California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Edwards Lifesciences, LLC Recalls Optisite Arterial Cannula

Recall Date	Product Description	Recalling Firm	Recall Reason
07/16/2025	Optisite Arterial Cannula Product Name: Optisite Arterial Cannula Model/Catalog Number: OPTI16 Software Version: N/A Product Description: Cardiac cannula. The Edwards OptiSite Arterial Perfusion Cannluae provides or establishes arterial perfusion in the extracorporeal circuit for d 6 hours. Component: No.	Edwards Lifesciences, LLC	Due to complaints received for 3mm to 4mm section wire exposed/protruding from the outside of the cannula body.
07/16/2025	Brand Name: Optisite Arterial Cannula Product Name: Optisite Arterial Cannula Model/Catalog Number: OPTI18 Software Version: N/A Product Description: Cardiac cannula. The Edwards OptiSite Arterial Perfusion Cannluae provides or establishes arterial perfusion in the extracorporeal circuit for d 6 hours. Component: No	Edwards Lifesciences, LLC	Due to complaints received for 3mm to 4mm section wire exposed/protruding from the outside of the cannula body.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Code: Model No:OPTI16; UDI: 00690103180558; All lots up to BSLC9149 Serial Numbers: 130467 130471 130602 130765 130816 130822 130852 130949 131039 131041 131044 131237 131312 131428 131509 131826 131887 131908 132338 132436 132503 132831 BSLC0040	Worldwide - US Nationwide distribution including in the states of ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA,	May 2025 and prior

	BSLC0165 BSLC0165 BSLC0320 BSLC1309 BSLC1309 BSLC1468 BSLC1468 BSLC1557 BSLC1682 BSLC1688 BSLC1825 BSLC1830 BSLC5302 BSLC5899 BSLC6166 BSLC7142 BSLC7142 BSLC7513 BSLC8176 BSLC8659 BSLC9149	FLORIDA, GEORGIA, HAWAII, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, Puerto Rico, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, VIRGINIA, WASHINGTON, WEST VIRGINIA, WISCONSIN and the countries of Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, CANARY ISLANDS, Chile, Colombia, Cyprus, Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, Malta, Netherlands, Northern Ireland, Norway, Pakistan, Panama, Poland, Portugal, Romania, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, United Arab Emirates (UAE), United Kingdom.	
I	Lot Code: Model No: OPTI18; UDI: 00690103180565; All lots up to: BSLC9155 Serial Numbers: 130451 130466 130472 130593 130709 130764 130818 130821 130847 130948 130952 131038 131043 131047 131182 131193 131231 131236	Worldwide - US Nationwide distribution including in the states of ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE,	May 2025 and prior.

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	131289 131311 131317 131433 131435 131513 131516 131553 131554 131606 131623 131625 131628 131682 131737 131909 131929 131966 132175 132201 132366 132395 132416 132430 132435 132505 132832 132958 132959 BSLC0110 BSLC0166 BSLC0661 BSLC0661 BSLC0826 BSLC0826 BSLC0826 BSLC0826 BSLC0855 BSLC0855 BSLC0887 BSLC0887 BSLC0979 BSLC1114 BSLC1114 BSLC1211 BSLC1308 BSLC1469 BSLC1656 BSLC1660 BSLC1815 BSLC3221 BSLC4153 BSLC4400 BSLC4461 BSLC4513 BSLC5027 BSLC5027 BSLC5320 BSLC5367 BSLC5765 BSLC6421 BSLC6467 BSLC7335 BSLC7514 BSLC7515 BSLC8175 BSLC8385 BSLC8535 BSLC8657 BSLC9100 BSLC9104 BSLC9105 BSLC9152 BSLC9155	DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, Puerto Rico, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, VIRGINIA, WASHINGTON, WEST VIRGINIA, WISCONSIN and the countries of Albania, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, CANARY ISLANDS, Chile, Colombia, Cyprus, Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, Malta, Netherlands, Northern Ireland, Norway, Pakistan, Panama, Poland, Portugal, Romania, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, United Arab Emirates (UAE), United Kingdom.	

For additional information, please visit the FDA Website 1.

For additional information, please visit the FDA Website 2.

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