California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Edwards Lifesciences LLC Recalls FEM-FLEX II

Recall Date	Product Description	Recalling Firm	Recall Reason
07/16/2025	Brand Name: FEM-FLEX II Product Name: Femoral Arterial Cannula Model/Catalog Number: FEMII016AS Software Version: N/A Product Description: The Edwards FEMFLEXII Femoral 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: FEM-FLEX II Product Name: Femoral Arterial Cannula Model/Catalog Number: FEMII018A Software Version: N/A Product Description: The Edwards FEMFLEXII Femoral 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: FEM-FLEX II Product Name: Femoral Arterial Cannula Model/Catalog Number: FEMII016A Software Version: N/A Product Description: The Edwards FEMFLEXII Femoral 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: FEM-FLEXII Product Name: Femoral Arterial Cannula Model/Catalog Number: FEMII018AS Software Version: N/A Product Description: The Edwards FEMFLEXII Arterial Perfusion Cannluae provides or establishes arterial perfusion	**Edwards Lifesciences LLC**	due to complaints received for 3mm to 4mm section wire exposed/protruding from the outside of the cannula body.

	in the extracorporeal circuit for d 6 hours. Component: No		

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Code: Model No; FEMII016AS; UDI: 0060913168341; All lots up to: BSLC1689 Serial Numbers: FEMII016AS FEMII016AS FEMII016AS	Worldwide - US Nationwide distribution including in the states of ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, 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,	May 2025 and prior.

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		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: FEMII018A; UDI: 0069013031256; All lots up to: BSLC9148 Serial Numbers: 130468 130599 130704 130848 130953 131048 131286 131430 131626 131774 131775 132004 132005 132510 BSLC0025 BSLC0121 BSLC0422 BSLC1115 BSLC1470 BSLC4161 BSLC4472 BSLC5041 BSLC5293 BSLC5842 BSLC6163 BSLC6164 BSLC7336 BSLC7794 BSLC8660 BSLC9148	Worldwide - US Nationwide distribution including in the states of ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, 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,	May 2025 and prior.

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		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: FEMII016A; UDI: 00690103031232; All lots up to: BSLC8179 Serial Numbers: 130544 130757 131105 131313 131511 131535 131888 131925 132504 BSLC0184 BSLC0386 BSLC0596 BSLC1311 BSLC3741 BSLC4162 BSLC5040 BSLC6487 BSLC8179	Worldwide - US Nationwide distribution including in the states of ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, 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,	May 2025 and prior.

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		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: FEMII018AS; UDI: 00690103168358; All lots up to: BSLC9064 Serial Numbers: 131776 BSLC4190 BSLC9064	Worldwide - US Nationwide distribution including in the states of ALABAMA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, 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,	May 2025 and prior.

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		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.

For additional information, please visit the FDA Website 3.

For additional information, please visit the FDA Website 4.

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