California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Bard Peripheral Vascular Inc Rotarex Atherectomy System

Recall Date	Product Description	Recalling Firm	Recall Reason
03/05/2025	Rotarex Atherectomy System and Instructions for Use, BD SET Rotarex: S 6 F x 110 cm REF: 80236 S 6 F x 135 cm REF: 80237 S 8 F x 85 cm REF: 80238 S 8 F x 110 cm REF: 80239	Bard Peripheral Vascular Inc	Atherectomy Catheter eIFU updated to clarify and emphasize procedural steps intended to reduce the likelihood of catheter breakage events. Catheter has an outer cylinder connected to a rotating helix, which could fracture and/or break, which would require retrieval, and helix facture/break could cause vessel injury and lead to severe bleeding.

Recall Class	Product Identification	Distribution	Affected Dates
I	Instructions for Use versions prior to ZE10895 revision C1 09/24. REF: 80236 UDI-DI: 07640142811855 Lot(Expiration): 230893(2025-12-15) - 242691(2024-12-13)	15,755 units nationwide	February and prior

	REF: 80237 UDI-DI: 07640142811862 Lot(Expiration): 230897(2026-04-11) - 242693(2027-11-06) REF: 80238 UDI-DI: 07640142811879 Lot(Expiration): 230895(2025-11-23) - 242520(2026-09-30) REF: 80239 UDI-DI: 07640142811886 Lot(Expiration): 230896(2025-11-23) - 242695(2027-10-25)		

For additional information, please visit the FDA Website.