Product Code: PT-12709-WC The Arrow-Trerotola™ Percutaneous Thrombolytic Device (PTDTM) Catheter, in conjunction with the Arrow Rotator Drive Unit, permits mechanical declotting of native arterio-venous fistulae and synthetic dialysis grafts	Arrow International LLC Reading, Pennsylvania	7FR Percutaneous Thrombolytic Device (PTD) Inner lumen (orange) detached from the device basket result in embolization and retrieval with an additional intervention and consequent delay of therapy.
10/27/2021	Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device : 7FR Product Code: PT-65709-HFWC	Arrow International LLC Reading, Pennsylvania	Inner lumen detachment
10/27/2021	Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device : 7FR Product Code: PT-65709-W	Arrow International LLC Reading, Pennsylvania	Inner lumen detachment
10/27/2021	Arrow-Trerotola Over-The-Wire PTD Kit Percutaneous Thrombolytic Device : 7FR Product Code: PT-65709-WC	Arrow International LLC Reading, Pennsylvania	Inner lumen detachment

Recall Class	Product Identification	Distribution	Affected Dates
II	PT-12709-WC Lot Number: 13F19K0564 13F20C0094 13F20G0284	447 Units Worldwide	September 2021 and prior

	13F20L0282 13F21A0497 13F21A0718 13X21E0008 13F21F1187		
II	PT-65709-HFWC Lot Number: 13F19K0369 13F20A0323 13F20B0139 13F20C0594 13F20F0083 13F20F0230 13F20F0577 13F20H0756 13F20K0849 13F20L0283 13F20M0182 13F21A0498 13F21B0158 13F21C0747 13F21E0555	1,245 Units Worldwide	September 2021 and prior
II	PT-65709-W Lot Number: 13F19M0129 13F20B0053 13F20C0595 13F20F0231 13F20G0361 13F20K0632 13F21A0353 13F21C0748 13F21D0721 13F21E0823 13F21F1189	1,167 Units Worldwide	September 2021 and prior
II	PT-65709-WC Lot Number: 13F19J0656 13F19K0368 13F19K0342 13F20C0596 13F20F0081 13F20F0229 13F20F0509 13F20F0578 13F20G0177 13F20G0566 13F20H0531 13F20J0379 13F20L0514 13F21A0354 13F21C0081 13F21C0749 13F21D0870 13F21E0415 13F21F1188	1,918 Units Worldwide	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov

