

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medtronic Perfusion Systems Aortic Root Cannula

Recall Date	Product Description	Recalling Firm	Recall Reason
03/13/2025	Aortic Root Cannula: 1. DLP Aortic Root Cannula CANNULA 11012 AR FLOWGUARD 12GA model no 11012 CANNULA 11014 AR FLOWGUARD 14GA model no. 11014 MiAR Cannula: CANNULA 11012L AR FLOWGUARD LONG 12GA model no 11012L CANNULA 11014L AR FLOWGUARD 14FR LONG model no. 11014L DLP Aortic Root Cannula with Vent Line CANNULA 21012 AR VENT FLOW 12GA model no. 21012 CANNULA 21014 AR VENT FLOW 14GA model no. 21014	Medtronic Perfusion Systems	Unexpected loose material in the male luer used in the aortic root cannula has been identified. Potential harms when identified prior to use - procedure delay. Potential harm if not identified and used - stroke (reversible and irreversible).

Recall Class	Product Identification	Distribution	Affected Dates
I	DLP Aortic Root Cannula CANNULA 11012 AR FLOWGUARD 12GA, model no 11012 UDI-DI 00613994495457 lots 2022050698 - 2024051028 UDI-DI 00673978175959 lots 2022050698 - 2024040475 UDI-DI 20613994495451 lots 2022020438 - 2024100441 CANNULA 11014 AR FLOWGUARD 14GA, model no. 11014 UDI-DI 00613994495488 lots 2022070410 - 2024040576 UDI-DI 00673978175997, lots 2022050367 - 2024030965 UDI-DI 20613994495482 lots 2022010949 - 202409C108 MiAR Cannula: CANNULA 11012L AR FLOWGUARD LONG 12GA, model no 11012L UDI-DI 00613994495464 lots 2022010947 - 2024040042 UDI-DI 20613994495468 lots 2022010947 - 2024070499 CANNULA 11014L AR FLOWGUARD 14FR LONG, model no. 11014L UDI-DI 00613994495495 lots 2022010948 - 2024050392 UDI-DI 20613994495499 lots 2022010948 - 2024100986 DLP Aortic Root Cannula with Vent Line CANNULA 21012 AR VENT FLOW 12GA, model no. 21012	316,205 units nationwide	February and prior

	UDI-DI 00613994495396 lots 2022050019 - 2024080930 UDI-DI 00673978178325 lots 2022030796 - 2024051287 UDI-DI 20613994495390 lots 2022011031 - 202410C026 CANNULA 21014 AR VENT FLOW 14GA, model no. 21014 UDI-DI 00613994495402 lots 2022011174 - 2024090936 UDI-DI 00673978178356 lots 2022011033 - 2024090658 UDI-DI 20613994495406 lots 2022011033 - 2024100071		
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For additional information, please visit the [FDA Website](#).