California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medtronic Perfusion Systems DLP Left Heart Vent Catheter Malleable body and vented connector

Recall Date	Product Description	Recalling Firm	Recall Reason
9/3/25	DLP Left Heart Vent Catheter Malleable body and vented connector, SUCTION 12115 LV VENT 15FR, Model Number 12115	Medtronic Perfusion Systems	The catheters may not retain their shape.
9/3/25	DLP Left Heart Vent Catheter Malleable body and vented connector, SUCTION 12110 LV VENT 10FR, Model Number 12110	Medtronic Perfusion Systems	The catheters may not retain their shape.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: 20643169880935, 00643169880931, 00681490463423; Serial Numbers: 2023051189 2023060145 2023060432 2023061147 2023070491 2023070980 2023080157 2023080407 2023080408 2023080799 2023080800 2023081133 2023081134 2023081549 2023090236 2023090429 2023091017 2023091107 2023091108 2023100097 2023100098 2023100098 2023100643 2023100644 2023101026 2023101027 2023101367 2023101367 2023101368 2023110168 2023111663 2023111663 2023111663 2023111700 2023111701 2023111702 2023111703	25261 units worldwide	August 2025 and prior.

	2023111703 2023120176 2023120177 2023120178 2023120179 2023120719 2023120719 2023121046 2023121046 2023121256 2024010194 2024010195 2024010196 2024010197 2024010198 2024010199 2024010200 2024010201 2024010202 2024010202 2024011215 2024011216 2024011216 2024011217 2024011218 2024011219 2024011219 2024011220 2024011221 2024011221 2024030367 2024030367 2024030368 2024030368 2024030841 2024030842 202307C113 202308C250 202309C023 202311C008 202311C009 202312C206 202312C207 202312C208 202401C008 202402C088 202403C101 202403C102 202406C058		
I	UDI-DI: 20643169880676, 00643169880672, 00673978176468, 00763000946432, 20763000946436; Serial Numbers: 2023120708 2023120708 2023120709 2023120710 2023120711 2023120712 2023121041 2023121041 2023121042 2024011203 2024011203 2024011204 2024020135 2024020136 2024020137 2024020138 2024020138 2024020139 2024020140 2024020141 2024020141 2024020471 2024020472 2024020473 2024020474 2024020474 2024020474 2024020475 2024020475 2024020475 2024020806 2024020806 2024020806 2024030359 2024030360	41200 units worldwide	August 2025 and prior.

	2024030360 2024030361 2024030361 2024030361 2024030833 2024030833 2024030834 2024030834 2024030835 2024030835 2024031088 2024031088 2024050074 2024050075 2024050076 2024050403 2024050404 2024050761 2024050762 2024050763 2024050763 2024051075 2024051076 2024051265 2024060283 2024060284 2024060284 2024060285 2024060529 2024070340 2024070340 2024071120 2024071120 2024071121 2024071121 2024071122 2024071122 2024080225 2024080225 2024080465 2024080465 2024080690 2024081023 2024081024 2024090228 2024090229 2024090470 2024090470 2024090471 2024090767 2024090768 2024100621 2024100622 202312C204 202312C205 202401C295 202401C296 202403C144 202403C145 202403C146 202405C079 202405C080 202406C064 202406C065 202406C066 202409C128		

For additional information, please visit the FDA Website Model Number 12115 and Model Number 12110.